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

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318 and 381

[Docket No. FSIS 2016–0032]

RIN 0583–AD66

Preparation of Uninspected Products Outside of the Hours of Inspectional Supervision

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to eliminate prescriptive requirements governing the manufacture of uninspected products, such as pet food, in edible product areas of official establishments and to allow official establishments to manufacture such products outside the hours of inspection. These prescriptive regulations are no longer necessary and are inconsistent with the Hazard Analysis and Critical Control Point (HACCP) and sanitation regulations. Removal of these unnecessary provisions will provide establishments the flexibility to be innovative and operate in the most efficient, cost effective manner.

DATES: *Effective* October 15, 2019.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, FSIS; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

On, July 31, 2018 (83 FR 36797), FSIS proposed to eliminate the prescriptive regulatory requirements at 9 CFR 318.12 and 381.152 that govern the manufacture of uninspected, inedible products, such as pet food, and restrict the hours during which such products may be prepared in an official establishment. These prescriptive regulations were issued before FSIS published its regulations requiring HACCP, Sanitation Standard Operating Procedures (sanitation SOPs), and compliance with the Sanitation Performance Standards. Under HACCP and sanitation requirements, an establishment that produces both edible and inedible meat and poultry products must develop and implement the controls and procedures necessary to prevent the adulteration of edible products by insanitary conditions and product commingling, as well as to prevent the movement of inedible products into commerce as human food.

FSIS is finalizing the proposed rule with one non-substantive technical correction. Specifically, FSIS is adding a reference to the revised regulations in 9 CFR 381.193, which govern the labeling of uninspected, inedible poultry products. This citation was inadvertently left out of the proposal to revise the regulations at 9 CFR 381.152, but an analogous citation was proposed for meat regulations at 9 CFR 318.12(b).

Responses to Comments

FSIS received eight comments on the proposed rule submitted by a trade association representing the pet food industry, a trade organization representing the meat and poultry industry, five individuals, and a commenter purporting to be an airline. The meat and poultry trade organization and one individual supported the proposal. A summary of issues raised by other commenters follows:

Comment: The trade association representing the pet food industry urged FSIS to work with the U.S. Food and Drug Administration (FDA) to ensure that all establishments under FSIS regulatory oversight are aware that FDA regulations implementing the Food Safety Modernization Act (FSMA) require certain firms that produce animal food to perform a hazard analysis and establish and implement risk-based preventive controls (*see* 80 FR 56169).

Response: FSIS will continue to work with FDA regarding official FSIS establishments that may need to comply with FDA's good manufacturing practice and/or preventive controls for animal food regulations.

Comment: Two individuals opposed the rule, expressing concerns that it would result in there being no regulatory oversight of pet food production.

Response: Pet food products will continue to be regulated at both the Federal and State levels. At the Federal level, FDA regulates animal feed and companion animal food. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. Most states also have laws that require registration or licensing to sell animal food.

Comment: An individual asked for clarification on how the proposed change affects or applies to retail exempt facilities.

Response: This final rule removes requirements in 9 CFR 318.12 and 381.152, which only apply to official establishments producing meat and poultry products under Federal inspection. This final rule does not address the preparation or processing of animal food at retail firms, including those that operate under FSIS's retail exemption.

Comment: One comment from a former inspector expressed concerns that the proposal would lessen the ability of FSIS inspectors to ensure that inedible products are not put into commerce as human food.

Response: This rule does not affect the authority or ability of FSIS inspectors to verify that official establishments manufacturing inedible product are keeping it separate from meat and poultry products and not otherwise creating insanitary conditions through its manufacture. Nor does this rule affect the authority or ability of FSIS inspectors to take enforcement actions to prevent inedible product from entering commerce as human food.

Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting

flexibility. This final rule has been designated as a ''non-significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Economic Impact Analysis

As stated above, compliance with HACCP and sanitation regulations facilitates the production of safe, unadulterated product by establishments and makes the prescriptive requirements in 9 CFR 318.12 and 381.152 unnecessary. Because these prescriptive requirements are no longer necessary to ensure the production of safe, unadulterated food, removing them will have no negative public health impact. In addition, this rule will not impose costs on the industry or the Agency.

Further, removing the unnecessary, prescriptive requirements should allow establishments additional flexibility to be innovative and to operate in the most efficient, cost effective manner. Similarly, the rule should also allow FSIS to use its resources more appropriately. However, FSIS cannot quantify these savings.

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602), this final rule will not have a significant economic impact on a substantial number of small entities in the United States. The final rule will not increase costs to the industry.

Executive Order 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), FSIS has estimated that this final rule will yield cost savings. Therefore, this final rule is an E.O. 13771 deregulatory action.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments.'' E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.* FSIS will also announce and provide a link to it through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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9 CFR Part 318

Food additives, Food packaging, Laboratories, Meat inspection, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 381

Administrative practice and procedure, Animal diseases, Crime, Exports, Food grades and standards, Food labeling, Food packaging, Government employees, Grant programs-agriculture, Intergovernmental relations, Laboratories, Meat inspection, Nutrition, Polychlorinated biphenyls, Poultry and poultry products, Reporting and recordkeeping requirements, Seizures and forfeitures, Signs and symbols, Technical Assistance, Transportation.

For the reasons set forth in the preamble, FSIS amends 9 CFR parts 318 and 381 as follows:

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601 695; 7 CFR 2.18, 2.53.

■ 2. Section 318.12 is revised to read as follows:

§ 318.12 Manufacture of uninspected, inedible products at official establishments.

(a) Official establishments may manufacture pet food or similar uninspected, inedible products in areas where edible products also are produced, provided that the manufacture of uninspected, inedible products does not:

(1) Adulterate edible products;

(2) Create insanitary conditions in the official establishment whereby edible products may be adulterated; or

(3) Prevent or interfere with inspection or other program tasks performed by FSIS personnel in the official establishment.

(b) Pet food and similar uninspected, inedible products must be distinguished from edible products so as to avoid their distribution as human food. Pet food or similar uninspected, inedible products must be labeled or otherwise identified in accordance with § 325.11(d) of this subchapter.

PART 381—POULTRY PRODUCTS INSPECTIONS REGULATIONS

■ 3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

■ 4. Section 381.152 is revised to read as follows:

§ 381.152 Manufacture of uninspected, inedible products at official establishments.

(a) Official establishments may manufacture pet food or similar uninspected, inedible products in areas where edible products also are produced, provided that the manufacture of uninspected, inedible products does not:

(1) Adulterate edible products;

(2) Create insanitary conditions in the official establishment whereby edible products may be adulterated; or

(3) Prevent or interfere with inspection or other program tasks performed by FSIS personnel in the official establishment.

(b) The immediate container of uninspected, inedible products manufactured in an official establishment shall be conspicuously labeled so as to distinguish them from human food in accordance with § 381.193 of this subchapter.

Done in Washington, DC.

Carmen M. Rottenberg,

Administrator.

[FR Doc. 2019–17344 Filed 8–13–19; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0358; Airspace Docket No. 19–AEA–7]

RIN 2120–AA66

Establishment of Class E Airspace; Minersville, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface at Primrose Heliport, Minersville, PA, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures serving this heliport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this heliport.

DATES: Effective 0901 UTC, October 10, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace extending upward from 700 feet above the surface for Primrose Heliport, Minersville, PA, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures serving this heliport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (84 FR 26377, June 6, 2019) for Docket No. FAA–2019–0358 to establish Class E airspace extending upward from 700 feet above the surface for Primrose Heliport, Minersville, PA.

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

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E

airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 700 feet above the surface within a 6-mile radius at Primrose Heliport, Minersville, PA, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for IFR operations at the heliport.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, effective September 15, 2018, is amended as follows:

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

* * * * *

AEA PA E5 Minersville, PA [New]

Primrose Heliport, PA
(Lat. 40°41′21″ N, long. 76°16′47″ W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Primrose Heliport.

Issued in College Park, Georgia, on August 7, 2019.

Matt Cathcart,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2019–17371 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31266; Amdt. No. 3864]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective August 14, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 14, 2019.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register**

expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on July 26, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
12-Sep-19	MO	Boonville	Jesse Viertel Memorial	9/0157	7/10/19	RNAV (GPS) RWY 18, Orig.
12-Sep-19	MO	Boonville	Jesse Viertel Memorial	9/0158	7/10/19	RNAV (GPS) RWY 36, Orig.
12-Sep-19	TX	Austin	Austin-Bergstrom Intl	9/0414	7/10/19	RNAV (GPS) Y RWY 35L, Amdt 2.
12-Sep-19	TX	Austin	Austin-Bergstrom Intl	9/0415	7/10/19	ILS OR LOC RWY 17R, Amdt 5A.
12-Sep-19	AL	Eufaula	Weedon Field	9/1529	7/10/19	VOR RWY 18, Amdt 8.
12-Sep-19	AL	Eufaula	Weedon Field	9/1530	7/10/19	VOR/DME RWY 36, Amdt 3.
12-Sep-19	TX	Austin	Austin-Bergstrom Intl	9/1725	7/10/19	RNAV (GPS) Y RWY 17L, Amdt 2.
12-Sep-19	KY	Louisville	Bowman Field	9/2554	7/10/19	NDB RWY 33, Amdt 16B.
12-Sep-19	MO	Poplar Bluff	Poplar Bluff Muni	9/3069	7/23/19	RNAV (GPS) RWY 18, Orig-A.
12-Sep-19	KY	Greenville	Muhlenberg County	9/3806	7/19/19	RNAV (GPS) RWY 6, Orig-B.
12-Sep-19	MN	Minneapolis	Crystal	9/4381	7/10/19	RNAV (GPS) RWY 14L, Orig.
12-Sep-19	MN	Minneapolis	Crystal	9/4382	7/10/19	VOR OR GPS–A, Amdt 9D.
12-Sep-19	ME	Princeton	Princeton Muni	9/4475	7/19/19	RNAV (GPS) RWY 15, Amdt 1B.
12-Sep-19	MA	Bedford	Laurence G Hanscom Fld	9/4760	7/10/19	RNAV (GPS) Z RWY 29, Amdt 1A.
12-Sep-19	MA	Bedford	Laurence G Hanscom Fld	9/4762	7/10/19	RNAV (GPS) Z RWY 11, Amdt 1A.
12-Sep-19	MA	Bedford	Laurence G Hanscom Fld	9/4769	7/10/19	RNAV (GPS) RWY 23, Orig-B.
12-Sep-19	CO	Canon City	Fremont County	9/5169	7/10/19	RNAV (GPS) RWY 29, Amdt 1.
12-Sep-19	PA	Allentown	Allentown Queen City Muni.	9/5467	7/10/19	RNAV (GPS) RWY 7, Amdt 1E.

AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
12-Sep-19	IL	Chicago	Chicago O'Hare Intl	9/6346	7/10/19	RNAV (GPS) RWY 27R, Amdt 3B.
12-Sep-19	IL	Chicago	Chicago O'Hare Intl	9/6347	7/10/19	ILS OR LOC RWY 27R, ILS RWY 27R (SA CAT I), ILS RWY 27R (CAT II), ILS RWY 27R (CAT III), Amdt 4A.
12-Sep-19	MI	Grand Rapids	Gerald R Ford Intl	9/6800	7/15/19	RNAV (GPS) RWY 26R, Amdt 1A.
12-Sep-19	MI	Grand Rapids	Gerald R Ford Intl	9/6801	7/15/19	RNAV (GPS) RWY 8R, Amdt 1B.
12-Sep-19	MI	Grand Rapids	Gerald R Ford Intl	9/6802	7/15/19	RNAV (GPS) RWY 35, Amdt 1B.
12-Sep-19	GA	Columbus	Columbus	9/7562	7/10/19	VOR–A, Amdt 23A.
12-Sep-19	GA	Columbus	Columbus	9/7564	7/10/19	RNAV (GPS) RWY 24, Orig-B.
12-Sep-19	GA	Atlanta	Hartsfield—Jackson Atlanta Intl.	9/7838	7/19/19	Takeoff Minimums and Obstacle DP, Amdt 7.
12-Sep-19	IL	Chicago	Chicago O'Hare Intl	9/7941	7/10/19	RNAV (GPS) RWY 9L, Amdt 3B.
12-Sep-19	IL	Chicago	Chicago O'Hare Intl	9/7965	7/10/19	ILS OR LOC RWY 9L, ILS RWY 9L (SA CAT I), ILS RWY 9L (CAT II), ILS RWY 9L (CAT III), Amdt 4A.
12-Sep-19	NC	Sanford	Raleigh Exec Jetport At Sanford-Lee County.	9/8064	7/10/19	ILS Y OR LOC Y RWY 3, Orig-A.
12-Sep-19	NC	Sanford	Raleigh Exec Jetport At Sanford-Lee County.	9/8075	7/10/19	RNAV (GPS) RWY 21, Amdt 2.
12-Sep-19	NV	Carson City	Carson	9/8596	7/10/19	RNAV (GPS)-A, Amdt 1.
12-Sep-19	LA	Monroe	Monroe Rgnl	9/8678	7/10/19	ILS OR LOC RWY 4, Amdt 23A.
12-Sep-19	LA	Monroe	Monroe Rgnl	9/8680	7/10/19	ILS OR LOC RWY 22, Amdt 4A.
12-Sep-19	LA	Monroe	Monroe Rgnl	9/8683	7/10/19	RADAR 1, Amdt 7.
12-Sep-19	LA	Monroe	Monroe Rgnl	9/8684	7/10/19	VOR/DME RWY 22, Amdt 9A.

[FR Doc. 2019–16929 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31262; Amdt. No. 3861]

Standard Instruction Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective August 14, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 14, 2019.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29 Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical.

Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979) ; and (3)does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on July 12, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 15 August 2019

Huntsville, AL, Huntsville Intl-Carl T Jones Field, ILS OR LOC RWY 18L, Amdt 5A
Huntsville, AL, Huntsville Intl-Carl T Jones Field, ILS OR LOC RWY 18R, ILS RWY 18R CAT II, Amdt 25
Huntsville, AL, Huntsville Intl-Carl T Jones Field, ILS OR LOC RWY 36L, Amdt 11A
Phoenix, AZ, Phoenix Deer Valley, RNAV (GPS)-C, Orig, CANCELLED
Phoenix, AZ, Phoenix Sky Harbor Intl, ILS OR LOC RWY 26, Amdt 1
Merced, CA, Merced Rgnl/Macready Field, ILS OR LOC RWY 30, Amdt 15
Merced, CA, Merced Rgnl/Macready Field, LOC BC RWY 12, Amdt 11
Merced, CA, Merced Rgnl/Macready Field, RNAV (GPS) RWY 12, Amdt 1
Merced, CA, Merced Rgnl/Macready Field, RNAV (GPS) RWY 30, Amdt 1
Merced, CA, Merced Rgnl/Macready Field, VOR RWY 30, Amdt 1
San Diego, CA, San Diego Intl, ILS Y OR LOC Y RWY 9, Amdt 2B
San Diego, CA, San Diego Intl, ILS Z OR LOC Z RWY 9, Orig-A
San Diego, CA, San Diego Intl, LOC RWY 27, Amdt 6A
San Diego, CA, San Diego Intl, RNAV (GPS) RWY 9, Amdt 1B
San Diego, CA, San Diego Intl, RNAV (GPS) Y RWY 27, Amdt 4A
San Diego, CA, San Diego Intl, RNAV (RNP) Z RWY 27, Orig-A
Sioux Center, IA, Sioux Center Muni, RNAV (GPS) RWY 18, Orig, CANCELLED
Sioux Center, IA, Sioux Center Muni, Takeoff Minimums and Obstacle DP, Amdt 2, CANCELLED
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (GPS) RWY 29, Orig-D
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (GPS) Y RWY 17L, Amdt 1F
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (GPS) Y RWY 17R, Amdt 1F
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (GPS) Y RWY 35L, Amdt 1E
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (GPS) Y RWY 35R, Amdt 1F
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (RNP) Z RWY 17L, Orig-F
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (RNP) Z RWY 17R, Orig-D
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (RNP) Z RWY 35L, Amdt 1E
Louisville, KY, Louisville Muhammad Ali Intl, RNAV (RNP) Z RWY 35R, Orig-D
Lawrence, MA, Lawrence Muni, ILS OR LOC RWY 5, Amdt 6
Lawrence, MA, Lawrence Muni, ILS Z OR LOC Z RWY 5, Amdt 1, CANCELLED
Jackman, ME, Newton Field, RNAV (GPS) RWY 13, Orig
Jackman, ME, Newton Field, RNAV (GPS) Y RWY 31, Orig
Owosso, MI, Owosso Community, RNAV (GPS) RWY 29, Amdt 2
Austin, MN, Austin Muni, VOR RWY 17, Amdt 3
Fort Leonard Wood, MO, Waynesville-St Robert Rgnl Forney Fld, Takeoff Minimums and Obstacle DP, Amdt 1
Charlotte, NC, Charlotte/Douglas Intl, ILS OR LOC RWY 18C, Amdt 11
Charlotte, NC, Charlotte/Douglas Intl, ILS OR LOC RWY 18L, Amdt 10
Charlotte, NC, Charlotte/Douglas Intl, ILS OR LOC RWY 18R, ILS RWY 18R SA CAT I, ILS RWY 18R CAT II, ILS RWY 18R CAT III, Amdt 2
Charlotte, NC, Charlotte/Douglas Intl, RNAV (GPS) Y RWY 18C, Amdt 4
Charlotte, NC, Charlotte/Douglas Intl, RNAV (GPS) Y RWY 18L, Amdt 5
Charlotte, NC, Charlotte/Douglas Intl, RNAV (GPS) Y RWY 18R, Amdt 2
Charlotte, NC, Charlotte/Douglas Intl, RNAV (RNP) Z RWY 18C, Amdt 1
Cisco, TX, Gregory M Simmons Memorial, RNAV (GPS) Y RWY 18, Orig
Cisco, TX, Gregory M Simmons Memorial, RNAV (RNP) Z RWY 18, Amdt 1

Cisco, TX, Gregory M Simmons Memorial, Takeoff Minimums and Obstacle DP, Amdt 1
Sherman/Denison, TX, North Texas Rgnl/Perrin Field, ILS OR LOC RWY 17L, Amdt 1B
Sherman/Denison, TX, North Texas Rgnl/Perrin Field, RNAV (GPS) RWY 17L, Orig-B
Sherman/Denison, TX, North Texas Rgnl/Perrin Field, RNAV (GPS) RWY 35R, Orig-B
Sherman/Denison, TX, North Texas Rgnl/Perrin Field, Takeoff Minimums and Obstacle DP, Amdt 1
Sherman/Denison, TX, North Texas Rgnl/Perrin Field, VOR–A, Amdt 1A
Roanoke, VA, Roanoke-Blacksburg Rgnl/Woodrum Field, RNAV (GPS) Y RWY 6, Amdt 3A
Roanoke, VA, Roanoke-Blacksburg Rgnl/Woodrum Field, RNAV (GPS) Y RWY 24, Amdt 2
Roanoke, VA, Roanoke-Blacksburg Rgnl/Woodrum Field, RNAV (GPS) Y RWY 34, Amdt 2
Roanoke, VA, Roanoke-Blacksburg Rgnl/Woodrum Field, RNAV (RNP) Z RWY 6, Orig
Roanoke, VA, Roanoke-Blacksburg Rgnl/Woodrum Field, RNAV (RNP) Z RWY 24, Orig
Roanoke, VA, Roanoke-Blacksburg Rgnl/Woodrum Field, RNAV (RNP) Z RWY 34, Orig

RESCINDED: On July 5, 2019 (84 FR 32033), the FAA published an Amendment in Docket No. 31256, Amdt No. 3855, to Part 97 of the Federal Aviation Regulations under sections 97.23, 97.29, 97.33, 97.37. The following entries for Fresno, CA, and LaGrange, GA, effective August 15, 2019, are hereby rescinded in their entirety:

Fresno, CA, Fresno Chandler Executive, RNAV (GPS) RWY 12, Amdt 1
Fresno, CA, Fresno Chandler Executive, RNAV (GPS) RWY 30, Amdt 1
Fresno, CA, Fresno Chandler Executive, Takeoff Minimums and Obstacle DP, Amdt 3
Fresno, CA, Fresno Chandler Executive, VOR/DME OR GPS–C, Amdt 5A, CANCELLED
LaGrange, GA, LaGrange-Callaway, ILS OR LOC RWY 31, Amdt 3
LaGrange, GA, LaGrange-Callaway, RNAV (GPS) RWY 3, Amdt 1
LaGrange, GA, LaGrange-Callaway, RNAV (GPS) RWY 13, Amdt 1
LaGrange, GA, LaGrange-Callaway, RNAV (GPS) RWY 31, Amdt 1
LaGrange, GA, LaGrange-Callaway, Takeoff Minimums and Obstacle DP, Amdt 2
LaGrange, GA, LaGrange-Callaway, VOR RWY 13, Amdt 17

[FR Doc. 2019–16927 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31263; Amdt. No. 3862]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective August 14, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 14, 2019.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866;(2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on July 12, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
15-Aug-19	NE	Minden	Pioneer Village Field	9/0816	6/27/19	RNAV (GPS) RWY 34, Orig-A.
15-Aug-19	AZ	Marana	Marana Rgnl	9/0836	6/28/19	RNAV (GPS) RWY 3, Orig-B.
15-Aug-19	AZ	Marana	Marana Rgnl	9/0837	6/28/19	RNAV (GPS) RWY 21, Amdt 1B.
15-Aug-19	CA	Bishop	Bishop	9/0838	6/27/19	LDA RWY 17, Orig-C.
15-Aug-19	CA	Bishop	Bishop	9/0839	6/27/19	RNAV (GPS) Y RWY 12, Orig-D.
15-Aug-19	CA	Chico	Chico Muni	9/0841	6/27/19	RNAV (GPS) RWY 31R, Orig-C.
15-Aug-19	CA	Davis/Woodland/Winters ..	Yolo County	9/0842	6/27/19	RNAV (GPS) RWY 16, Amdt 2B.
15-Aug-19	CA	Davis/Woodland/Winters ..	Yolo County	9/0843	6/27/19	RNAV (GPS) RWY 34, Amdt 2B.
15-Aug-19	CA	Groveland	Pine Mountain Lake	9/0845	6/27/19	GPS RWY 27, Orig-B.
15-Aug-19	CA	Groveland	Pine Mountain Lake	9/0847	6/27/19	RNAV (GPS) RWY 9, Orig-B.
15-Aug-19	MI	Alpena	Alpena County Rgnl	9/0886	6/28/19	ILS OR LOC RWY 1, Amdt 9B.
15-Aug-19	OK	Idabel	McCurtain County Rgnl	9/0893	6/28/19	RNAV (GPS) RWY 2, Amdt 1.
15-Aug-19	OK	Ardmore	Ardmore Muni	9/0895	6/28/19	RNAV (GPS) RWY 13, Orig-B.
15-Aug-19	OK	Blackwell	Blackwell-Tonkawa Muni	9/0897	6/28/19	RNAV (GPS) RWY 17, Orig.
15-Aug-19	OK	Blackwell	Blackwell-Tonkawa Muni	9/0901	6/28/19	RNAV (GPS) RWY 35, Orig.
15-Aug-19	OK	Chandler	Chandler Rgnl	9/0902	6/28/19	RNAV (GPS) RWY 17, Orig-B.
15-Aug-19	NY	Hudson	Columbia County	9/0906	6/28/19	RNAV (GPS) RWY 3, Orig-B.
15-Aug-19	OK	Chandler	Chandler Rgnl	9/0910	6/28/19	RNAV (GPS) RWY 35, Orig-A.
15-Aug-19	NY	Weedsport	Whitfords	9/0912	6/28/19	RNAV (GPS) RWY 10, Orig-A.
15-Aug-19	OK	Perry	Perry Muni	9/0913	6/28/19	RNAV (GPS) RWY 17, Orig-A.
15-Aug-19	NY	Buffalo	Buffalo Airfield	9/0919	6/28/19	RNAV (GPS) RWY 24, Amdt 1B.
15-Aug-19	NY	Buffalo	Buffalo Airfield	9/0921	6/28/19	RNAV (GPS) RWY 6, Orig-B.
15-Aug-19	NY	Saratoga Springs	Saratoga County	9/0932	6/28/19	RNAV (GPS) RWY 5, Amdt 1C.
15-Aug-19	NY	Ticonderoga	Ticonderoga Muni	9/0933	6/28/19	RNAV (GPS) RWY 2, Amdt 1A.
15-Aug-19	NY	South Bethlehem	South Albany	9/0934	6/28/19	RNAV (GPS) RWY 1, Orig-A.
15-Aug-19	OH	Kent	Kent State Univ	9/0935	6/28/19	RNAV (GPS) RWY 1, Amdt 2.
15-Aug-19	OH	Kent	Kent State Univ	9/0936	6/28/19	RNAV (GPS) RWY 19, Amdt 1B.
15-Aug-19	NM	Tucumcari	Tucumcari Muni	9/0937	6/28/19	RNAV (GPS) RWY 3, Orig.
15-Aug-19	MS	Yazoo City	Yazoo County	9/0938	6/27/19	RNAV (GPS) RWY 35, Orig-A.
15-Aug-19	NM	Silver City	Grant County	9/0939	6/28/19	RNAV (GPS) RWY 8, Orig-A.
15-Aug-19	NM	Raton	Raton Muni/Crews Field ..	9/0940	6/28/19	RNAV (GPS) RWY 2, Orig-B.
15-Aug-19	MS	Ripley	Ripley	9/0941	6/27/19	RNAV (GPS) RWY 21, Amdt 1A.
15-Aug-19	MS	Ripley	Ripley	9/0942	6/27/19	RNAV (GPS) RWY 3, Amdt 1A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
15-Aug-19	NM	Grants	Grants-Milan Muni	9/0943	6/28/19	RNAV (GPS) RWY 13, Orig-A.
15-Aug-19	NJ	Princeton/Rocky Hill	Princeton	9/0944	6/28/19	RNAV (GPS) RWY 28, Orig-B.
15-Aug-19	NJ	Berlin	Camden County	9/0948	6/28/19	RNAV (GPS) RWY 5, Orig-E.
15-Aug-19	NJ	Berlin	Camden County	9/0949	6/28/19	RNAV (GPS) RWY 23, Orig-B.
15-Aug-19	NJ	Old Bridge	Old Bridge	9/0962	6/28/19	RNAV (GPS) RWY 6, Orig-B.
15-Aug-19	NJ	Blairstown	Blairstown	9/0963	6/28/19	RNAV (GPS) RWY 25, Amdt 2B.
15-Aug-19	NJ	Blairstown	Blairstown	9/0964	6/28/19	RNAV (GPS) RWY 7, Orig-B.
15-Aug-19	MO	Monticello	Lewis County Rgnl	9/0973	6/28/19	RNAV (GPS) RWY 18, Orig-B.
15-Aug-19	MO	Monticello	Lewis County Rgnl	9/0974	6/28/19	RNAV (GPS) RWY 36, Orig-B.
15-Aug-19	KS	Concordia	Blosser Muni	9/0977	6/28/19	RNAV (GPS) RWY 17, Orig-B.
15-Aug-19	KS	Concordia	Blosser Muni	9/0978	6/28/19	RNAV (GPS) RWY 35, Orig-A.
15-Aug-19	NC	Charlotte	Charlotte/Douglas Intl	9/1540	7/1/19	RNAV (GPS) Y RWY 36C, Amdt 3D.
15-Aug-19	NC	Charlotte	Charlotte/Douglas Intl	9/1541	7/1/19	RNAV (GPS) Y RWY 36R, Amdt 4B.
15-Aug-19	OH	Wilmington	Clinton Field	9/2131	7/1/19	RNAV (GPS) RWY 21, Amdt 1A.
15-Aug-19	OH	Wilmington	Clinton Field	9/2132	7/1/19	RNAV (GPS) RWY 3, Orig.
15-Aug-19	MI	Oscoda	Oscoda-Wurtsmith	9/2619	6/27/19	ILS OR LOC RWY 25, Amdt 4.
15-Aug-19	MS	Winona	Winona-Montgomery County.	9/3249	6/28/19	RNAV (GPS) RWY 3, Amdt 1A.
15-Aug-19	MO	Clinton	Clinton Rgnl	9/4781	7/2/19	RNAV (GPS) RWY 4, Amdt 1A.
15-Aug-19	MO	Clinton	Clinton Rgnl	9/4782	7/2/19	RNAV (GPS) RWY 18, Orig-A.
15-Aug-19	MO	Clinton	Clinton Rgnl	9/4783	7/2/19	RNAV (GPS) RWY 22, Amdt 1A.
15-Aug-19	MO	Clinton	Clinton Rgnl	9/4784	7/2/19	RNAV (GPS) RWY 36, Orig-A.
15-Aug-19	AZ	Prescott	Ernest A Love Field	9/9470	7/1/19	RNAV (GPS) RWY 12, Orig-A.
15-Aug-19	AZ	Prescott	Ernest A Love Field	9/9471	7/1/19	ILS OR LOC/DME RWY 21L, Amdt 4B.
15-Aug-19	AZ	Prescott	Ernest A Love Field	9/9472	7/1/19	RNAV (GPS) Y RWY 3R, Orig-A.
15-Aug-19	AZ	Prescott	Ernest A Love Field	9/9473	7/1/19	RNAV (RNP) Z RWY 3R, Amdt 1A.
15-Aug-19	AZ	Prescott	Ernest A Love Field	9/9474	7/1/19	RNAV (GPS) RWY 21L, Amdt 2B.

[FR Doc. 2019–16928 Filed 8–13–19; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31265; Amdt. No. 3863]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective August 14, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of August 14, 2019.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html* .

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated

by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on July 26, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 12 September 2019

Atlanta, GA, Hartsfield—Jackson Atlanta Intl, RNAV (GPS) RWY 09L, Amdt 4C
Atlanta, GA, Hartsfield—Jackson Atlanta Intl, RNAV (GPS) PRM RWY 9L (SIMULTANEOUS CLOSE PARALLEL), Orig-C
Augusta, GA, Augusta Rgnl at Bush Field, RNAV (GPS) Z RWY 8, Orig-B
Winder, GA, Barrow County, ILS OR LOC RWY 31, Orig-E
Winder, GA, Barrow County, NDB RWY 31, Amdt 9D
Winder, GA, Barrow County, RNAV (GPS) RWY 13, Amdt 1B
Winder, GA, Barrow County, RNAV (GPS) RWY 23, Orig-C
Winder, GA, Barrow County, RNAV (GPS) RWY 31, Amdt 1D

Effective 10 October 2019

Atqasuk, AK, Atqasuk Edward Burnell Sr Memorial, NDB RWY 6, Amdt 2B, CANCELLED
Heber Springs, AR, Heber Springs Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Texarkana, AR, Texarkana Rgnl-Webb Field, RNAV (GPS) RWY 13, Orig-B
St Johns, AZ, St Johns Industrial Air Park, RNAV (GPS) RWY 32, Amdt 1
St Johns, AZ, St Johns Industrial Air Park, VOR–A, Amdt 2A
Fresno, CA, Fresno Chandler Executive, RNAV (GPS) RWY 12, Amdt 1
Fresno, CA, Fresno Chandler Executive, RNAV (GPS) RWY 30, Amdt 1
Fresno, CA, Fresno Chandler Executive, Takeoff Minimums and Obstacle DP, Amdt 3
Fresno, CA, Fresno Chandler Executive, VOR/DME OR GPS–C, Amdt 5A, CANCELLED
Little River, CA, Little River, RNAV (GPS) RWY 29, Amdt 2
Madera, CA, Madera Muni, RNAV (GPS) RWY 12, Amdt 2
Madera, CA, Madera Muni, RNAV (GPS) RWY 30, Amdt 2
Madera, CA, Madera Muni, Takeoff Minimums and Obstacle DP, Amdt 5
Madera, CA, Madera Muni, VOR RWY 30, Amdt 10, CANCELLED
Ontario, CA, Ontario Intl, ILS OR LOC RWY 26L, ILS RWY 26L CAT II, ILS RWY 26L CAT III, Amdt 8B
Ontario, CA, Ontario Intl, ILS OR LOC RWY 26R, Amdt 5A
Palo Alto, CA, Palo Alto, RNAV (GPS) RWY 31, Amdt 2
Palo Alto, CA, Palo Alto, VOR RWY 31, Amdt 1
Santa Monica, CA, Santa Monica Muni, RNAV (GPS) Y RWY 3, Amdt 1A
Ormond Beach, FL, Ormond Beach Muni, Takeoff Minimums and Obstacle DP, Orig-B
Pensacola, FL, Pensacola Intl, RNAV (GPS) RWY 8, Amdt 2E
Belle Plaine, IA, Belle Plaine Muni, RNAV (GPS) RWY 18, Orig-C
Belle Plaine, IA, Belle Plaine Muni, RNAV (GPS) RWY 36, Orig-C
Council Bluffs, IA, Council Bluffs Muni, ILS OR LOC RWY 36, Amdt 1A
Council Bluffs, IA, Council Bluffs Muni, RNAV (GPS) RWY 18, Amdt 1A
Council Bluffs, IA, Council Bluffs Muni, RNAV (GPS) RWY 36, Amdt 2A
Council Bluffs, IA, Council Bluffs Muni, VOR–A, Amdt 5A

Waterloo, IA, Waterloo Rgnl, VOR RWY 6, Amdt 4
Waterloo, IA, Waterloo Rgnl, VOR RWY 18, Amdt 10
Carmi, IL, Carmi Muni, RNAV (GPS) RWY 18, Orig
Carmi, IL, Carmi Muni, RNAV (GPS) RWY 36, Amdt 1
Jeffersonville, IN, Clark Rgnl, ILS OR LOC RWY 18, Amdt 4A
Jeffersonville, IN, Clark Rgnl, RNAV (GPS) RWY 18, Amdt 1A
Sullivan, IN, Sullivan County, RNAV (GPS) RWY 36, Amdt 1A
Ottawa, KS, Ottawa Muni, RNAV (GPS) RWY 17, Amdt 2
Ottawa, KS, Ottawa Muni, RNAV (GPS) RWY 35, Amdt 2
Scott City, KS, Scott City Muni, RNAV (GPS) RWY 17, Orig-A
Winfield/Arkansas City, KS, Strother Field, RNAV (GPS) RWY 35, Amdt 1A
Bowling Green, KY, Bowling Green-Warren County Rgnl, ILS Y OR LOC Y RWY 3, Amdt 2
Bowling Green, KY, Bowling Green-Warren County Rgnl, ILS Z OR LOC Z RWY 3, Orig
Bowling Green, KY, Bowling Green-Warren County Rgnl, NDB RWY 3, Amdt 3
Bowling Green, KY, Bowling Green-Warren County Rgnl, VOR–A, Orig-A, CANCELLED
Hartford, KY, Ohio County, RNAV (GPS) RWY 3, Orig-C
Hartford, KY, Ohio County, RNAV (GPS) RWY 21, Orig-C
Mansfield, LA, C E 'Rusty' Williams, NDB RWY 18, Amdt 2A, CANCELLED
Marquette, MI, Sawyer Intl, ILS OR LOC RWY 1, Amdt 1A
Duluth, MN, Duluth Intl, COPTER ILS OR LOC RWY 27, Amdt 2B, CANCELLED
Duluth, MN, Duluth Intl, ILS OR LOC RWY 27, Amdt 11
Duluth, MN, Duluth Intl, RNAV (GPS) RWY 27, Amdt 1
Duluth, MN, Duluth Intl, Takeoff Minimums and Obstacle DP, Amdt 1
Bowling Green, MO, Bowling Green Muni, VOR/DME–A, Amdt 2A, CANCELLED
Harrisonville, MO, Lawrence Smith Memorial, RNAV (GPS) RWY 35, Orig-B
Manteo, NC, Dare County Regional, VOR RWY 17, Amdt 4A, CANCELLED
Maxton, NC, Laurinburg-Maxton, ILS OR LOC RWY 5, Amdt 2B
Maxton, NC, Laurinburg-Maxton, RNAV (GPS) RWY 5, Amdt 1C
Maxton, NC, Laurinburg-Maxton, RNAV (GPS) RWY 23, Amdt 2
Williamston, NC, Martin County, RNAV (GPS) RWY 3, Amdt 1B
Williamston, NC, Martin County, RNAV (GPS) RWY 21, Amdt 1B
Minot, ND, Minot Intl, VOR RWY 8, Amdt 11A
Minot, ND, Minot Intl, VOR RWY 13, Amdt 11A
Minot, ND, Minot Intl, VOR RWY 26, Amdt 13A
Minot, ND, Minot Intl, VOR RWY 31, Amdt 11A
Williston, ND, Sloulin Fld Intl, ILS OR LOC RWY 29, Amdt 4C
Williston, ND, Sloulin Fld Intl, VOR RWY 11, Amdt 13A
Williston, ND, Williston Basin Intl, ILS OR LOC RWY 32, Orig
Williston, ND, Williston Basin Intl, RNAV (GPS) RWY 14, Orig
Williston, ND, Williston Basin Intl, RNAV (GPS) RWY 32, Orig Williston, ND, Williston Basin Intl, Takeoff Minimums and Obstacle DP, Orig
Williston, ND, Williston Basin Intl, VOR RWY 14, Orig
Williston, ND, Williston Basin Intl, VOR RWY 32, Orig
Mount Holly, NJ, South Jersey Rgnl, RNAV (GPS) RWY 8, Orig-C
Buffalo, NY, Buffalo Niagara Intl, ILS OR LOC RWY 5, Amdt 17B
Dunkirk, NY, Chautauqua County/Dunkirk, RNAV (GPS) RWY 15, Amdt 1A
Dunkirk, NY, Chautauqua County/Dunkirk, RNAV (GPS) RWY 33, Orig-C
Dunkirk, NY, Chautauqua County/Dunkirk, RNAV (GPS) A, Orig-A
Dunkirk, NY, Chautauqua County/Dunkirk, RNAV (GPS) B, Orig-A
Ellenville, NY, Joseph Y Resnick, RNAV (GPS) RWY 22, Orig-A
New York, NY, Long Island Mac Arthur, ILS OR LOC RWY 24, Amdt 4D
Potsdam, NY, Potsdam Muni/Damon Fld/, RNAV (GPS) RWY 24, Amdt 1
Bellefontaine, OH, Bellefontaine Rgnl, VOR RWY 7, Orig-C
Urbana, OH, Grimes Field, VOR–A, Amdt 6
West Union, OH, Alexander Salamon, RNAV (GPS) RWY 5, Orig-B
West Union, OH, Alexander Salamon, RNAV (GPS) RWY 23, Orig-B
Corry, PA, Corry-Lawrence, VOR RWY 32, Amdt 5, CANCELLED
Quakertown, PA, Quakertown, RNAV (GPS) RWY 11, Orig-C
Quakertown, PA, Quakertown, RNAV (GPS) RWY 29, Amdt 1C
San Juan, PR, Luis Munoz Marin Intl, RNAV (GPS) RWY 26, Orig-C
San Juan, PR, Luis Munoz Marin Intl, RNAV (GPS) RWY 28, Orig
Highmore, SD, Highmore Muni, RNAV (GPS) RWY 13, Orig-A
Rapid City, SD, Rapid City Rgnl, VOR OR TACAN RWY 14, Orig-G
Rapid City, SD, Rapid City Rgnl, VOR OR TACAN RWY 32, Amdt 24H
Vermillion, SD, Harold Davidson Field, RNAV (GPS) RWY 12, Orig-A
Vermillion, SD, Harold Davidson Field, RNAV (GPS) RWY 30, Amdt 2A
Abilene, TX, Abilene Rgnl, ILS OR LOC RWY 35R, Amdt 7B
Abilene, TX, Abilene Rgnl, RNAV (GPS) RWY 22, Orig-B
Abilene, TX, Abilene Rgnl, RNAV (GPS) RWY 35R, Amdt 1C
Amarillo, TX, Rick Husband Amarillo Intl, RNAV (GPS) Y RWY 4, Amdt 1A
Baytown, TX, Baytown, Takeoff Minimums and Obstacle DP, Orig-A
Brady, TX, Curtis Field, NDB RWY 17, Amdt 4A, CANCELLED
Center, TX, Center Muni, NDB RWY 17, Amdt 2B
Center, TX, Center Muni, RNAV (GPS) RWY 35, Orig-B
Cleburne, TX, Cleburne Rgnl, LOC RWY 15, Orig-F
Cleburne, TX, Cleburne Rgnl, RNAV (GPS) RWY 15, Amdt 1B
Cleburne, TX, Cleburne Rgnl, RNAV (GPS) RWY 33, Amdt 1B
Coleman, TX, Coleman Muni, RNAV (GPS) RWY 15, Amdt 1
Coleman, TX, Coleman Muni, RNAV (GPS) RWY 33, Amdt 1
Corsicana, TX, C David Campbell Field-Corsicana Muni, RNAV (GPS) RWY 32, Amdt 1
Dallas-Fort Worth, TX, Dallas-Fort Worth Intl, ILS RWY 18L (CONVERGING), Amdt 2B
Dallas-Fort Worth, TX, Dallas-Fort Worth Intl, ILS RWY 18R (CONVERGING), Amdt 6B
Dallas-Fort Worth, TX, Dallas-Fort Worth Intl, ILS OR LOC RWY 17C, ILS RWY 17C SA CAT I, ILS RWY 17C CAT II, ILS RWY 17C CAT III, Amdt 11A
Dallas-Fort Worth, TX, Dallas-Fort Worth Intl, ILS OR LOC RWY 17R, ILS RWY 17R SA CAT I, ILS RWY 17R SA CAT II, Amdt 23C
Fort Worth, TX, Bourland Field, RNAV (GPS) RWY 35, Amdt 2
Fort Worth, TX, Bourland Field, VOR/DME–A, Orig-C, CANCELLED
Granbury, TX, Granbury Rgnl, RNAV (GPS) RWY 14, Amdt 1
Hamilton, TX, Hamilton Muni, RNAV (GPS) RWY 18, Amdt 1C
Hamilton, TX, Hamilton Muni, RNAV (GPS) RWY 36, Amdt 1C
Mineral Wells, TX, Mineral Wells Rgnl, RNAV (GPS) RWY 31, Orig-A
Stephenville, TX, Clark Field Muni, VOR/DME–A, Amdt 1A, CANCELLED
Sulphur Springs, TX, Sulphur Springs Muni, RNAV (GPS) RWY 1, Amdt 1B
Sulphur Springs, TX, Sulphur Springs Muni, RNAV (GPS) RWY 19, Orig-C
Sulphur Springs, TX, Sulphur Springs Muni, VOR–B, Amdt 7
Sweetwater, TX, Avenger Field, NDB RWY 17, Amdt 4A, CANCELLED
Waco, TX, Heart of Texas Industrial, ILS OR LOC RWY 17L, Amdt 13C
Waco, TX, Heart of Texas Industrial, NDB RWY 35R, Amdt 12A
Waco, TX, Heart of Texas Industrial, RNAV (GPS) RWY 17L, Amdt 2
Waco, TX, Heart of Texas Industrial, RNAV (GPS) RWY 35R, Amdt 2A
Waco, TX, Heart of Texas Industrial, Takeoff Minimums and Obstacle DP, Orig-A
Duchesne, UT, Duchesne Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Norfolk, VA, Hampton Roads Executive, ILS OR LOC RWY 10, Orig
West Point, VA, Middle Peninsula Rgnl, RNAV (GPS) RWY 28, Orig-D, CANCELLED
West Point, VA, Middle Peninsula Rgnl, RNAV (GPS)-B, ORIG
Antigo, WI, Langlade County, RNAV (GPS) RWY 9, Orig-B
Antigo, WI, Langlade County, RNAV (GPS) RWY 27, Amdt 1A
Fond Du Lac, WI, Fond Du Lac County, LOC RWY 36, Amdt 1B
Fond Du Lac, WI, Fond Du Lac County, RNAV (GPS) RWY 36, Amdt 1A
Morgantown, WV, Morgantown Muni-Walter L Bill Hart Fld, ILS OR LOC RWY 18, Amdt 13C

Morgantown, WV, Morgantown Muni-Walter L Bill Hart Fld, RNAV (GPS) Y RWY 18, Orig-C
Morgantown, WV, Morgantown Muni-Walter L Bill Hart Fld, RNAV (GPS) Z RWY 18, Orig-B
Fort Bridger, WY, Fort Bridger, Takeoff Minimums and Obstacle DP, Amdt 1
Saratoga, WY, Shively Field, RNAV (GPS) RWY 5, Orig-C

RESCINDED: On July 18, 2019 (84 FR 34290), the FAA published an Amendment in Docket No. 31260, Amdt No. 3859, to Part 97 of the Federal Aviation Regulations under sections 97.23, 97.33, 97.37. The following entries for Madera, CA, effective August 15, 2019, are hereby rescinded in their entirety:

Madera, CA, Madera Muni, RNAV (GPS) RWY 12, Amdt 2
Madera, CA, Madera Muni, RNAV (GPS) RWY 30, Amdt 2
Madera, CA, Madera Muni, Takeoff Minimums and Obstacle DP, Amdt 5
Madera, CA, Madera Muni, VOR RWY 30, Amdt 10, CANCELLED

[FR Doc. 2019–16922 Filed 8–13–19; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 190808–0011]

RIN 0694–AH50

Addition of Certain Entities to the Entity List, Revision of Entries on the Entity List, and Removal of Entities From the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding seventeen entities, under a total of nineteen entries, to the Entity List. These seventeen entities have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. These entities will be listed on the Entity List under the destinations of Armenia, Belgium, Canada, the People's Republic of China (China), Georgia, Hong Kong, Malaysia, the Netherlands, Russia, the United Arab Emirates (U.A.E.), and the United Kingdom (U.K.). This rule also modifies a total of twenty-three entries on the Entity List under the destinations of China, Hong Kong, and Russia. Finally, this rule removes a total of three entities under the destinations of China and the U.A.E. The removals are made in connection with requests for removal that BIS received pursuant to the EAR and a review of information provided in those requests.

DATES: This rule is effective August 14, 2019.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Entity List (Supplement No. 4 to part 744 of the Export Administration Regulations (EAR)) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States. The EAR (15 CFR parts 730–774) impose additional license requirements on, and limit the availability of most license exceptions for, exports, reexports, and transfers (in-country) to listed entities. The license review policy for each listed entity is identified in the ''License review policy'' column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** notice adding entities to the Entity List. BIS places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

Additions to the Entity List

Under § 744.11(b) (Criteria for revising the Entity List) of the EAR, entities for which there is reasonable cause to believe, based on specific and articulable facts, have been involved, are involved, or pose a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States, and those acting on behalf of such persons, may be added to the Entity List.

This rule implements the decision of the ERC to add seventeen entities, under a total of nineteen entries, to the Entity List; one of these entities is being added under three entries. The seventeen entities being added are located in Armenia, Belgium, Canada, China, Georgia, Hong Kong, Malaysia, the Netherlands, Russia, the U.A.E. and the U.K. The seventeen entities are being added based on § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. The nineteen entries consist of two entries located in Armenia, two entries located in Belgium, one entry located in Canada, four entries located in China, one entry located in Georgia, one entry located in Hong Kong, one entry located in Malaysia, one entry located in the Netherlands, one entry located in Russia, four entries located in the U.A.E., and one entry located in the U.K.

The ERC reviewed and applied § 744.11(b) in making the determination to add these seventeen entities to the Entity List. Under that section, entities for which there is reasonable cause to believe, based on specific and articulable facts, have been involved, are involved, or pose a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States, along with those acting on behalf of such persons, may be added to the Entity List. Paragraphs (b)(1) through (b)(5) of § 744.11 provide an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States. For each of the seventeen entities described below, the ERC made the requisite determination under the standard set forth in § 744.11(b).

Pursuant to § 744.11(b), the ERC determined to add Al Merikh General Trading, an Emirati entity, to the Entity List, because Al Merikh General Trading has transshipped U.S.-origin items to sanctioned destinations without the required authorizations; to add four Chinese entities, China General Nuclear Power Group, China General Nuclear Power Corporation (CGNPC), China Nuclear Power Technology Research Institute Co. Ltd., and Suzhou Nuclear Power Research Institute Co. Ltd., because each of these four Chinese entities has engaged in or enabled efforts to acquire advanced U.S. nuclear technology and material for diversion to military uses in China; and to add Corad

Technology Limited, a Hong Kong entity, because Corad Technology Limited has been involved in the sale of U.S. technology to Iran's military and space programs, to front companies of the Democratic People's Republic of Korea (North Korea), and to subordinate entities of China's Government and its defense industry. The ERC also determined to add two Belgian entities, Industrial Metals and Commodities and Nicolas Kaiga; three Emirati entities, Emirates Alloys, Super Alloys, and Saeed Valadbaigi; one Malaysian entity, NBH Industries; and one Georgian entity, Georgia Petrochemical and Aviatech, to the Entity List, because each of these seven entities unlawfully attempted to procure and divert export-controlled aluminum tubing via Malaysia to Iran. Nicolas Kaiga also has been added under entries for the Netherlands and the U.K., in addition to Belgium.

Pursuant to § 744.11(b), the ERC also determined to add Kelvo Inc., a Canadian entity, to the Entity List, because the sole proprietor of Kelvo Inc. engaged in unlawful reexports from Canada to Russia and Armenia of items subject to the EAR and controlled on the Commerce Control List (CCL) for national security reasons; to add two Armenian entities, Markel Closed Joint Stock Company (Markel CJSC) and Yerevan Telecommunications Research Institute (YETRI) Closed Joint Stock Company (CJSC), because YETRI CJSC has obtained CCL items that were reexported without the required BIS licenses, and the person who is both Executive Director of YETRI CJSC and President of Markel CJSC has been engaged in a business relationship with a sanctioned Iranian organization; and to add one Russian entity Joint Stock Company Kaluga Scientific Research Institute of Radio Engineering (KNIRTI), because KNIRTI is a majority-owned subsidiary of the sanctioned Russian entity Joint-Stock Company Concern Radio-Electronic Technologies (*a.k.a.,* KRET), and is subject to existing designations by the Department of the Treasury, pursuant to Executive Order 13661.

Pursuant to § 744.11(b), the ERC determined that the conduct of these seventeen entities raises sufficient concerns that prior review of exports, reexports, or transfers (in-country) of all items subject to the EAR involving these entities, and the possible imposition of license conditions or license denials on shipments to the persons, will enhance BIS's ability to prevent violations of the EAR.

For the seventeen entities added to the Entity List in this final rule, BIS imposes a license requirement for all items subject to the EAR and a license review policy of presumption of denial. The license requirement applies to any transaction in which items subject to the EAR are to be exported, reexported, or transferred (in-country) to any of these entities. The acronym ''a.k.a.'' (also known as) is used in entries on the Entity List to identify aliases, thereby assisting exporters, reexporters, and transferors in identifying entities on the Entity List.

This final rule adds the following seventeen entities, under a total of nineteen entries, to the Entity List:

Armenia

- Markel Closed Joint Stock Company (Markel CJSC); *and*
- Yerevan Telecommunications Research Institute (YETRI) Closed Joint Stock Company (CJSC).

Belgium

- Industrial Metals and Commodities; *and*
- Nicolas Kaiga, including one alias (Nicholas Kaiga).

Canada

- Kelvo Inc.

China

- China General Nuclear Power Corporation (CGNPC), including one alias (China Guangdong Nuclear Power Corporation);
- China General Nuclear Power Group;
- China Nuclear Power Technology Research Institute Co. Ltd.; *and*
- Suzhou Nuclear Power Research Institute Co. Ltd.

Georgia

- Georgia Petrochemical and Aviatech.

Hong Kong

- Corad Technology Limited, including one alias (Corad Technology (China) Limited).

Malaysia

- NBH Industries.

Netherlands

- Nicolas Kaiga, including one alias (Nicholas Kaiga).

Russia

- Joint Stock Company Kaluga Scientific Research Institute of Radio Engineering (KNIRTI).

United Arab Emirates

- Al Merikh General Trading;
- Emirates Alloys, including two aliases (Emirates Alloys General Trading LLC; *and* Emirates Aero);
- Super Alloys; *and*
- Saeed Valadbaigi, including two aliases (Saeed Valad; *and* Saeed Baigi).

United Kingdom

- Nicolas Kaiga, including one alias (Nicholas Kaiga).

Modification to the Entity List

This final rule implements the decision of the ERC to modify twenty-three existing entries. The modifications consist of revising seventeen entries under China, four entries under Hong Kong, and two entries under Russia. The modifications to the entities under China consist of revising five entries, and, to reflect changes to ten separate entities, removing the entries for these ten entities and adding in their place twelve new entries. The final rule adds twelve entries under the destination of China as part of the modifications of these ten entries because one entry that is being modified is being removed and in its place three separate entities are being added to reflect a reorganization that occurred at that entity whereby the single entity has now become three distinct entities.

The modifications to twenty-three existing entries is described further as follows:

This final rule implements the decision of the ERC to modify one existing entry, First Department, Chinese Academy of Launch Vehicle Technology (CALT), which was first added to the Entity List under the destination of China on May 14, 2001 (66 FR 24266) and most recently modified on September 9, 2012 (77 FR 58006). BIS is modifying the existing entry by updating names (including entity name and aliases) and addresses for this entry. This rule changes the existing entity name to China Aerospace Science and Technology Corporation (CASC) 1st Academy First Design Department.

This final rule implements the decision of the ERC to modify one existing entry, Beijing Aerospace Automatic Control Institute (BICD), which was first added to the Entity List under the destination of China on May 28, 1999 (64 FR 28909) and most recently modified on September 20, 2016 (81 FR 64696). BIS is modifying the existing entry by updating names (including the entity name and aliases) for this entry. This rule changes the existing entity name to China Aerospace Science and Technology Corporation (CASC) 1st Academy 12 Research Institute.

This final rule implements the decision of the ERC to modify one existing entry, 13 Institute, China

Academy of Launch Vehicle Technology (CALT), which was first added to the Entity List under the destination of China on May 14, 2001 (66 FR 24265) and most recently modified on December 17, 2010 (75 FR 78877). BIS is modifying the existing entry by updating names (including entity name and aliases) and addresses and correcting the organizational structure for this entity, which is now a part of the CASC 9th Academy. This rule changes the existing entity name to China Aerospace Science and Technology Corporation (CASC) 9th Academy 13 Research Institute.

This final rule implements the decision of the ERC to modify one existing entry, Beijing Institute of Structure and Environmental Engineering (BISE), which was first added to the Entity List under the destination of China on May 28, 1999 (64 FR 28909) and most recently modified on September 20, 2016 (81 FR 64696). BIS is modifying the existing entry by updating names (including the entity name and aliases) for this entity. This rule changes the existing entity name to China Aerospace Science and Technology Corporation (CASC) 1st Academy 702 Research Institute.

This final rule implements the decision of the ERC to modify one existing entry, Beijing Power Machinery Institute, which was first added to the Entity List under the destination of China on May 14, 2001 (66 FR 24266) and most recently modified on December 17, 2010 (75 FR 78877). BIS is modifying the existing entry by updating names (including the entity name and aliases) and addresses for this entity. This rule changes the existing entity name to China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 31 Research Institute.

This final rule implements the decision of the ERC to modify one existing entry, Xiangdong Machinery Factory, within the China Aerospace Science and Industry Corps Third Academy (CASIC), which was first added to the Entity List under the destination of China on May 14, 2001 (66 FR 24267) and most recently modified on September 19, 2012 (77 FR 58006). BIS is modifying the existing entry by updating names (including the entity name and aliases) and addresses. These modifications also update the entry to reflect the organizational structure for Xiangdong Machinery Factory, within the China Aerospace Science and Industry Corp's Third Academy (CASIC). This rule changes the existing entry to reflect that Xiangdong Machinery Factory is three separate entities, to be listed as follows:

- China Aerospace Science and Industry Corporation (CASIC) 3rd Academy;
- China Aerospace Science and Industry Corporation (CASIC) 3rd Academy's 159 Factory; *and*
- China Aerospace Science and Industry Corporation (CASIC) 3rd Academy's 239 Factory.

This final rule implements the decision of the ERC to modify one existing entry, 33 Institute, which was first added to the Entity List under the destination of China on May 14, 2001 (66 FR 24266) and most recently modified on September 20, 2016 (81 FR 64696). BIS is modifying the existing entry for 33 Institute by updating names (including the entity name and aliases) and addresses for this entity. This rule changes the existing entity name to China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 33 Research Institute.

This final rule implements the decision of the ERC to modify one existing entry, 35 Institute, which was first added to the Entity List under the destination of China on May 14, 2001 (66 FR 24266) and most recently modified on September 20, 2016 (81 FR 64696). BIS is modifying the existing entry for 35 Institute by updating names (including the entity name and aliases) and addresses for this entity. This rule changes the existing entity name to China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 35 Research Institute.

This final rule implements the decision of the ERC to modify one existing entry, Shanghai Academy of Spaceflight Technology (SAST), which was first added to the Entity List under the destination of China on May 28, 1999 (64 FR 28909) and most recently modified on September 20, 2016 (81 FR 64696). BIS is modifying the existing entry for Shanghai Academy of Spaceflight Technology by updating the names (including the entity name and aliases) and addresses for this entry. This rule changes the existing entity name to China Aerospace Science and Technology Corporation (CASC) 8th Academy.

This final rule implements the decision of the ERC to modify one existing entry, Shanghai Institute of Space Power Sources, which was first added to the Entity List under the destination of China on May 28, 1999 (64 FR 28909) and most recently modified on September 20, 2016 (81 FR 64696). BIS is modifying the existing entry for Shanghai Institute of Space Power Sources by updating names (including the entity name and aliases) and addresses for this entity. This rule changes the existing entity name to China Aerospace Science and Technology Corporation (CASC) 8th Academy 811 Research Institute.

This final rule implements the decision of the ERC to modify four existing entries, Chen Qu, Edward Fan, Sharon Yang, and TanWei, which were added to the Entity List under the destination of China on March 21, 2016 (81 FR 14958). These four persons had the same address as Jereh International and Yantai Jereh Oilfield Services, which are removed from the Entity List in this rule. BIS is modifying the existing entries Chen Qu, Edward Fan, Sharon Yang, and TanWei by revising the addresses to provide new addresses associated with each of these four persons that are being retained on the Entity List.

This final rule implements the decision of the ERC to modify one existing entry, Northwestern Polytechnical University, which was first added to the Entity List under the destination of China on May 14, 2001 (66 FR 24266) and most recently modified on September 20, 2016 (81 FR 64696). BIS is modifying the existing entry for Northwestern Polytechnical University by adding a reference to see § 744.11 of the EAR in the License Requirement. BIS is also modifying the existing entry by changing the License Review Policy to a presumption of denial.

This final rule implements the decision of the ERC to modify four existing entries, Calvin Law, CLC Holdings Limited, LHI Technology (H.K.) Company Limited, and ZM International Company Ltd., which were added to the Entity List under the destination of Hong Kong on September 4, 2018 (83 FR 44824). BIS is modifying these existing entries by revising the addresses to add ''N.T.'' before Hong Kong.

This final rule implements the decision of the ERC to modify one existing entry, Obinsk Research and Production Enterprise (ORPE), which was added to the Entity List under the destination of Russia on September 26, 2018 (83 FR 48534). BIS is modifying the existing entry to correct a spelling error by inserting an ''n'' after ''b,'' so it reads as ''Obninsk'' in the three places where the term is referenced in this entry.

This final rule implements the decision of the ERC to modify one existing entry, Limited Liability Company Concord Management and Consulting, which was added to the Entity List under the destination of Russia on June 22, 2017 (82 FR 28408). BIS is modifying the existing entry of

Limited Liability Company Concord Management and Consulting to insert text for the License Requirement, License Review Policy, and **Federal Register** citation columns that was inadvertently not included in the final rule that originally added this entity.

Removals From the Entity List

This rule implements a decision of the ERC to remove Jereh International and Yantai Jereh Oilfield Services Group Co., Ltd., two entities located in China, from the Entity List on the basis of a removal request. The entries for Jereh International and Yantai Jereh Oilfield Services Group Co., Ltd. were added to the Entity List on March 21, 2016 (81 FR 14958). This rule also implements a decision of the ERC to remove Deira General Marketing, an entity located in the U.A.E., from the Entity List on the basis of a removal request. The entry for Deira General Marketing was added to the Entity List on January 26, 2018 (83 FR 3580). The ERC decided to remove these three entries based on information BIS received pursuant to § 744.16 of the EAR and the review the ERC conducted in accordance with procedures described in Supplement No. 5 to part 744.

This final rule implements the decision to remove the following three entities, consisting of two located in China and one in the U.A.E., from the Entity List:

China

- Jereh International; *and*
- Yantai Jereh Oilfield Services Group Co., Ltd.

United Arab Emirates

- Deira General Marketing.

Savings Clause

Shipments of items removed from eligibility for a License Exception or for export or reexport without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export or reexport, on August 14, 2019, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export or reexport without a license (NLR).

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA). ECRA, as amended (50 U.S.C. 4801–4852), provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. As set forth in Sec. 1768 of ECRA, all delegations, rules, regulations, orders, determinations, licenses, or other forms of administrative action that have been made, issued, conducted, or allowed to become effective under the Export Administration Act of 1979 (50 U.S.C. 4601 *et seq.*) (as in effect prior to August 13, 2018 and as continued in effect pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 8, 2018, 83 FR 39871 (August 13, 2018)), or the Export Administration Regulations, and were in effect as of August 13, 2018, shall continue in effect according to their terms until modified, superseded, set aside, or revoked under the authority of ECRA.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications, and carries a burden estimate of 42.5 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to Section 1762 of the Export Control Reform Act of 2018 (50 U.S.C. 4801–4852), which was included in the John S. McCain National Defense Authorization Act for Fiscal Year 2019, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. This action involves the removal of three entities from the Entity List. Removals from the Entity List involve interagency deliberation and result from review of public and non-public sources, including, where applicable, sensitive law enforcement information and classified information, and the measurement of such information against the Entity List removal criteria. This information is reviewed according to the procedures and criteria for evaluating removal requests from the Entity List, as set forth in 15 CFR 744.11, 15 CFR 744.16, and 15 CFR part 744, Supplement No. 5. For reasons of national security, BIS is not at liberty to provide to the public detailed information on which the ERC relies to make the decisions to remove these entities. In addition, the information included in a removal request is exchanged between the applicant and the ERC, which by law (§ 1761(h) of the ECRA), BIS is restricted from sharing with the public. Moreover, removal requests from the Entity List may contain confidential business information that is necessary for the extensive review conducted by the ERC.

6. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of August 8, 2018, 83 FR 39871 (August 13, 2018); Notice of September 19, 2018, 83 FR 47799 (September 20, 2018); Notice of November 8, 2018, 83 FR 56253 (November 9, 2018); Notice of January 16, 2019, 84 FR 127 (January 18, 2019).

■ 2. Supplement No. 4 to part 744 is amended:

■ a. Under Armenia, by adding in alphabetical order, two Armenian entities, ''Markel Closed Joint Stock Company (Markel CJSC),'' and ''Yerevan Telecommunications Research Institute (YETRI) Closed Joint Stock Company (CJSC)'';

■ b. Under Belgium, by adding in alphabetical order, two Belgian entities, ''Industrial Metals and Commodities'' and ''Nicolas Kaiga;''

■ c. Under Canada, by adding in alphabetical order, one Canadian entity, ''Kelvo Inc.'';

■ d. Under China,

■ i. By adding in alphabetical order, sixteen Chinese entities, ''China Aerospace Science and Industry Corporation (CASIC) 3rd Academy,'' ''China Aerospace Science and Industry Corporation (CASIC) 3rd Academy's 159 Factory,'' ''China Aerospace Science and Industry Corporation (CASIC) 3rd Academy's 239 Factory,'' ''China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 31 Research Institute,'' ''China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 33 Research Institute,'' ''China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 35 Research Institute,'' ''China Aerospace Science and Technology Corporation (CASC) 1st Academy 12 Research Institute,'' ''China Aerospace Science and Technology Corporation (CASC) 1st Academy 702 Research Institute,'' ''China Aerospace Science and Technology Corporation (CASC) 1st Academy First Design Department,'' ''China Aerospace Science and Technology Corporation (CASC) 8th Academy,'' ''China Aerospace Science and Technology Corporation (CASC) 8th Academy 811 Research Institute,'' ''China Aerospace Science and Technology Corporation (CASC) 9th Academy 13 Research Institute,'' ''China General Nuclear Power Corporation (CGNPC),'' ''China General Nuclear Power Group,'' ''China Nuclear Power Technology Research Institute Co. Ltd.,'' and ''Suzhou Nuclear Power Research Institute Co. Ltd.'';

■ ii. By removing twelve Chinese entities, ''13 Institute, China Academy of Launch Vehicle Technology (CALT),'' ''33 Institute,'' ''35 Institute,'' ''Beijing Aerospace Automatic Control Institute (BICD),'' ''Beijing Institute of Structure and Environmental Engineering (BISE),'' ''Beijing Power Machinery Institute,'' ''First Department, Chinese Academy of Launch Vehicle Technology (CALT),'' ''Jereh International,'' ''Shanghai Academy of Spaceflight Technology (SAST),'' ''Shanghai Institute of Space Power Sources,'' ''Xiangdong Machinery Factory, within the China Aerospace Science and Industry Corporation's (CASIC) Third Academy,'' and ''Yantai Jereh Oilfield Services Group Co., Ltd.''; and

■ iii. By revising five Chinese entities, ''Chen Qu,'' ''Edward Fan,'' ''Northwestern Polytechnical University,'' ''Sharon Yang,'' and ''TanWei'';

■ e. Under Georgia, by adding in alphabetical order, one Georgian entity, ''Georgia Petrochemical and Aviatech''

■ f. Under Hong Kong,

■ i. By adding in alphabetical order, one Hong Kong entity, ''Corad Technology Limited,'' and

■ ii. By revising four Hong Kong entities, ''Calvin Law,'' ''CLC Holdings Limited,'' ''LHI Technology (H.K.) Company Limited,'' and ''ZM International Company Ltd.'';

■ g. Under Malaysia, by adding one Malaysian entity, ''NBH Industries;''

■ h. Under the Netherlands, by adding in alphabetical order, one Dutch entity, ''Nicolas Kaiga''.

■ i. Under Russia,

■ i. By adding in alphabetical order, one Russian entity, ''Joint Stock Company Kaluga Scientific Research Institute of Radio Engineering (KNIRTI)''; and

■ ii. By revising two Russian entities ''Limited Liability Company Concord Management and Consulting,'' and ''Obninsk Research and Production Enterprise (ORPE)''; and

■ j. Under the United Arab Emirates,

■ i. By adding in alphabetical order, four Emirati entities, ''Al Merikh General Trading,'' ''Emirates Alloys,'' ''Super Alloys,'' and ''Saeed Valadbaigi'' and

■ ii. By removing one Emirati entity, ''Deira General Marketing''.

■ k. Under the United Kingdom, by adding in alphabetical order, one British entity, ''Nicolas Kaiga.''

The additions and revisions read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
*	* * *	*	* *	*
ARMENIA	* *	*	* *	*
	Markel Closed Joint Stock Company (Markel CJSC), 17, Apt 31, Mashtoc Avenue, Yerevan, Armenia, 375002; *and* 26 Dzorapi Street, Yerevan, 0015, Armenia	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Yerevan Telecommunications Research Institute (YETRI) Closed Joint Stock Company (CJSC), 26, Dzorapy Street, 0015, Yerevan, Armenia	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.

Country	Entity	License requirement	License review policy	Federal Register citation
*	* * *	*	* *	*
BELGIUM	* *	*	* *	*
	Industrial Metals and Commodities, Goffarstraad 16, B–1050, Brussels, Belgium	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	Nicolas Kaiga, a.k.a., the following one alias: Nicholas Kaiga Goffarstraad 16, B–1050, Brussels, Belgium. (See alternate addresses under Netherlands and United Kingdom)	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
*	* * *	*	* *	*
CANADA	* *	*	* *	*
	Kelvo Inc 6600 21st Avenue, Laval, Quebec H7R3G8, Canada; *and* 7169 19th Avenue, Laval, Quebec H7R3E5, Canada	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
*	* * *	*	* *	*
CHINA, PEOPLE'S REPUBLIC OF	* *	*	* *	*
	Chen Qu, a.k.a., the following one alias:—Chen Choo No. 4 Nanhuan Road, Jinzhou City, Hubei Province, China	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	81 FR 14958, 3/21/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, a.k.a., the following three aliases: —China Haiying Electro-Mechanical Technology Academy (CHETA); —HiWING Mechanical & Electrical Technology Corporation; *and* —Beijing HY Electronic Tech Co No. 1 Haiying Rd, Fengtai Technology District, Tower 1, 7/F, Beijing; *and* F/5 #5 BLDG Hangtian Haiying Tech No 1 Kaiying Rd, Feng Tai District, Beijing 100089; *and* No. 11, Hepingli East Street, Dongcheng District, Beijing; *and* P.O. Box 7200–80, Beijing 100074	For all items subject to the EAR	See § 744.3(d) of this part	66 FR 24267, 5/14/01. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Aerospace Science and Industry Corporation (CASIC) 3rd Academy's 159 Factory, a.k.a., the following two aliases: —159th Factory; *and* —Beijing Xinghang Electromechanical Equipment Factory No. 9, DongWangzuo North Road, Yungang, Fengtai District, Beijing, 100074	For all items subject to the EAR	See § 744.3(d) of this part	66 FR 24267, 5/14/01. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Aerospace Science and Industry Corporation (CASIC) 3rd Academy's 239 Factory, a.k.a., the following two aliases: —239th Factory; *and* —Beijing Hangxing Machinery Manufacturing Corporation., Ltd No. 11 Hepingli East Street, Dongcheng District, Beijing 100013	For all items subject to the EAR	See § 744.3(d) of this part	66 FR 24267, 5/14/01. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.

Country	Entity	License requirement	License review policy	Federal Register citation
	China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 31 Research Institute, a.k.a., the following two aliases: —31st Institute; *and* —Beijing Power Machinery Institute. No. 17, Yungang West Road, Fengtai District, Beijing	For all items subject to the EAR	See § 744.3(d) of this part	66 FR 24266, 5/14/01. 75 FR 78877, 12/17/10. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 33 Research Institute, a.k.a., the following two aliases: —33rd Institute; *and* —Beijing Automation Control Equipment Institute (BACEI) No. 1, Yungang Beili, Fengtai District, Beijing 100074	For all items subject to the EAR	See § 744.3(d) of this part	66 FR 24266, 5/14/01. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 81 FR 64696, 9/20/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Aerospace Science and Industry Corporation (CASIC) 3rd Academy, 35 Research Institute, a.k.a, the following two aliases: —35th Institute; *and* —Huahang Institute of Radio Measurement No. 3 South Street, Hepingli East Road, Dongcheng, Beijing, 100013	For all items subject to the EAR	See § 744.3(d) of this part	66 FR 24266, 5/14/01. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 81 FR 64696, 9/20/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
*	*	*	*	*
	China Aerospace Science and Technology Corporation (CASC) 1st Academy 12 Research Institute, a.k.a., the following two aliases: —Beijing Aerospace Automatic Control Institute (BICD); *and* —12th Institute 51 Yong Ding Road, Beijing; *and* No. 50 Yongding Road, Haidian District, Beijing 100854	For all items subject to the EAR	See § 744.3 of this part	64 FR 28909, 5/28/99. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 81 FR 64696, 9/20/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Aerospace Science and Technology Corporation (CASC) 1st Academy 702 Research Institute, a.k.a., the following two aliases: —702nd Institute; *and* —Beijing Institute of Structure and Environmental Engineering (BISE) No. 30 Wanyuan Road, Beijing	For all items subject to the EAR	See § 744.3 of this part	64 FR 28909, 5/28/99. 75 FR 78877, 12/17/10. 81 FR 64696, 9/20/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Aerospace Science and Technology Corporation (CASC) 1st Academy First Design Department, a.k.a., the following one alias: —1st General Design Department 1 South Dahongmen Road, Fengtai District, Beijing 100076	For all items subject to the EAR	See § 744.3(d) of this part	66 FR 24266, 5/14/01. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Aerospace Science and Technology Corporation (CASC) 8th Academy, and the following three aliases: —Shanghai Academy of Spaceflight Technology (SAST); —Shanghai Institute of Space; *and* —MOA#8 Academy Shanghai Spaceflight Tower, 222 Cao Xi Road, Shanghai, 200233; *and* No. 3888 Yuanjiang Road, Minhang District, Shanghai 201109; *and* No. 2965 Dongchuan Rd Minhang District Shanghai, China	For all items subject to the EAR	See § 744.3 of this part	64 FR 28909, 5/28/99. 75 FR 78877, 12/17/10. 81 FR 64696, 9/20/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.

Country	Entity	License requirement	License review policy	Federal Register citation
	China Aerospace Science and Technology Corporation (CASC) 8th Academy 811 Research Institute, and the following two aliases: —811th Institute; *and* —Shanghai Institute of Space Power Sources 388 Cang Wu Road, Shanghai; *and* 2965 Dongchuan Road, Minhang District, Shanghai 200245	For all items subject to the EAR	See § 744.3 of this part	64 FR 28909, 5/28/99. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 81 FR 64696, 9/20/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Aerospace Science and Technology Corporation (CASC) 9th Academy 13 Research Institute, a.k.a., the following four aliases: —13th Institute; —Beijing Institute of Aerospace Control Devices (BIACD); —230 Factory; *and* —Beijing Aerospace Times Optical-Electronic Technology Co., Ltd No. 1 Fengying East Road, Haidian District, Beijing 100094	For all items subject to the EAR	See § 744.3(d) of this part	66 FR 24265, 5/14/01. 75 FR 78877, 12/17/10. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	China General Nuclear Power Corporation (CGNPC), a.k.a., the following one alias: —China Guangdong Nuclear Power Corporation South Building, CGN Tower, 2002 Shennan Boulevard, Futian District, Shenzhen, Guangdong Province, China; *and* 1001 Shangbuzhong Road, Shenzhen Sci & Tech Building, Shenzhen, China	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China General Nuclear Power Group, South Building, CGN Tower, 2002 Shennan Boulevard, Futian District, Shenzhen, Guangdong Province, China	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	China Nuclear Power Technology Research Institute Co. Ltd., 47 F/A Jiangsu Building, Yitian Road, Futian District, Shenzhen, 518026, China	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Edward Fan, Hucun, Huafeng Town, Ningyang County, Tai'an City, Shandong Province, China	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	81 FR 14958, 3/21/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Northwestern Polytechnical University, a.k.a., the following three aliases: —Northwestern Polytechnic University; —Northwest Polytechnic University; *and* —Northwest Polytechnical University. 127 Yonyi Xilu, Xi'an 71002 Shaanxi, China; *and* Youyi Xi Lu, Xi'an, Shaanxi, China; *and* No. 1 Bianjia Cun, Xi'an; *and* West Friendship Rd. 59, Xi'an; *and* 3 10 W Apt 3, Xi'an	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	66 FR 24266, 5/14/01. 75 FR 78883, 12/17/10. 77 FR 58006, 9/19/12. 81 FR 64696, 9/20/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Sharon Yang, No. 96 Haining Road, Zhifu District, Yantai City, Shandong Province, China	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	81 FR 14958, 3/21/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Suzhou Nuclear Power Research Institute Co. Ltd., 1788 Xihuan Road, Suzhou, 215000, China	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*

Country	Entity	License requirement	License review policy	Federal Register citation
	TanWei, a.k.a., the following one alias: —Terry Tan No. 288, Fuhai Road, Fushan District, Yantai City, Shandong Province, China	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	81 FR 14958, 3/21/16. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
*	* * *	*	* *	*
GEORGIA	Georgia Petrochemical and Aviatech, No. 35 Bldg. V Moscow Avenue, Tbilisi, Georgia	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19].
	* *	*	* *	*
*	* * *	*	* *	*
HONG KONG	* *	*	* *	*
	Calvin Law, Flat 2808, 28/F, Asia Trade Centre, 79 Lei Muk Road, Kwai Chung, N.T., Hong Kong; *and* Units 801–803 and 805, Park Sun Building, No. 97–107 Wo Yi Hop Road, Kwai Chung, N.T., Hong Kong	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	83 FR 44824, 9/4/18. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	CLC Holdings Limited, a.k.a., the following one alias: —CLC Xpress Flat 2808, 28/F, Asia Trade Centre, 79 Lei Muk Road, Kwai Chung, N.T., Hong Kong; *and* Units 801–803 and 805, Park Sun Building, No. 97–107 Wo Yi Hop Road, Kwai Chung, N.T., Hong Kong	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	83 FR 44824, 9/4/18. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Corad Technology Limited, a.k.a., the following one alias: —Corad Technology (China) Limited Unit 1306, 13/F, Nanyang Plaza 57 Hung To Road Kwun Tong, Hong Kong; *and* Room K, 5/F, Winner Factory Building No. 55 Hung To Road Kwun Tong Kowloon, Hong Kong	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	LHI Technology (H.K.) Company Limited, Units 801–803 and 805, Park Sun Building, No. 97–107 Wo Yi Hop Road, Kwai Chung, N.T., Hong Kong	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	83 FR 44824, 9/4/18. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	ZM International Company Ltd., 4/F Enterprise Bldg 228–238, Queen's Road Central, Hong Kong; *and* Room C, 22/F, 235 Wing Lok Street, Trade Centre, Sheung Wan, N.T., Hong Kong	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	83 FR 44824, 9/4/18. 83 FR 44824, 9/4/18. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
MALAYSIA	* *	*	* *	*
	NBH Industries, No. 154, Persiaran Raja Muda, Klang Selangor, Malaysia	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	83 FR 44824, 9/4/18. 83 FR 44824, 9/4/18. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
*	* * *	*	* *	*
NETHERLANDS	* *	*	* *	*

Country	Entity	License requirement	License review policy	Federal Register citation
	Nicolas Kaiga, a.k.a., the following one alias: —Nicholas Kaiga 32 Disneystrook, 2726CT Zoetemeer, Netherlands. (See alternate addresses under Belgium and United Kingdom)	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
*	* * *	*	* *	*
Russia	* *	*	* *	*
	Joint Stock Company Kaluga Scientific Research Institute of Radio Engineering (KNIRTI), 2 Lenina Street, Zhukov, Zhukovski Region, Kaluzhskaya Oblast, Russian Federation, 249190	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Limited Liability Company Concord Management and Consulting, a.k.a. the following three aliases: —Konkord Menedzhment I Konsalting, OOO; —LLC Concord Management and Consulting; *and* —Obshchestvo S Ogrannichennoi Otvetstvennostyu Konkord Menedzhment I Konsalting d. 13 Litera A, Pom. 2–N N4, Naberezhnaya Reki Fontanki, St. Petersburg 191011, Russia	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	82 FR 28408, 6/22/17. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Obninsk Research and Production Enterprise (ORPE), a.k.a., the following three aliases: —ORPE Technologiya; —ONPP Technologiya; *and*—Obninsk Composite Materials Plant Kievskoe Shosse 15, Obninsk, 249031, Russia	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	83 FR 48534, 9/26/18. 84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
*	* * *	*	* *	*
UNITED ARAB EMIRATES	* *	*	* *	*
	Al Merikh General Trading, Suite #203, Bani Yas Tower Dubai, UAE; and P.O. Box 3559, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Emirates Alloys, a.k.a., the following two aliases: —Emirates Alloys General Trading LLC; *and* —Emirates Aero No. 101 Marwan Ahmed Ali Building, Port Saeed Road, P.O. Box 183799, Dubai, U.A.E.; *and* No. 104b Sh Maryam Palace, Deira, Dubai U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*
	Saeed Valadbaigi, a.k.a., the following two aliases: —Saeed Valad; *and* —Saeed Baigi. No. 101 Marwan Ahmed Ali Building, Port Saeed Road, P.O. Box 183799, Dubai, U.A.E.; *and* No. 104b Sh Maryam Palace, Deira, Dubai U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	* *	*

Country	Entity	License requirement	License review policy	Federal Register citation
	Super Alloys, No. 101 Marwan Ahmed Ali Building, Port Saeed Road, P.O. Box 183799, Dubai, U.A.E.; *and* No. 104b Sh Maryam Palace, Deira, Dubai U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	*	*
UNITED KINGDOM	* *	*	*	*
	Nicolas Kaiga, a.k.a., the following one alias: —Nicholas Kaiga Flat #6, Philibeach Gardens, Kensington Chelsea, London, United Kingdom. (See alternate addresses under Belgium and Netherlands)	For all items subject to the EAR. (See § 744.11 of the EAR.)	Presumption of denial	84 FR [INSERT FR PAGE NUMBER, 8/14/19.
	* *	*	*	*
*	* *	*	*	*

Dated: August 7, 2019.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2019–17409 Filed 8–13–19; 8:45 am]

BILLING CODE 3510–33–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–86590; File No. S7–22–18]

RIN 3235–AM05

Amendments to Rules for Nationally Recognized Statistical Rating Organizations

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is adopting amendments to rules for nationally recognized statistical rating organizations (''NRSROs'') under the Securities Exchange Act of 1934 (''Exchange Act''). The amendments provide an exemption from a rule for NRSROs with respect to credit ratings if the issuer of the security or money market instrument referred to in the rule is not a U.S. person, and the NRSRO has a reasonable basis to conclude that all offers and sales of such security or money market instrument by any issuer, sponsor, or underwriter linked to such security or money market instrument will occur outside the United States. In addition, the amendments make conforming changes to similar exemptions in two other Exchange Act rules and technical corrections with respect to one of these rules.

DATES: *Effective Date:* September 13, 2019.

FOR FURTHER INFORMATION CONTACT: Harriet Orol, Kevin Vasel, or Patrick Boyle, at (212) 336–9080, Office of Credit Ratings, Securities and Exchange Commission, New York Regional Office, 200 Vesey Street, Suite 400, New York, NY 10281.

SUPPLEMENTARY INFORMATION: The Commission is adopting amendments to:

Commission reference	CFR citation (17 CFR)
Securities Exchange Act of 1934 (Exchange Act): [1]	
Rule 17g–5(a)(3)	§ 240.17g–5(a)(3)
Rule 17g–7(a)	§ 240.17g–7(a)
Rule 15Ga–2	§ 240.15Ga–2

[1] 15 U.S.C. 78a *et seq.*

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I. Introduction

On September 26, 2018, the Commission published for comment proposed amendments to Rule 17g–5(a)(3) to provide an exemption from the

rule for NRSROs with respect to credit ratings if the issuer of the security or money market instrument referred to in the rule is not a U.S. person, and the NRSRO has a reasonable basis to conclude that all offers and sales of such security or money market instrument by any issuer, sponsor, or underwriter linked to such security or money market instrument will occur outside the United States.[2] The Commission also proposed amendments to Rule 17g–7(a) and Rule 15Ga–2 that would conform the exemptions contained in such rules with the exemption proposed with respect to Rule 17g–5(a)(3).

As discussed in Section III of this release, the Commission has considered the comment letters received in response to the proposed amendments and is adopting the amendments as proposed.[3] The Commission believes that codifying the exemption to Rule 17g–5(a)(3) is appropriate given notions of international comity and the generally limited interest of the Commission in regulating securities offered and sold exclusively outside of the United States. With respect to the conforming amendments to Rule 17g–7(a) and Rule 15Ga–2, the Commission continues to believe that it is important to maintain a consistent approach to determining how Rule 17g–5(a)(3), Rule 17g–7(a), and Rule 15Ga–2 apply to offshore transactions. The Commission further believes that the changes made to the conditions to the exemptions will promote clarity and consistency regarding the intended application of the exemptions and their relationship to 17 CFR 230.901 through 230.905 (''Regulation S'').

II. Background

A. Rule 17g–5(a)(3)

In 2009, the Commission adopted amendments to 17 CFR 240.17g–5 (''Rule 17g–5'') designed to address conflicts of interest arising from the business of determining credit ratings, and to improve competition and the quality of credit ratings for structured finance products, by making it possible for more NRSROs to rate such securities.[4] The amendments established a program (''Rule 17g–5 Program'') by which an NRSRO that is not hired by an issuer, sponsor, or underwriter (collectively, ''arranger'') is able to obtain the same information that the arranger provides to an NRSRO hired to determine a credit rating for the structured finance product at the same time the information is provided to the hired NRSRO.[5]

The Rule 17g–5 Program operates by requiring a hired NRSRO to maintain a password-protected website containing a list of each structured finance product for which it is currently in the process of determining an initial credit rating.[6] The list must be in chronological order and identify the type of structured finance product, the name of the issuer, the date the credit rating process was initiated, and the website where the arranger of the structured finance product represents that the information provided to the hired NRSRO can be accessed by non-hired NRSROs.[7] The hired NRSRO must provide free and unlimited access to the website it maintains pursuant to the Rule 17g–5 Program to any non-hired NRSRO that provides a copy of a certification it has furnished to the Commission in accordance with 17 CFR 240.17g–5(e).[8]

The Rule 17g–5 Program also requires the hired NRSRO to obtain a written representation from the arranger of the structured finance product that can be reasonably relied on by the hired NRSRO.[9] Such representation must include: That the arranger will maintain a password-protected website that other NRSROs can access; that the arranger will post on this website all information the arranger provides to the hired NRSRO (or contracts with a third party to provide to the hired NRSRO) for the purpose of determining the initial credit rating and undertaking credit rating surveillance; and that the arranger will post this information to the website at the same time such information is provided to the hired NRSRO.[10]

Prior to the June 2, 2010, compliance date for the Rule 17g–5 Program, the Commission by order granted a temporary conditional exemption to NRSROs from Rule 17g–5(a)(3). This temporary conditional exemption (the ''existing Rule 17g–5(a)(3) exemption'') applies solely with respect to credit ratings if: (1) The issuer of the security or money market instrument is not a U.S. person (as defined under 17 CFR 230.902(k)); and (2) the NRSRO has a reasonable basis to conclude that the structured finance product will be offered and sold upon issuance, and that any arranger linked to the structured finance product will effect transactions of the structured finance product after issuance, only in transactions that occur outside the United States.[11] These conditions were designed to confine the existing Rule 17g–5(a)(3) exemption's application to credit ratings of structured finance products issued in, and linked to, financial markets outside of the United States. The Commission granted this relief in light of concerns raised by various foreign securities regulators and market participants that local securitization markets may be disrupted if the rule applied to transactions outside the United States.[12] The Commission has extended the existing Rule 17g–5(a)(3) exemption several times, most recently until the earlier of December 2, 2019, or the compliance date set forth in any final rule that may be adopted by the Commission that provides for a similar exemption.[13]

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[2] *See Amendments to Rules for Nationally Recognized Statistical Rating Organizations,* Exchange Act Release No. 84289 (Sept. 26, 2018), 83 FR 50297 (Oct. 5, 2018) (''Proposing Release''). The comment period for the proposed amendments expired on November 5, 2018.

[3] In the Proposing Release, the Commission also discussed comment letters received with respect to the existing temporary conditional exemption to Rule 17g–5(a)(3). *See Proposing Release, supra* note 2, 83 FR at 50299–300.

[4] *Amendments to Rules for Nationally Recognized Statistical Rating Organizations,* Exchange Act Release No. 61050 (Nov. 23, 2009), 74 FR 63832 (Dec. 4, 2009) (''Rule 17g–5 Adopting Release''). The term ''structured finance product'' as used throughout this release refers broadly to any security or money market instrument issued by an asset pool or as part of any asset-backed securities transaction. This broad category of financial instruments includes an asset-backed security as defined in Section 3(a)(79) of the Exchange Act (15 U.S.C. 78c(a)(79)) and other types of structured debt instruments, including synthetic and hybrid collateralized debt obligations. *See, e.g., Nationally Recognized Statistical Rating Organizations,* Exchange Act Release No. 72936 (Aug. 27, 2014), 79 FR 55078, 55081 n.18 (Sept. 15, 2014) (''2014 NRSRO Amendments'').

[5] *Rule 17g–5 Adopting Release, supra* note 4, 74 FR at 63832. *See also* 17 CFR 240.17g–5. Throughout this release, an NRSRO that is not hired by an arranger is referred to as a ''non-hired NRSRO.'' An NRSRO that is hired by an arranger is referred to as a ''hired NRSRO.''

[6] *See* 17 CFR 240.17g–5(a)(3)(i).

[7] *Id.*

[8] *See* 17 CFR 240.17g–5(a)(3)(ii); 17 CFR 240.17g–5(e).

[9] *See* 17 CFR 240.17g–5(a)(3)(iii).

[10] *Id.*

[11] *See Order Granting Temporary Conditional Exemption for Nationally Recognized Statistical Rating Organizations from Requirements of Rule 17g–5 Under the Securities Exchange Act of 1934 and Request for Comment,* Exchange Act Release No. 62120 (May 19, 2010), 75 FR 28825 (May 24, 2010) (''Exemptive Order'').

[12] *Id.* at 28826–27. Such foreign securities regulators and market participants indicated that arrangers of structured finance products located outside the United States generally were not aware that they would be required to make the representations prescribed in Rule 17g–5 in order to obtain credit ratings from NRSROs and were not prepared to make and adhere to the new requirements set forth in Rule 17g–5(a)(3). These commenters also identified potential conflicts with local law in non-U.S. jurisdictions as a concern. *Id.*

[13] *See Order Extending Conditional Temporary Exemption for Nationally Recognized Statistical Rating Organizations from Requirements of Rule 17g–5(a)(3) Under the Securities Exchange Act of 1934,* Exchange Act Release No. 82144 (Nov. 22, 2017), 82 FR 56309 (Nov. 28, 2017).

B. Rule 17g–7(a) and Rule 15Ga–2

In 2014, the Commission adopted Rule 17g–7(a) and Rule 15Ga–2. Rule 17g–7(a) requires an NRSRO, when taking a rating action, to publish an information disclosure form containing specified information about the related credit rating.[14] For example, the information disclosure form must specify, among other things, the version of the methodology used to determine the credit rating, a description of the types of data relied upon to determine the credit rating, and information on the sensitivity of the credit rating to assumptions made by the NRSRO.[15] The NRSRO must also attach to the information disclosure form an attestation affirming that no part of the credit rating was influenced by any other business activities, that the credit rating was based solely upon the merits of the obligor, security, or money market instrument being rated, and that the rating was an independent evaluation of the credit risk of the obligor, security, or money market instrument.[16]

Rule 17g–7(a) also requires an NRSRO, when taking a rating action, to publish any executed Form ABS Due Diligence–15E containing information about the security or money market instrument subject to the rating action received by the NRSRO or obtained by the NRSRO through the website maintained by an arranger under the Rule 17g–5 Program.[17] Form ABS Due Diligence–15E is the form on which a person employed by an NRSRO, issuer, or underwriter to provide third-party due diligence services in connection with an asset-backed security must, among other things, describe the scope and manner of the due diligence provided, summarize the findings and conclusions of its review, and certify that it conducted a thorough review in performing the due diligence.[18]

Rule 15Ga–2 also relates to third-party due diligence services and requires the issuer or underwriter of an asset-backed security that is to be rated by an NRSRO to furnish to the Commission Form ABS–15G containing the findings and conclusions of any third-party due diligence report obtained by the issuer or underwriter.[19]

In response to concerns raised by commenters when the rules were proposed,[20] the Commission included paragraph (3) in Rule 17g–7(a) and paragraph (e) in Rule 15Ga–2 to provide an exemption from the disclosure requirements for certain offshore transactions.[21] The Commission closely modeled the language of the Rule 17g–7(a) exemption on the existing Rule 17g–5(a)(3) exemption.[22] The Commission noted that it was appropriate for the Rule 15Ga–2 exemption to be aligned with the Rule 17g–7(a) exemption so that there is a consistent approach to determining when the Commission's NRSRO rules apply to offshore transactions.[23]

III. Description of Rule Amendments

A. Rule 17g–5(a)(3)

In the Proposing Release, the Commission proposed to codify, with certain clarifying changes, the existing Rule 17g–5(a)(3) exemption. Specifically, the Commission proposed to add new paragraph (iv) to Rule 17g–5(a)(3) to provide that the provisions of paragraphs (i) through (iii) of Rule 17g–5(a)(3) will not apply to an NRSRO when issuing or maintaining a credit rating for a security or money market instrument issued by an asset pool or as part of any asset-backed securities transaction, if: (1) The issuer of the security or money market instrument is not a U.S. person (as defined in 17 CFR 230.902(k)); and (2) the NRSRO has a reasonable basis to conclude that all offers and sales of the security or money market instrument by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States (as that phrase is used in Regulation S).

Three commenters, including an NRSRO and two industry groups, submitted comment letters in response to the proposed amendments.[24] The commenters all supported the Commission's proposal to codify the existing Rule 17g–5(a)(3) exemption.[25] One commenter stated that concerns that have been raised over time about extraterritorial application of Rule 17g–5(a)(3) remain relevant and that adoption of the proposed amendment would be an effective means by which to provide permanent relief.[26] This commenter also expressed the belief that adopting the proposed amendment would be consistent with notions of international comity and the generally limited interest of the Commission in regulating securities offered and sold exclusively outside the United States.[27] Another commenter stated that Rule 17g–5(a)(3) should not apply with respect to non-U.S. offerings absent a substantial effect in the United States or on U.S. persons, arguing that applying the rule to all credit ratings of an NRSRO or a registered affiliate,

[14] 17 CFR 240.17g–7(a)(1). Rule 17g–7(a) sets forth the required format and content of the information disclosure form and specifies that the form (and other items required by Rule 17g–7(a)) must be published in the same manner as the credit rating that is the result or subject of the rating action.

[15] *See* 17 CFR 240.17g–7(a)(1)(ii)(B), (H), and (M). For a comprehensive discussion of the required content of the form, *see 2014 NRSRO Amendments, supra* note 4, 79 FR at 55167–77.

[16] 17 CFR 240.17g–7(a)(1)(iii).

[17] 17 CFR 240.17g–7(a)(2).

[18] Rule 17g–10 identifies Form ABS Due Diligence–15E as the form on which the certification required pursuant to Exchange Act Section 15E(s)(4)(B) must be set forth. *See* 17 CFR 240.17g–10; *see also* 15 U.S.C. 78o–7(s)(4)(B).

[19] *See* 17 CFR 240.15Ga–2; 17 CFR 249.1400. Forms ABS–15G are made publicly available through the Commission's EDGAR system. *See* 17 CFR 232.101(a)(xvi).

[20] With respect to Rule 17g–7(a), a commenter suggested that local laws could impede the ability of an NRSRO to obtain or disclose information about the issuer as required by the proposed rule. *See 2014 NRSRO Amendments, supra* note 4, 79 FR at 55165. Similarly, with respect to Rule 15Ga–2, a commenter indicated that application of the rule to offshore transactions may conflict with foreign securities laws and other laws, rules, and regulations. *See 2014 NRSRO Amendments, supra* note 4, 79 FR at 55184, n. 1420. As discussed in the Proposing Release, similar concerns regarding potentially overlapping or conflicting foreign regulations have been raised by commenters with respect to Rule 17g–5(a)(3).

[21] *See 2014 NRSRO Amendments, supra* note 4, 79 FR at 55165, 55184–85. *See also* 17 CFR 240.17g–7(a)(3) (providing for an exemption if: (1) The rated obligor or issuer of the rated security or money market instrument is not a U.S. person; and (2) the NRSRO has a reasonable basis to conclude that a security or money market instrument issued by the rated obligor or the issuer will be offered and sold upon issuance, and that any underwriter or arranger linked to the security or money market instrument will effect transactions in the security or money market instrument, only in transactions that occur outside the United States); 17 CFR 240.15Ga–2(e) (providing for an exemption with respect to offerings of asset-backed securities if: (1) The offering is not required to be, and is not, registered under the Securities Act; (2) the issuer of the rated security is not a U.S. person; and (3) the security will be offered and sold upon issuance, and any underwriter or arranger linked to the security will effect transactions of the security after issuance, only in transactions that occur outside the United States).

[22] *2014 NRSRO Amendments, supra* note 4, 79 FR at 55165.

[23] *Id.* at 55185 n.1422.

[24] *See* letter from Thomas L. Guest, dated October 5, 2018 (''Guest letter''); letter from Ryan Mensing, Vice President, Senior Regulatory Officer, Government and Public Affairs, Moody's Investors Service, dated November 5, 2018 (''Moody's letter''); letter from Sairah Burki, Senior Director and Head of ABS Policy, Structured Finance Industry Group, and Chris Dalton, Chief Executive Officer, Australian Securitisation Forum, dated November 5, 2018 (''SFIG/ASF letter''). The comments are available at *https://www.sec.gov/comments/s7-22-18/s72218.htm.*

[25] *Id.*

[26] *See* Moody's letter. According to the commenter, ''[t]hese concerns have included: possible disruption to local securitization markets; overlapping and potentially conflicting regulatory requirements in other jurisdictions; conflicts with local confidentiality and data protection laws; misalignment with varying international market practices; and possible inconsistency with principles of international comity.'' *Id.* In the Proposing Release, the Commission discussed comments received with respect to the Exemptive Order that raised similar concerns. *See Proposing Release, supra* note 2, 83 FR at 50299–300.

[27] *See* Moody's letter.

regardless of whether the relevant transaction involves a U.S. investor connection, would be inconsistent from a policy perspective with the wider U.S. legislative and regulatory framework as well as principles of international comity.[28] Commenters also indicated that codification of the existing Rule 17g–5(a)(3) exemption would benefit NRSROs and other securitization market participants worldwide by providing certainty and predictability regarding continued application of the exemption.[29]

One of the commenters, though supportive of the proposal, expressed the view that Rule 17g–5(a)(3) has been ineffective, citing longstanding discussions among its issuer member firms as evidence that very few non-hired NRSROs have requested access to the websites that arrangers are required to maintain under the rule.[30] This commenter noted that concerns with respect to the effectiveness of the rule are compounded by lingering international uncertainty regarding the potential future applicability of Rule 17g–5(a)(3) to extraterritorial transactions.[31]

The Commission has considered the views and policy considerations expressed by commenters and continues to believe it is appropriate to provide relief regarding the application of Rule 17g–5(a)(3) to transactions offered and sold exclusively outside the United States. As stated in the Proposing Release, the Commission believes that such an approach is consistent with the approach it has taken in other contexts and with notions of international comity and the generally limited interest of the Commission in regulating securities offered and sold exclusively outside of the United States. Thus, the Commission is adopting new paragraph (iv) to Rule 17g–5(a)(3) as proposed. The Commission has also directed staff to further evaluate the effectiveness of Rule 17g–5(a)(3) with respect to credit ratings of structured finance products that are not eligible for relief under the adopted exemption.

The conditional exemption that the Commission is adopting in new paragraph (iv) to Rule 17g–5(a)(3) is narrowly tailored to provide relief only with respect to structured finance products issued by non-U.S. issuers and offered and sold exclusively outside of the United States. Further, the exemption only applies to the provisions of paragraphs (i) through (iii) of Rule 17g–5(a)(3). It does not limit in any way the scope or applicability of the other requirements in Rule 17g–5 or other provisions of the federal securities laws, including the antifraud provisions.

The first condition of the exemption to Rule 17g–5(a)(3)—that the issuer of the structured finance product must not be a U.S. person—limits the relief to credit ratings of structured finance products issued by non-U.S. issuers. To this end, and for purposes of the exemption, ''U.S. person'' has the same definition as under Regulation S.[32] Consequently, to qualify for the exemption, the NRSRO has to be determining a credit rating for a structured finance product issued by a person that is not a U.S. person.

The second condition of the exemption to Rule 17g–5(a)(3)—that the NRSRO has a reasonable basis to conclude that all offers and sales of the structured finance product by any arranger linked to the structured finance product will occur outside the United States—is intended to limit the relief to credit ratings of structured finance products offered and sold exclusively outside the United States. This condition closely tracks the language of Regulation S [33] and specifies that the phrase ''occur outside the United States'' has the same meaning as in Regulation S.

The determination of whether an NRSRO has a reasonable basis to conclude that all offers and sales of the structured finance product by any arranger linked to the structured finance product will occur outside the United States depends on the facts and circumstances of a given situation. To have a reasonable basis to reach such a conclusion, the NRSRO generally should ascertain how any arranger linked to the structured finance product intends to market and sell the structured finance product and to engage in any secondary market activities (*i.e.,* re-sales) of the structured finance product, and whether any such efforts and activities will occur in the United States (including any ''directed selling efforts,'' as defined in Regulation S).[34]

For instance, an NRSRO could obtain from the applicable arranger a representation upon which the NRSRO can reasonably rely that all offers and sales by the arranger of the structured finance product to be rated by the NRSRO will occur outside the United States. For example, the arranger's representation could provide assurances that all such offers and sales will be conducted in accordance with the applicable safe harbor under Regulation S.[35] In determining whether it is reasonable to rely on any such representation, an NRSRO should evaluate the representation in light of other information known to the NRSRO, such as information in the relevant transaction documents, any ongoing or prior failures by the arranger to adhere to its representations, and any pattern of conduct by the arranger of it failing to promptly correct breaches of its representations.

An NRSRO generally should reevaluate the reasonableness of its basis for concluding that the structured finance product will be offered and sold outside the United States if the NRSRO obtains information during the course of its engagement that could cause it to reasonably believe there are offering or sales activities occurring inside the United States. In this regard, one option would be for the NRSRO to include in any representation obtained from an arranger a mechanism for the arranger to promptly notify the NRSRO of any change that would render the representation untrue or inaccurate.

B. Conforming Amendments to Rule 17g–7(a) and Rule 15Ga–2

In the Proposing Release, the Commission proposed amendments to Rule 17g–7(a) and Rule 15Ga–2 to align the exemptions in such rules with the exemption proposed with respect to Rule 17g–5(a)(3). Specifically, the Commission proposed amending paragraph (3)(ii) of Rule 17g–7(a) to clarify that the exemption to Rule 17g–7(a) is available only if an NRSRO has a reasonable basis to conclude that: (1) With respect to any security or money market instrument issued by a rated obligor, all offers and sales by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States (as that phrase is used in Regulation S); or (2) with respect to a rated security or money market instrument, all offers and sales by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States (as that phrase is used in Regulation S). Likewise, the Commission proposed amending

[28] *See* SFIG/ASF letter. This commenter also stated its view that imposition of Rule 17g–5(a)(3) on transactions offered by foreign issuers solely to foreign investors would have an undue negative impact on global issuance of asset-backed securities and exact extensive costs on securitization issuers and NRSROs around the globe without tangible benefits to, or protection of, U.S. investors.

[29] *See* Moody's letter; SFIG/ASF letter.

[30] *See* SFIG/ASF letter.

[31] *Id.*

[32] *See* 17 CFR 230.902(k).

[33] *See* 17 CFR 230.901.

[34] 17 CFR 230.902(c).

[35] *See* 17 CFR 230.903 and 904.

paragraph (e)(3) of Rule 15Ga–2 to clarify that the exemption to Rule 15Ga–2 is available only if all offers and sales of an asset-backed security by any issuer, sponsor, or underwriter linked to the security will occur outside the United States (as that phrase is used in Regulation S).

One commenter addressed the proposed amendments to Rule 17g–7(a) and Rule 15Ga–2. The commenter supported the Commission's efforts to align the exemptions to these rules with the exemption proposed for Rule 17g–5(a)(3).[36] The Commission continues to believe that it is appropriate for there to be a consistent approach to determining how Rule 17g–5(a)(3), Rule 17g–7(a), and Rule 15Ga–2 apply to offshore transactions. The Commission is therefore adopting the amendments to Rule 17g–7(a) and Rule 15Ga–2 as proposed.

As is the case with the exemption to Rule 17g–5(a)(3), the determination of whether an NRSRO has a reasonable basis to conclude that all offers and sales of the applicable securities or money market instruments by any arranger linked to such securities or money market instruments will occur outside the United States depends on the facts and circumstances of a given situation. The discussion in Section III.A. of this release regarding how an NRSRO may obtain such a reasonable basis for purposes of the exemption to Rule 17g–5(a)(3) also applies for purposes of the amendment to Rule 17g–7(a).

As described in the Proposing Release, the amendment to Rule 17g–7(a) also clarifies that the second condition of the Rule 17g–7(a) exemption applies differently in the case of rated obligors than it does in the case of rated securities or money market instruments. In the case of rated securities or money market instruments, the condition to the Rule 17g–7(a) exemption applies in the same way as the condition to the Rule 17g–5(a)(3) exemption—*i.e.,* an NRSRO must have a reasonable basis to conclude that all offers and sales of the rated security or money market instrument by any arranger linked to that security or money market instrument will occur outside the United States. For the Rule 17g–7(a) exemption to apply with respect to a rating of an obligor, however, an NRSRO must have a reasonable basis to conclude that the condition is satisfied with respect to all securities or money market instruments issued by that obligor. Accordingly, if any of a rated obligor's securities or money market instruments are offered and sold by an arranger linked to those securities or money market instruments within the United States, the exemption would not apply to rating actions involving the credit rating assigned to the obligor as an entity. The Commission previously discussed the distinction between the application of the exemption with respect to rated obligors and rated securities or money market instruments in the adopting release for Rule 17g–7(a).[37] As amended, Rule 17g–7(a) more clearly states this distinction in the rule text itself.

C. Technical Amendments

The proposed amendment to Rule 15Ga–2 also included technical amendments to the rule text, which the Commission is adopting as proposed. Specifically, the subparagraph designations of paragraph (e) of Rule 15Ga–2 are revised to use numerals ((1), (2), and (3)) instead of romanettes ((i), (ii), and (iii)). Additionally, the reference to 17 CFR 230.902 in paragraph (e)(2) of Rule 15Ga–2 is revised to read ''§ 230.902(k)'' in place of ''Securities Act Rule 902(k).'' In addition, the Commission is adopting a technical amendment to correct the subparagraph designations of paragraph (f) of Rule 15Ga–2 to use numerals ((1) and (2)) instead of romanettes ((i) and (ii)).

IV. Paperwork Reduction Act

The amendments to Rule 17g–5(a)(3) and Rule 17g–7(a) contain new ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[38] The Commission submitted revisions to the currently approved collections of information to the Office of Management and Budget (''OMB'') for review in accordance with the PRA.[39] An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. The titles for the collections of information are:

Rule	Rule title	OMB control No.
Rule 17g–5	Conflicts of Interest	3235–0649
Rule 17g–7	Reports to be made public by nationally recognized statistical rating organizations (NRSROs).	3235–0656

The amendment to Rule 15Ga-2 does not contain a collection of information requirement within the meaning of the PRA.

In the Proposing Release, the Commission provided estimates of the burden of complying with the proposed amendments to Rule 17g–5(a)(3) and Rule 17g–7(a) and requested comment on the proposed collections of information. The Commission did not receive any comment letters addressing the collection of information aspects of the proposal.

A. Summary of Collection of Information Under the Rule Amendments and Use of Information

1. Amendment to Rule 17g–5(a)(3)

The Commission is adopting, as proposed, an amendment to Rule 17g–5(a)(3) that provides an exemption to the rule with respect to credit ratings of structured finance products if the issuer of the structured finance product is not a U.S. person and the NRSRO has a reasonable basis to conclude that all offers and sales of the structured finance product by any arranger linked to the structured finance product will occur outside the United States.[40] In order to have a reasonable basis for such a conclusion, an NRSRO may collect information from an arranger. For instance, an NRSRO may elect to obtain a representation from an arranger regarding the manner in which the structured finance product will be offered and sold. Such information regarding the manner in which the structured finance product will be offered and sold may be necessary for an NRSRO to determine whether the exemption applies with respect to the rating of the structured finance product.

[36] *See* Moody's letter.

[37] *See 2014 NRSRO Amendments, supra* note 4, 79 FR at 55165 n.1107.

[38] 44 U.S.C. 3501 *et seq.*

[39] *See* 44 U.S.C. 3507(d); 5 CFR 1320.11.

[40] *See* paragraph (a)(3)(iv) of Rule 17g–5; *see also supra* Section III.A. (discussing the adopted exemption in more detail).

2. Amendment to Rule 17g–7(a)

The Commission is adopting, as proposed, an amendment to the existing exemption in Rule 17g–7(a). The amendment clarifies that, in order for the exemption to apply, an NRSRO must have a reasonable basis to conclude that: (1) With respect to any security or money market instrument issued by a rated obligor, all offers and sales by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States; or (2) with respect to a rated security or money market instrument, all offers and sales by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States.[41] In order to have a reasonable basis for such a conclusion, an NRSRO may collect information from an arranger or obligor. For instance, an NRSRO may elect to obtain a representation from an arranger regarding the manner in which a rated security or money market instrument will be offered and sold or from an obligor regarding the manner in which all its securities and money market instruments have been offered and sold. Such information may be necessary for an NRSRO to determine whether the exemption applies with respect to a rating action.

B. Respondents

Rule 17g–5(a)(3) applies to NRSROs that rate structured finance products. Currently, there are seven NRSROs that are registered in the issuers of asset-backed securities ratings class that could rely on the exemption to Rule 17g–5(a)(3).[42]

Rule 17g–7(a) applies to all rating actions taken by an NRSRO. There are currently 10 credit rating agencies registered with the Commission as NRSROs that could rely on the exemption to Rule 17g–7(a).[43]

C. Burden and Cost Estimates Related to the Amendments

1. Amendment to Rule 17g–5(a)(3)

The amendment to Rule 17g–5(a)(3) codifies the existing exemption, with certain clarifying changes.

The Commission believes that NRSROs will modify their processes to account for the changes to the conditions of the exemption as adopted. For instance, an NRSRO that has sought written representations from an arranger to support the reasonable belief required under the existing Rule 17g–5(a)(3) exemption may modify the form of the representation to conform to the language of the condition as adopted. In the Proposing Release, the Commission estimated that it would take an NRSRO approximately five hours to update its process for obtaining a reasonable basis to reflect the clarifying language in the exemption, for an industry-wide one-time burden of approximately 35 hours.[44] The Commission received no comments on this estimate and continues to estimate an industry-wide one-time burden of approximately 35 hours.

In order to have a reasonable basis to conclude that all offers and sales of the structured finance product by any arranger linked to the structured finance product will occur outside the United States, the Commission believes that NRSROs will likely seek information from arrangers, thereby resulting in associated costs. In the Proposing Release, the Commission estimated that an NRSRO would spend approximately two hours per transaction gathering and reviewing information received from arrangers to determine if the exemption applies. The Commission also estimated in the Proposing Release that approximately 267 rated transactions would be eligible for the exemption in a given year and that each transaction would be rated by approximately two NRSROs, resulting in a total aggregate annual hour burden of 1,068 hours.[45] The Commission received no comments on these estimates.

The Commission continues to estimate that an NRSRO would spend approximately two hours per transaction gathering and reviewing information received from arrangers to determine if the exemption applies and that each transaction would be rated by approximately two NRSROs. The Commission is updating its estimate of the number of rated transactions that would be eligible for the exemption in a given year to reflect more current data. The Commission currently estimates that approximately 284 rated transactions would be eligible for the exemption annually,[46] resulting in a total aggregate annual hour burden of 1,136 hours.[47]

2. Amendment to Rule 17g–7(a)

The Commission is adopting, as proposed, amendments to the existing exemption in Rule 17g–7(a). The amendments clarify that, in order for the exemption to apply, an NRSRO must have a reasonable basis to conclude that: (1) With respect to any security or money market instrument issued by a rated obligor, all offers and sales by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States; or (2) with respect to a rated security or money market instrument, all offers and sales by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States.[48]

The Commission believes that NRSROs will modify their processes to reflect the amendment to the Rule 17g–7(a) exemption. For instance, an NRSRO that has sought written representations from an obligor or arranger to support the reasonable belief required under the existing Rule 17g–7(a) exemption may modify the form of the representation to conform to the language of the condition as amended. In the Proposing Release, the Commission estimated that it would take an NRSRO approximately five hours to update its process for obtaining

[41] *See* paragraph (3)(ii) of Rule 17g–7(a); *see also supra* Section III.B. (discussing the amended exemption in more detail).

[42] The seven NRSROs registered to rate asset-backed securities are: A.M. Best Rating Services, Inc. (''A.M. Best''); DBRS, Inc. (''DBRS''); Fitch Ratings, Inc. (''Fitch''); Kroll Bond Rating Agency, Inc. (''KBRA''); Moody's Investors Service, Inc. (''Moody's''); Morningstar Credit Ratings, LLC (''Morningstar''); and S&P Global Ratings (''S&P'').

[43] In addition to the seven NRSROs listed in note 42 *supra,* three additional credit rating agencies are currently registered as NRSROs: Egan-Jones Ratings Company; HR Ratings de México, S.A. de C.V.; and Japan Credit Rating Agency, Ltd.

[44] 5 hours × 7 NRSROs registered to rate asset-backed securities = 35 hours.

[45] 2 hours × 267 transactions × 2 NRSROs per transaction = 1,068 hours. The estimates of the number of annual transactions and the number of NRSROs per transaction in the Proposing Release were calculated using information from the databases maintained by Asset-Backed Alert and Commercial Mortgage Alert and represented the average number of transactions and NRSROs per transaction for the years ended December 31, 2015, 2016, and 2017. *See Proposing Release, supra* note 2, 83 FR at 50303 n. 63.

[46] This estimate was calculated using information, as of March 25, 2019, from the databases maintained by Asset-Backed Alert and Commercial Mortgage Alert. Isolating the transactions coded in the databases as ''Non-U.S.'' offerings provided an estimate of the number of transactions that would have been eligible for the exemption. The databases also specify the number of NRSROs rating each transaction, which was used to calculate the average number of NRSROs per transaction (1.88). For purposes of the Commission's estimates, the number of NRSROs per transaction was rounded to the nearest whole number, resulting in no change from the estimate used in the Proposing Release. The estimates represent the average number of transactions and NRSROs per transaction for the years ended December 31, 2016, 2017, and 2018.

[47] 2 hours × 284 transactions × 2NRSROs per transaction = 1,136 hours.

[48] *See* paragraph (3)(ii) of Rule 17g–7(a); *see also supra* Section III.B. (discussing the amended exemption in more detail).

a reasonable basis to reflect the amendment to the Rule 17g–7(a) exemption, for an industry-wide one-time burden of approximately 50 hours.[49] The Commission received no comments on this estimate and continues to estimate an industry-wide one-time burden of approximately 50 hours.

D. Collection of Information Is Required To Obtain a Benefit

The collection of information is required to obtain or maintain a benefit—*i.e.,* to qualify for the relevant exemption and eliminate the need to incur the costs associated with complying with the corresponding rule. In order to form a reasonable basis to conclude that all offers and sales of a security or money market instrument will occur outside the United States, an NRSRO likely will gather certain information from the obligor or an arranger including, for example, obtaining a representation to that effect. The determination of a reasonable basis would be necessary for the exemption to Rule 17g–5(a)(3) and the amended exemption to Rule 17g–7(a) to apply.

E. Confidentiality

Any information obtained by an NRSRO from an obligor or arranger to establish a reasonable basis will not be made public, unless the NRSRO, obligor, or arranger chooses to make it public. Information provided to the Commission in connection with staff examinations or investigations would be kept confidential, subject to the provisions of applicable law.

V. Other Matters

Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs has designated these rules as not a major rule as defined by 5 U.S.C. 804(2).

VI. Economic Analysis

A. Introduction

As discussed above, the Commission is adopting, as proposed, an amendment to Rule 17g–5(a)(3) to provide an exemption from the rule with respect to credit ratings where the issuer of the structured finance product is not a U.S. person, and the NRSRO has a reasonable basis to conclude that all offers and sales of the structured finance product by any arranger linked to the structured finance product will occur outside the United States. The Commission is also adopting conforming amendments to similar exemptions set forth in Rule 17g–7(a) and Rule 15Ga–2. The Commission is sensitive to the costs and benefits of its rules. When engaging in rulemaking that requires the Commission to consider or determine whether an action is necessary or appropriate in the public interest, Section 3(f) of the Exchange Act requires that the Commission consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.[50] In addition, Section 23(a)(2) of the Exchange Act requires the Commission to consider the effects on competition of any rules the Commission adopts under the Exchange Act, and prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.[51]

The Commission has considered the effects of the amendments on competition, efficiency, and capital formation. Many of the benefits discussed below are difficult to quantify, in particular when considering the potential impact on conflicts of interest or competition. Consequently, while the Commission has, wherever possible, attempted to quantify the economic effects expected to result from the amendments, much of the discussion below is qualitative in nature. Moreover, because the existing Rule 17g–5(a)(3) exemption is currently in effect (and has been in effect since May 19, 2010—*i.e.,* prior to the compliance date for Rule 17g–5(a)(3)), there has been no effect on transactions outside the United States because changes in the market related to the application of Rule 17g–5(a)(3) have not occurred with respect to these transactions as a consequence of the Exemptive Order.

The Commission continues to believe that the codification of current practices with respect to Rule 17g–5(a)(3) is appropriate when compared to the alternative of allowing the existing Rule 17g–5(a)(3) exemption to expire. As discussed above, the commenters supported the proposal to codify the exemption to Rule 17g–5(a)(3).[52] The Commission received no comments addressing the alternative considered in the Proposing Release.

The Commission continues to believe that the amendments to Rule 17g–7(a) and Rule 15Ga–2 will not have a material impact on efficiency, competition, and capital formation or impose new costs of any significance. As discussed in the Proposing Release, the amendments to Rule 17g–7(a) and Rule 15Ga–2 are conforming and clarifying in nature. Further, unlike the existing Rule 17g–5(a)(3) exemption, the Rule 17g–7(a) and Rule 15Ga–2 exemptions are already included as part of the rule text, and thus not subject to expiration.

B. Baseline and Affected Parties

The Exemptive Order serves as the economic baseline against which the costs and benefits, as well as the impact on efficiency, competition, and capital formation, of the codification of the existing Rule 17g–5(a)(3) exemption is considered.

As discussed in the Proposing Release, pursuant to the Exemptive Order, NRSROs have been exempt from the requirements of paragraphs (i) through (iii) of Rule 17g–5(a)(3) for credit ratings where: (1) The issuer of the security or money market instrument is not a U.S. person (as defined under 17 CFR 230.902(k)); and (2) the NRSRO has a reasonable basis to conclude that the structured finance product will be offered and sold upon issuance, and that any arranger linked to the structured finance product will effect transactions of the structured finance product after issuance, only in transactions that occur outside the United States. As a result, with respect to such structured finance products, NRSROs have not been required to comply with the requirements of Rule 17g–5(a)(3), including the requirement to obtain from the arranger a representation that the arranger will maintain a website containing all information the arranger provides to the hired NRSRO in connection with the rating.

Similarly, the existing exemptive language of paragraph (3) of Rule 17g–7(a) and paragraph (e) of Rule 15Ga–2, before giving effect to the amendments adopted today, serves as the economic baseline against which the costs and benefits, as well as the impact on efficiency, competition, and capital formation, of the amendments to such rules are considered. As previously noted, the Commission believes the amendments to Rule 17g–7(a) and Rule 15Ga–2 are clarifying and conforming in nature and do not substantively deviate from the baseline.

The economic and regulatory analysis in this section reflects structured finance product markets and the credit rating industry as they exist today. We begin with a summary of the approximate number of NRSROs that would be directly affected by the codification and features of the regulatory and economic environment

[49] 5 hours × 10 NRSROs = 50 hours.

[50] *See* 15 U.S.C. 78c(f).

[51] *See* 15 U.S.C. 78w(a)(2).

[52] *See supra* notes 25–29 and accompanying text.

in which the affected entities operate. A discussion of the current economic environment will provide a framework for assessing how the regulation may impact efficiency, competition, and capital formation in this market.

Currently, 10 credit rating agencies are registered with the Commission as NRSROs. Of the 10 NRSROs, seven are currently registered in the class of credit ratings for issuers of asset-backed securities.[53] Three of the larger NRSROs accounted for approximately 95 percent of credit ratings outstanding as of December 31, 2018;[54] these three firms have operations outside of the United States.

The credit rating industry is highly concentrated and this market structure persists, in part, as a result of the costs associated with building the necessary reputational capital. In addition, large and incumbent NRSROs benefit from economies of scale, as well as from switching costs that issuers are likely to bear if they were to consider using different NRSROs. These costs provide incentives for issuers to use the services of NRSROs with which they have preexisting relationships and represent a barrier that newcomers entering the market for credit ratings would need to overcome to compete with incumbent credit rating agencies.

In addition to the above economic barriers to entry, there exist some commercial and other barriers to entry.[55] For instance, the investment guidelines of fixed income mutual fund managers and pension plan sponsors often specify use of the ratings of particular credit rating agencies, and many of these guidelines refer to the larger NRSROs by name. Some fixed income indices also require ratings by specific NRSROs, thus increasing the demand for ratings from those NRSROs. However, it has been reported that some investors are changing their guidelines to include ratings from additional NRSROs, and several of the smaller NRSROs have reported success in gaining market share with respect to the issuers of asset-backed securities.[56] Market participants and academics have also identified regulatory barriers to entry in the credit rating industry.[57]

Gathering comprehensive data on foreign issuances of asset-backed securities is difficult given the breadth of markets and products one needs to consider and that data may not be available for several lesser-developed markets. Further, it is often not clear whether these issuances are made by non-U.S. persons. However, there has been an increase in the issuances of asset-backed securities worldwide since 2011, with the issuances amounting to approximately $754.7 billion in 2018.[58] For example, when considering all underwriters for deals in Europe, while the trend has varied over the past five years, the three highest annual issuance totals over such period were achieved in 2016 through 2018, the highest of which occurred in 2018.[59] Asset-backed securities constitute a growing market in Europe and other major financial markets, and, as discussed below, any application of Rule 17g–5(a)(3) to transactions outside the United States could affect the functioning of these foreign markets.[60]

C. Anticipated Costs and Benefits, Including Potential Effects on Efficiency, Competition, and Capital Formation

1. Potential Benefits

As discussed above, the Commission issued the Exemptive Order in 2010, and an extension of the Exemptive Order is currently in effect. Because the amendments to Rule 17g–5(a)(3), Rule 17g–7(a), and Rule 15Ga–2 would generally maintain the status quo,[61] we do not expect the amendments would result in any major economic effects. For the same reason, we also do not expect this rulemaking to affect efficiency, competition, or capital formation in any major way.

To the extent that the amendment of Rule 17g–5(a)(3) would enhance the certainty of the future status of an exemption to this rule, it could result in marginal economic benefits to arrangers, NRSROs, and regulators. Specifically, if NRSROs and arrangers expect to be required to comply with Rule 17g–5(a)(3) in the future, they may allocate personnel and financial resources to correspond with foreign and U.S. regulators and to set up applicable websites in anticipation of future compliance. The Commission believes the amendment would eliminate the need to incur such costs since the exemption being adopted does not have a termination date. Furthermore, by reducing the need to incur such costs, the amendment could allow issuers and smaller NRSROs to expand in the global structured finance market, and could improve competition. Commenters on the Proposing Release generally agreed that the proposed amendment would provide certainty that would benefit market participants.[62]

The exemption to Rule 17g–5(a)(3), as adopted, would not necessarily result in more intense competition between issuers and other intermediaries because issuers would continue to offer structured finance products as they do under the current regulatory regime. Further, all existing NRSROs rating structured finance products could continue to rely on the exemption as they do currently under the extended Exemptive Order; therefore, competition among these existing credit rating agencies would most likely not be affected by adoption of the exemption.

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[53] *See supra* notes 42–43.

[54] The three NRSROs are Fitch, Moody's, and S&P. The percentage of credit ratings outstanding attributable to Fitch, Moody's, and S&P was calculated using information reported by each NRSRO on Item 7A of Form NRSRO with respect to its annual certification for calendar year 2018. Annual certifications on Form NRSRO must be filed with the Commission on EDGAR pursuant to Rule 17g–1(f) and made publicly and freely available on each NRSRO's website pursuant to Rule 17g–1(i). The number of outstanding credit ratings for each class of credit ratings for which an NRSRO is registered is reported on Item 7A of Form NRSRO.

[55] *See 2018 Annual Report on Nationally Recognized Statistical Rating Organizations, available at https://www.sec.gov/files/2018-annual-report-on-nrsros.pdf,* 25–26 (''Annual Report'').

[56] *See id.* at 22–25.

[57] *See id.* at 26. The Annual Report notes that regulatory barriers to entry include the costs associated with complying with statutory provisions and related rules. *See id.*

[58] *See* Asset-Backed Alert (Rankings for Issuers of Worldwide Asset- and Mortgage-Backed Securities), *available at https://www.abalert.com/rankings.pl?Q=100. See also* Commercial Mortgage Alert (CMBS Summary—Global CMBS Issuance in 2017), *available at https://www.cmalert.com/rankings.pl?Q=67.* The information on these websites, reported as of March 8, 2019, indicates that, notwithstanding a slight decline in issuances in 2016, there has been an upward trend in the total annual issuances of asset-backed securities from 2011 through 2018.

[59] *See* Asset-Backed Alert (Rankings for Bookrunners of European Structured Finance Deals), *available at https://www.abalert.com/rankings.pl?Q=98,* information reported as of March 8, 2019. Total issuances in Europe amounted to approximately $101.1 billion in 2016, approximately $95.5 billion in 2017, and approximately $118.0 billion in 2018. *Id.*

[60] *See, e.g.,* the SIFMA databases that cover historical issuances and outstanding values in Europe, the United States, and Australia for the following: Asset-backed securities, collateralized debt obligations/collateralized loan obligations, commercial mortgage-backed securities, and residential mortgage-backed securities, *available at http://www.sifma.org.*

[61] As discussed in the Proposing Release, although the language of the second condition of the exemption to Rule 17g–5(a)(3), as adopted, differs from the comparable condition set forth in the Exemptive Order, and conforming changes are being made to the corresponding conditions in Rule 17g–7(a) and Rule 15Ga–2, the changes are clarifying in nature and the Commission does not believe they will alter the status quo. The conforming changes to Rule 17g–7(a) and Rule 15Ga–2, however, could result in changes from the current state. Specifically, those changes could avoid potential confusion by arrangers and NRSROs that could result from differences in the language of the conditions set forth in the rules.

[62] *See* Moody's letter; SFIG/ASF letter.

2. Potential Costs and Other Anticipated Effects

Similarly, because the existing Rule 17g–5(a)(3) exemption is currently in effect, the amendment to Rule 17g–5(a)(3) should not impose any significant additional costs on NRSROs or arrangers of structured finance products relative to the baseline.

However, as is the case with the existing Rule 17g–5(a)(3) exemption, issuers and NRSROs may incur some expenses in relying on the exemption to Rule 17g–5(a)(3), which is conditioned on an NRSRO having a reasonable basis to conclude that all offers and sales of the structured finance product by any arranger linked to the structured finance product will occur outside the United States. In order to have a reasonable basis for such a conclusion, the Commission believes that NRSROs will likely seek representations from arrangers, thereby resulting in associated costs. The Commission currently estimates that approximately 284 rated transactions would be eligible for the exemption in a given year.[63] To the extent that NRSROs seek representations to support their reasonable belief, the Commission estimates that it would cost an arranger approximately $730 per transaction to provide such representations,[64] for total aggregate annual costs for all arrangers of approximately $207,320.[65]

Similarly, for an NRSRO that chooses to seek representations to support its reasonable belief, the Commission estimates that it would cost the NRSRO approximately $730 per transaction.[66] The Commission further estimates that each transaction is rated by approximately two NRSROs,[67] for total aggregate annual costs for all NRSROs of $414,640.[68] Thus, to the extent that all NRSROs seek representations for all transactions eligible to rely on the exemption to Rule 17g–5(a)(3) each year, the Commission estimates the amendment would result in total annual costs of $621,960.[69]

In addition, although the conditions with respect to the exemption to Rule 17g–5(a)(3) are substantially the same under the Exemptive Order, NRSROs may incur a modest one-time cost to conform their processes to reflect the clarifying change adopted with respect to one of the conditions to the exemption. For instance, an NRSRO that has sought written representations from an arranger to support the reasonable belief required under the Exemptive Order may modify the form of the representation to conform to the language of the condition as adopted. The Commission expects an NRSRO's in-house attorney would oversee revisions to the form representation and that there would be a one-time burden of five hours for the language to be revised, approved, and documented. Accordingly, the Commission estimates a one-time aggregate cost of $12,775 for NRSROs to adjust their procedures to reflect the clarifying language of the adopted exemption.[70]

Similarly, additional one-time costs may be incurred by NRSROs to modify their processes to reflect the conforming amendment to the conditions with respect to the Rule 17g–7(a) exemption. The Commission expects the one-time costs incurred by such NRSROs to approximate the costs set forth with respect to Rule 17g–5(a)(3) above. As with Rule 17g–5(a)(3), the Commission expects an NRSRO's in-house attorney would oversee revisions to the form representation with respect to the Rule 17g–7(a) exemption and that there would be a one-time burden of five hours for the language to be revised, approved, and documented. Accordingly, the Commission estimates a one-time aggregate cost of $18,250 for NRSROs to adjust their procedures to reflect the adopted conforming changes to the Rule 17g–7(a) exemption.[71]

The Commission believes that no similar costs will be incurred by issuers and underwriters as a result of the amendment to Rule 15Ga–2, given that such rule relates to an obligation of the issuer or underwriter of a structured finance product and there is no equivalent need to obtain information from a third party to determine if the Rule 15Ga–2 exemption applies.

3. Alternative Considered: Allow Exemptive Order To Expire

As discussed in the Proposing Release, the Commission considered the alternative of allowing the current extension of the Exemptive Order to expire without codifying an exemption to Rule 17g–5(a)(3). The Commission continues to believe that this alternative is not consistent with notions of international comity or the Commission's limited interest in regulating securities offered and sold exclusively outside the United States. As discussed in the Proposing Release, the Commission believes principles of international comity and reasonable expectations of participants would be better served by not allowing the expiration of the current extension of the Exemptive Order. The Commission has nevertheless considered the economic effects of this alternative.

a. Benefits

This alternative offers several potential economic benefits to the extent they could come to fruition. The last three decades have witnessed an increase in the globalization of financial markets and in cross-border trading. Greater international capital flows can contribute to the development of new product markets and industries by enabling issuers to raise capital in markets around the world. The Commission considered the potential implications of the expiration of the existing Rule 17g–5(a)(3) exemption on cross-listing activity for U.S. and non-U.S. issuers.[72] One possible factor that hypothetically could affect the flow of capital from U.S. markets to foreign alternative trading venues is the costs associated with complying with U.S. securities laws. If complying with Rule 17g–5(a)(3) implies higher costs for issuers of structured finance products, and the costs affect the choice of an issuer's venue, non-U.S. issuers may benefit from the current exemptive relief

[63] *See supra* note 46.

[64] 2 hours per transaction × legal fee for a compliance attorney at $365 per hour = $730. The Commission estimates the wage rate associated with these burden hours based on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association (SIFMA). For example, the estimated wage figure for compliance attorneys is based on published rates for compliance attorneys, modified to account for a 1,800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead, yielding an effective hourly rate for 2013 of $334 for compliance attorneys. *See* Securities Industry and Financial Markets Association, Report on Management & Professional Earnings in the Securities Industry 2013. These estimates are adjusted for inflation based on Bureau of Labor Statistics data on CPI–U between January 2013 (230.280) and January 2019 (251.792). Therefore, the 2019 inflation-adjusted effective hourly wage rates for compliance attorneys are estimated at $365 ($334 × 251.792/230.280). All effective hourly wage rates discussed throughout the release rely on the same SIFMA data inflation adjusted to January 2019.

[65] $730 per transaction × 284 annual transactions = $207,320.

[66] 2 hours per transaction × legal fee for a compliance attorney at $365 per hour = $730.

[67] *See supra* note 46.

[68] $730 per transaction × 284 annual transactions × 2 NRSROs per transaction = $414,640.

[69] $730 per transaction × 284 annual transactions (for arrangers) + $730 per transaction × 284 annual transactions × 2 NRSROs per transaction (for NRSROs) = $621,960.

[70] 5 hours per NRSRO × legal fee for a compliance attorney at $365 per hour × the 7 NRSROs registered to rate asset-backed securities = $12,775.

[71] 5 hours per NRSRO × legal fee for a compliance attorney at $365 per hour × all 10 NRSROs = $18,250.

[72] Although the Commission regulations are designed to promote competition, efficiency, and capital formation in U.S. markets and to protect U.S. investors, the Commission recognizes that some of its regulations impact market participants globally. When applicable, the economic effects to those market participants are discussed.

by obtaining funding at a lower all-in cost than similarly situated U.S. issuers. If the Exemptive Order were to expire, however, such non-U.S. issuers would be unable to pursue such a strategy because they would have the same regulatory treatment as U.S. issuers. As a result, if the existing Rule 17g–5(a)(3) exemption were to expire, U.S. and non-U.S. issuers would compete for funding on more even terms.

Investors and issuers globally could obtain potential economic benefits, such as reduced conflicts of interest and informational efficiency in credit ratings, if arrangers were required to comply with the Rule 17g–5 Program. With respect to certain debt and structured finance products, credit ratings provided by non-hired NRSROs using information provided pursuant to the Rule 17g–5 Program could serve a verification function in capital markets by offering market participants a broader set of opinions on the creditworthiness of those products.[73] This information could help investors in their decisions to augment the risk profiles of their portfolios through economic exposure to investment opportunities.[74]

Globalization, however, can be a conduit of risk and could lead to problems in one market or jurisdiction spilling over to other markets or jurisdictions.[75] If the existing Rule 17g–5(a)(3) exemption were to expire, then it is possible that any benefits of this rule with respect to the credit rating industry in the United States would apply to foreign markets as well, potentially reducing the risk of spillovers that may result from conflicts of interest that Rule 17g–5(a)(3) was designed to address.[76] Specifically, arrangers that engage in structured finance transactions in foreign markets would also need to maintain websites containing all information provided to hired NRSROs with respect to the rating of such structured finance products and provide access to any non-hired NRSRO that makes the required certifications. This would permit non-hired NRSROs to provide ratings of these products. The availability of additional ratings from an independent source could provide incentives to hired NRSROs to provide more accurate and unbiased ratings due to reputational concerns. Any additional ratings by non-hired NRSROs could, in turn, provide investors with independent views on the risk profiles of the structured finance products and improve the reliability of the credit ratings of these products.[77] The potential improvement in the quality of ratings in foreign markets could attenuate the risk of spillovers, which could benefit financial markets globally.

The Commission notes, however, that the possible benefits attributable to the expiration of the Exemptive Order for Rule 17g–5(a)(3) should be viewed in light of the concerns expressed by commenters about barriers preventing those benefits from being realized. For instance, one commenter identified potentially conflicting regulatory requirements and conflicts with local confidentiality and data protection laws in other jurisdictions among concerns regarding the application of Rule 17g–5(a)(3) to credit ratings of structured finance products offered and sold exclusively outside the United States.[78] If any foreign laws limit the information an arranger is able to post on the website maintained pursuant to the Rule 17g–5 Program, a hired NRSRO may not have sufficient information on which to base a credit rating or, if the arranger provides information to a hired NRSRO that it cannot also post to the website, the hired NRSRO will not be able to reasonably rely on the representation it received from the arranger. In either case, NRSROs effectively would be precluded from rating structured finance products in such jurisdictions, attenuating the benefits described above.

b. Costs

Several costs of expiration of the existing Rule 17g–5(a)(3) exemption are relevant to consider. As mentioned earlier, the Commission currently estimates that approximately 284 rated transactions would be eligible for the exemption to Rule 17g–5(a)(3) in a given year.[79] If the existing Rule 17g–5(a)(3) exemption were allowed to expire, the requirements of Rule 17g–5(a)(3) would apply with respect to these transactions. The Commission estimates the following costs as a result of expiration of the existing Rule 17g–5(a)(3) exemption.

The Commission estimates that expiration of the existing Rule 17g–5(a)(3) exemption would result in an annual increase in costs of $166,820 for NRSROs for additional website maintenance and associated compliance costs.[80] The Commission also estimates an annual increase in costs of $49,700 for arrangers to post information about new structured finance product transactions to the related websites.[81]

[73] *See Rule 17g–5 Adopting Release, supra* note 4, 74 FR at 63857.

[74] *See e.g.,* Arthur R. Pinto, *Control and Responsibility of Credit Rating Agencies in the United States,* American Journal of Comparative Law, Vol. 54 at 341–56 (2006). *See also* John R.M. Hand *et al., The Effect of Bond Rating Agency Announcements on Bond and Stock Prices,* Journal of Finance, Vol. 47, No. 2 at 733–52 (1992). However, these potential economic benefits to investors would only occur to the extent non-hired NRSROs use information obtained pursuant to the Rule 17g–5 Program to issue credit ratings. As discussed in Section III of this release, one commenter has expressed the view that Rule 17g–5(a)(3) has been ineffective, citing longstanding discussions among its issuer member firms as evidence that very few non-hired NRSROs have requested access to the websites that arrangers are required to maintain under the rule. *See supra* note 30 and accompanying text. The Commission has directed staff to further evaluate the effectiveness of Rule 17g–5(a)(3).

[75] For instance, the European sovereign debt crisis renewed the debate on the role credit rating agencies play during crises and the interdependence between different financial markets. This debt crisis has included sovereign credit rating downgrades, widening of sovereign bond and credit default swap spreads, and pressures on stock markets. *See, e.g.,* Manfred Gärtner *et al., PIGS or Lambs? The European Sovereign Debt Crisis and the Role of Rating Agencies,* International Advances in Economic Research, Vol. 17, No. 3 at 288 (2011). *See also* Valerie De Bruyckere *et al., Bank/Sovereign Risk Spillovers in the European Debt Crisis,* Journal of Banking & Finance, Vol. 37, Issue 12 at 4793–809 (2013).

[76] *See Rule 17g–5 Adopting Release, supra* note 4, 74 FR at 63857.

[77] *See, e.g.,* Daniel Covitz and Paul Harrison, *Testing Conflicts of Interest at Bond Rating Agencies with Market Anticipation: Evidence that Reputation Incentives Dominate,* Federal Reserve Board Working Paper No. 2003–68 (2003), for evidence on the role of reputation among credit rating agencies. However, there is also some evidence to the contrary, wherein the argument is that if reputation losses are lower in an industry due to increased competition, then there are lesser incentives to provide accurate ratings. *See* Bo Becker and Todd Milbourn, *How Did Increased Competition Affect Credit Ratings?,* Journal of Financial Economics, Vol. 101, No. 3 at 493–514 (2011).

[78] *See* Moody's letter. As discussed in the Proposing Release, comments received with respect to the Exemptive Order discussed these concerns in more detail. *See Proposing Release, supra* note 2, 83 FR at 50299–300.

[79] *See supra* note 46.

[80] The Commission estimates that it will take approximately one hour per transaction for website maintenance and that an NRSRO would have a webmaster perform these responsibilities, at a cost of $248 per hour. The Commission further estimates that each transaction will be rated by approximately two NRSROs (*see supra* note 46). Therefore, the estimated annual cost for website maintenance by NRSROs involved with 284 structured finance ratings would be $140,864 (284 transactions × 1 hour per transaction × $248 per hour × 2 NRSROs per transaction). In addition, the Commission estimates that compliance personnel at an NRSRO will spend, on average, one hour per month to monitor compliance with the requirements of the Rule 17g–5 Program. Staff estimates a $309 per hour figure for a compliance manager. Therefore, the estimated annual compliance cost would be $25,956 (12 months per year × 1 hour per month × $309 per hour × 7 NRSROs registered to rate asset-backed securities). As a result, the total estimated annual cost for NRSROs would be $166,820 ($140,864 website maintenance cost + $25,956 compliance cost).

[81] The Commission estimates that it will take an arranger approximately one hour per transaction to post the information it provides to a hired NRSRO to the related website. The Commission believes

Additionally, if certain sponsors do not also currently issue rated structured finance products in transactions that occur within the United States (which are currently subject to the requirements of Rule 17g–5(a)(3)), then they may incur one-time costs to set up websites. The Commission estimates that it would take a sponsor 300 hours to develop a system, as well as the policies and procedures governing the disclosures, resulting in a total of up to 43,800 hours across 146 sponsors.[82] The Commission estimates that the average one-time cost to each sponsor would be $82,350, and the total aggregate one-time cost across all sponsors would be up to $12,023,100.[83] Finally, on an ongoing basis, the Commission estimates an annual increase in costs of $2,412,225 for arrangers to make additional information about these transactions available on the related websites each month and to monitor compliance with its obligations over the life of the structured finance products. [84]

In addition to these direct compliance costs, expiration of the existing Rule 17g–5(a)(3) exemption could result in costs that are difficult to quantify. For instance, an incremental increase in costs resulting from the applicability of the Rule 17g–5 Program may vary significantly from transaction to transaction, contributing to the difficulty in quantifying such costs. A bespoke transaction may require significantly more communications between the arranger and the hired NRSRO than a transaction by a frequent issuer of similar securities, resulting in the incurrence of higher costs to arrangers. Moreover, the Rule 17g–5 Program requires that information must be posted to the arranger's website at the same time such information is provided to a hired NRSRO. If the exemption were to expire, information that may have previously been communicated verbally to a hired NRSRO may need to be memorialized in writing. In certain cases, an arranger could enlist outside counsel to draft or review materials to be provided to a hired NRSRO, resulting in additional costs.

Further, there are potential negative economic consequences. Since the global financial crisis there have been other efforts, in addition to the Dodd-Frank Wall Street Reform and Consumer Protection Act,[85] to assess and regulate the credit rating industry as well as to encourage market participants to establish stronger internal credit risk assessment practices. As discussed in the Proposing Release, commenters on the Exemptive Order have expressed concerns that the requirements of Rule 17g–5(a)(3) could potentially be duplicative of or conflict with regulations applicable to NRSROs and arrangers in foreign markets, and thus harm the competitive position of NRSROs in those markets.[86] Failure to provide relief regarding the application of Rule 17g–5(a)(3) to transactions offered and sold exclusively outside the United States may be viewed as inconsistent with notions of international comity.

The expiration of the existing Rule 17g–5(a)(3) exemption may lead to losses for NRSROs if, as commenters on the Exemptive Order have suggested, conflicts exist between the requirements of the Rule 17g–5 Program and foreign laws that limit the information available to NRSROs. Some NRSROs could be precluded from rating structured finance products in such jurisdictions, which could lead to loss of revenue associated with credit ratings that NRSROs currently provide under the existing Exemptive Order. NRSROs could also experience losses as a result of the expiration of the existing Rule 17g–5(a)(3) exemption due to competitive pressures in the foreign markets from credit rating agencies that are not registered as NRSROs (''non-NRSRO rating agencies'') and therefore not subject to Rule 17g–5(a)(3). Expiration of the existing Rule 17g–5(a)(3) exemption may also lead to new compliance costs for NRSROs and arrangers relating to posting information on the websites with respect to credit ratings maintained by NRSROs that had previously been subject to the exemption. From the point of view of arrangers, additional costs of compliance could result in a decline in their issuances of structured finance products if alternative non-NRSRO rating agencies are unavailable or unacceptable to arrangers or investors.

Finally, if the existing Rule 17g–5(a)(3) exemption were allowed to expire, this could also raise legal barriers to entry for smaller NRSROs that may be planning to expand their foreign ratings business.[87] The increased set-up costs may lower such NRSROs' incentives to rate structured finance products in those foreign markets.

that an arranger would have a junior business analyst perform these responsibilities, at a cost of $175 per hour. Therefore, based on the estimate of 284 rated transactions per year, the estimated annual cost for arrangers to make such information available on the related website would be $49,700 (284 transactions × 1 hour per transaction × $175 per hour).

[82] Total hours to develop systems would be 43,800 (146 sponsors × 300 hours per sponsor). The number of sponsors was estimated using information as of March 25, 2019 from the Asset-Backed Alert and Commercial Mortgage Alert databases. Isolating the transactions coded in the database as ''Non-U.S.'' offerings and sorting the data by sponsor (in the case of the Asset-Backed Alert database) or seller (in the case of the Commercial Mortgage Alert database) enables an estimate of the number of separate sponsors that would be eligible for the exemption. The estimate represents the average number of such sponsors for the years ended December 31, 2016, 2017, and 2018. We note that the estimate of the aggregate hours across all sponsors represents upper bounds, as it is plausible that some sponsors also issue structured finance products in U.S.-based transactions and would have already incurred any such one-time costs.

[83] As discussed in the Rule 17g–5 Adopting Release, the Commission believes that a sponsor would use a compliance manager and a programmer analyst to perform these functions, and each would spend half of the estimated hours conducting these tasks. The average hourly cost for a compliance manager is $309 and the average hourly cost for a programmer analyst is $240. Therefore, the average one-time cost to a sponsor would be $82,350 ([150 hours × $309 per hour] + [150 hours × $240 per hour]). The aggregate cost across all sponsors would be up to $12,023,100 (146 sponsors × $82,350 per sponsor). We note that these estimates represent upper bounds. As noted in note 82, some sponsors may have already incurred any one-time set up costs in connection with U.S.-based issuances. In addition, it is plausible that sponsors will obtain these services for a much lower cost from web service providers.

[84] The Commission estimates that it will take an arranger approximately half an hour per month for each transaction to make such information available on the related website. The hourly burden per transaction for a year is 6 hours (0.5 hours per month × 12 months). The Commission believes that an arranger would have a junior business analyst perform these responsibilities at a rate of $175. Further, we relied on the Rule 17g–5 Adopting Release to infer the total number of outstanding deals under surveillance. In that release, the Commission indicated that, on average, an arranger will issue 20 new deals a year and will have 125 outstanding deals, or 6.25 outstanding deals for every new deal. Combining this with our estimate of 284 new transactions per year yields an estimate of 6.25 × 284 = 1,775 outstanding deals. Combining these estimates, the annual cost for arrangers to provide information on ongoing deals is $1,863,750 (1,775 outstanding transactions × $175 per hour × 6 hours per year). In addition, the Commission estimates that compliance personnel at an arranger will spend, for each outstanding transaction, one hour per year to monitor compliance with its requirements in connection with the Rule 17g–5 Program. The Commission estimates a $309 per hour figure for a compliance manager. Therefore, the estimated annual compliance cost would be $548,475 (1 hour per transaction, per year × $309 per hour × 1,775 outstanding transactions). As a result, the total estimated annual ongoing cost for arrangers would be $2,412,225 ($1,863,750 website maintenance cost + $548,475 compliance cost).

[85] Public Law 111–203, 124 Stat. 1376, H.R. 4173 (July 21, 2010).

[86] *See Proposing Release, supra* note 2, 83 FR at 50299–300.

[87] Three of the four smaller NRSROs registered in the class of credit ratings for issuers of asset-backed securities list foreign affiliates as credit rating affiliates on their most recently filed Form NRSRO. Form NRSRO filings can be accessed through the Commission's EDGAR system.

VII. Regulatory Flexibility Act Certification

The Commission certified, under section 605(b) of the Regulatory Flexibility Act of 1980 (''RFA'') [88] that the proposed amendments to Rule 17g–5(a)(3), Rule 17g–7(a), and Rule 15Ga–2 would not have a significant economic impact on a substantial number of small entities. In Section VII of the Proposing Release, the Commission explained that the proposed amendment to Rule 17g–5(a)(3) applies exclusively to rated structured finance products and the NRSROs that are considered small for purposes of the RFA are not currently registered for the class of credit ratings for issuers of asset-backed securities.[89] The Commission further stated in the Proposing Release that it did not believe the economic impact of the proposed amendments to Rule 17g–7(a) and Rule 15Ga–2 would be significant, explaining that an exemption is already included in the text of such rules and that the amendments are clarifying in nature.[90] The Commission solicited comments regarding this certification and received none. The Commission continues to believe this certification is appropriate.

VIII. Statutory Authority

The Commission is adopting amendments to 17 CFR 240.17g–5(a)(3), 17 CFR 240.17g–7(a), and 17 CRF 240.15Ga–2 pursuant to the authority conferred by the Exchange Act, including Sections 15E, 17(a), and 36 (15 U.S.C. 78o–7, 78q, and 78mm).

List of Subjects in 17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

Text of Amendment

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7201 *et seq.;* and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; and Pub. L. 111–203, 939A, 124 Stat. 1887 (2010); and secs. 503 and 602, Pub. L. 112–106, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

Section 240.15Ga–2 is also issued under sec. 943, Pub. L. 111–203, 124 Stat. 1376.

* * * * *

Section 240.17g–7 is also issued under sec. 943, Pub. L. 111–203, 124 Stat. 1376.

* * * * *

■ 2. Amend § 240.15Ga–2 by revising paragraph (e) to read as follows:

§ 240.15Ga–2 Findings and conclusions of third-party due diligence reports.

* * * * *

(e) The requirements of this rule would not apply to an offering of an asset-backed security if certain conditions are met, including:

(1) The offering is not required to be, and is not, registered under the Securities Act of 1933;

(2) The issuer of the rated security is not a U.S. person (as defined in § 230.902(k)); and

(3) All offers and sales of the security by any issuer, sponsor, or underwriter linked to the security will occur outside the United States (as that phrase is used in §§ 230.901 through 230.905 (Regulation S)).

* * * * *

■ 3. Amend § 240.15Ga–2 by:

■ a. Redesignating paragraph (f)(i) as (f)(1); and

■ b. Redesignating paragraph (f)(ii) as (f)(2).

■ 4. Amend § 240.17g–5 by adding paragraph (a)(3)(iv) to read as follows:

§ 240.17g–5 Conflicts of interest.

(a) * * *

(3) * * *

(iv) The provisions of paragraphs (a)(3)(i) through (iii) of this section will not apply to a nationally recognized statistical rating organization when issuing or maintaining a credit rating for a security or money market instrument issued by an asset pool or as part of any asset-backed securities transaction, if:

(A) The issuer of the security or money market instrument is not a U.S. person (as defined in § 230.902(k) of this chapter); and

(B) The nationally recognized statistical rating organization has a reasonable basis to conclude that all offers and sales of the security or money market instrument by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States (as that phrase is used in §§ 230.901 through 230.905 (Regulation S) of this chapter).

* * * * *

■ 5. Amend § 240.17g–7 by revising paragraph (a)(3) to read as follows:

§ 240.17g–7 Disclosure requirements.

(a) * * *

(3) *Exemption.* The provisions of paragraphs (a)(1) and (2) of this section do not apply to a rating action if:

(i) The rated obligor or issuer of the rated security or money market instrument is not a U.S. person (as defined in § 230.902(k) of this chapter); and

(ii) The nationally recognized statistical rating organization has a reasonable basis to conclude that:

(A) With respect to any security or money market instrument issued by a rated obligor, all offers and sales by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States (as that phrase is used in §§ 230.901 through 230.905 (Regulation S) of this chapter); or

(B) With respect to a rated security or money market instrument, all offers and sales by any issuer, sponsor, or underwriter linked to the security or money market instrument will occur outside the United States (as that phrase is used in §§ 230.901 through 230.905 (Regulation S) of this chapter).

* * * * *

By the Commission.

Dated: August 7, 2019.

Vanessa Countryman,

Secretary.

[FR Doc. 2019–17218 Filed 8–13–19; 8:45 am]

BILLING CODE 8011–01–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket Nos. MC2010–21 and CP2010–36]

Update to Product List

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is updating the competitive product list. This action reflects a publication policy adopted by Commission order. The referenced policy assumes periodic updates. The updates are identified in the body of this document. The competitive product list, which is re-published in its entirety, includes these updates.

DATES: *Effective Date:* August 14, 2019. For applicability dates, *see* **SUPPLEMENTARY INFORMATION**.

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

[88] 5 U.S.C. 601 *et seq.*

[89] *See Proposing Release, supra* note 2, 83 FR at 50309.

[90] *See id.* at 50309–10.

SUPPLEMENTARY INFORMATION:

Applicability Dates: April 1, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 55 (MC2019–103 and CP2019–112); April 1, 2019, Parcel Select & Parcel Return Service Contract 9 (MC2019–102 and CP2019–111); April 1, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 53 (MC2019–99 and CP2019–107); April 3, 2019, Priority Mail & First-Class Package Service Contract 97 (MC2019–107 and CP2019–116); April 3, 2019, Priority Mail Contract 514 (MC2019–106 and CP2019–115); April 3, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 54 (MC2019–100 and CP2019–108); April 3, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 56 (MC2019–105 and CP2019–114); April 3, 2019, Priority Mail Contract 511 (MC2019–85 and CP2019–91); April 4, 2019, Parcel Return Service Contract 13 (MC2019–95 and CP2019–101); April 4, 2019, Parcel Return Service Contract 14 (MC2019–96 and CP2019–102); April 8, 2019, Priority Mail Contract 515 (MC2019–108 and CP2019–117); April 8, 2019, Parcel Return Service Contract 15 (MC2019–109 and CP2019–118); April 8, 2019, Priority Mail Contract 516 (MC2019–110 and CP2019–119); April 8, 2019, Priority Mail Contract 517 (MC2019–111 and CP2019–120); April 8, 2019, Priority Mail Express Contract 72 (MC2019–112 and CP2019–121); April 9, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 57 (MC2019–113 and CP2019–122); April 9, 2019, Priority Mail & First-Class Package Service Contract 98 (MC2019–114 and CP2019–123); April 9, 2019, Priority Mail Contract 518 (MC2019–115 and CP2019–124); April 16, 2019, Priority Mail Express & Priority Mail Contract 90 (MC2019–116 and CP2019–125); April 16, 2019, Priority Mail Contract 519 (MC2019–117 and CP2019–126); April 16, 2019, Priority Mail Contract 520 (MC2019–118 and CP2019–127); April 17, 2019, Priority Mail Express & Priority Mail Contract 89 (MC2019–104 and CP2019–113); April 23, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 58 (MC2019–119 and CP2019–128); April 23, 2019, Priority Mail Express & Priority Mail Contract 91 (MC2019–120 and CP2019–129); April 23, 2019, Priority Mail Express Contract 73 (MC2019–121 and CP2019–130); April 23, 2019, Priority Mail Contract 521 (MC2019–122 and CP2019–131); April 24, 2019, Priority Mail Express Contract 74 (MC2019–123 and CP2019–132); April 24, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 59 (MC2019–124 and CP2019–133); April 29, 2019, Priority Mail Contract 522 (MC2019–125 and CP2019–134); April 29, 2019, Priority Mail & First-Class Package Service Contract 99 (MC2019–126 and CP2019–135); April 30, 2019, Priority Mail Contract 523 (MC2019–128 and CP2019–137); April 30, 2019, Priority Mail Contract 524 (MC2019–129 and CP2019–138); April 30, 2019, Priority Mail Express & Priority Mail Contract 92 (MC2019–127 and CP2019–136); May 1, 2019, Priority Mail Contract 525 (MC2019–130 and CP2019–139); May 3, 2019, GEPS 11 (MC2019–132 and CP2019–142); May 3, 2019, Priority Mail Contract 526 (MC2019–133 and CP2019–143); May 9, 2019, Parcel Return Service Contract 16 (MC2019–131 and CP2019–140); May 15, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 60 (MC2019–134 and CP2019–146); May 15, 2019, Priority Mail Contract 527 (MC2019–135 and CP2019–147); May 21, 2019, Priority Mail Express Contract 75 (MC2019–136 and CP2019–149); May 29, 2019, Priority Mail Contract 528 (MC2019–138 and CP2019–152); May 29, 2019, Priority Mail & First-Class Package Service Contract 100 (MC2019–140 and CP2019–154); May 29, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 61 (MC2019–137 and CP2019–150); May 29, 2019, Priority Mail Express, Priority Mail & First-Class Package Service Contract 62 (MC2019–139 and CP2019–153); May 30, 2019, Priority Mail & First-Class Package Service Contract 101 (MC2019–141 and CP2019–156); June 3, 2019, Priority Mail Express Contract 76 (MC2019–142 and CP2019–157); June 3, 2019, Priority Mail & First-Class Package Service Contract 102 (MC2019–143 and CP2019–158); June 13, 2019, Priority Mail Contract 529 (MC2019–144 and CP2019–160); June 13, 2019, Priority Mail Contract 530 (MC2019–145 and CP2019–161); June 17, 2019, Priority Mail Express & Priority Mail Contract 93 (MC2019–146 and CP2019–162); June 17, 2019, Priority Mail Contract 531 (MC2019–147 and CP2019–163); June 18, 2019, First-Class Package Service Contract 99 (MC2019–148 and CP2019–165); June 19, 2019, Priority Mail & First-Class Package Service Contract 103 (MC2019–150 and CP2019–167); June 20, 2019, Priority Mail Contract 532 (MC2019–149 and CP2019–166); June 24, 2019, Priority Mail Contract 533 (MC2019–151 and CP2019–168); June 25, 2019, Priority Mail Contract 534 (MC2019–153 and CP2019–170); June 25, 2019, Priority Mail & First-Class Package Service Contract 104 (MC2019–152 and CP2019–169); June 27, 2019, Priority Mail Express & Priority Mail Contract 94 (MC2019–154 and CP2019–172); June 27, 2019, Priority Mail Contract 535 (MC2019–155 and CP2019–173); June 28, 2019, Priority Mail Express Contract 77 (MC2019–156 and CP2019–174).

This document identifies updates to the competitive product list, which appears as 39 CFR Appendix B to Subpart A of Part 3020—Competitive Product List. Publication of the updated product list in the **Federal Register** is addressed in the Postal Accountability and Enhancement Act (PAEA) of 2006.

Authorization. The Commission process for periodic publication of updates was established in Docket Nos. MC2010–21 and CP2010–36, Order No. 445, April 22, 2010, at 8.

Changes. The competitive product list is being updated by publishing a replacement in its entirety of 39 CFR Appendix B to Subpart A of Part 3020—Competitive Product List. The following products are being added, removed, or moved within the competitive product list:

Competitive Product List

1. Priority Mail Express, Priority Mail & First-Class Package Service Contract 55 (MC2019–103 and CP2019–112) (Order No. 5032), added April 1, 2019.
2. Parcel Select & Parcel Return Service Contract 9 (MC2019–102 and CP2019–111) (Order No. 5033), added April 1, 2019.
3. Priority Mail Express, Priority Mail & First-Class Package Service Contract 53 (MC2019–99 and CP2019–107) (Order No. 5034), added April 1, 2019.
4. Priority Mail & First-Class Package Service Contract 97 (MC2019–107 and CP2019–116) (Order No. 5035), added April 3, 2019.
5. Priority Mail Contract 514 (MC2019–106 and CP2019–115) (Order No. 5036), added April 3, 2019.
6. Priority Mail Express, Priority Mail & First-Class Package Service Contract 54 (MC2019–100 and CP2019–108) (Order No. 5037), added April 3, 2019.
7. Priority Mail Express, Priority Mail & First-Class Package Service Contract 56 (MC2019–105 and CP2019–114) (Order No. 5039), added April 3, 2019.
8. Priority Mail Contract 511 (MC2019–85 and CP2019–91) (Order No. 5040), added April 3, 2019.
9. Parcel Return Service Contract 13 (MC2019–95 and CP2019–101) (Order No. 5041), added April 4, 2019.
10. Parcel Return Service Contract 14 (MC2019–96 and CP2019–102) (Order No. 5042), added April 4, 2019.

11. Priority Mail Contract 515 (MC2019–108 and CP2019–117) (Order No. 5045), added April 8, 2019.
12. Parcel Return Service Contract 15 (MC2019–109 and CP2019–118) (Order No. 5046), added April 8, 2019.
13. Priority Mail Contract 516 (MC2019–110 and CP2019–119) (Order No. 5047), added April 8, 2019.
14. Priority Mail Contract 517 (MC2019–111 and CP2019–120) (Order No. 5048), added April 8, 2019.
15. Priority Mail Express Contract 72 (MC2019–112 and CP2019–121) (Order No. 5049), added April 8, 2019.
16. Priority Mail Express, Priority Mail & First-Class Package Service Contract 57 (MC2019–113 and CP2019–122) (Order No. 5050), added April 9, 2019.
17. Priority Mail & First-Class Package Service Contract 98 (MC2019–114 and CP2019–123) (Order No. 5051), added April 9, 2019.
18. Priority Mail Contract 518 (MC2019–115 and CP2019–124) (Order No. 5052), added April 9, 2019.
19. Priority Mail Express & Priority Mail Contract 90 (MC2019–116 and CP2019–125) (Order No. 5058), added April 16, 2019.
20. Priority Mail Contract 519 (MC2019–117 and CP2019–126) (Order No. 5059), added April 16, 2019.
21. Priority Mail Contract 520 (MC2019–118 and CP2019–127) (Order No. 5060), added April 16, 2019.
22. Priority Mail Express & Priority Mail Contract 89 (MC2019–104 and CP2019–113) (Order No. 5061), added April 17, 2019.
23. Priority Mail Express, Priority Mail & First-Class Package Service Contract 58 (MC2019–119 and CP2019–128) (Order No. 5064), added April 23, 2019.
24. Priority Mail Express & Priority Mail Contract 91 (MC2019–120 and CP2019–129) (Order No. 5065), added April 23, 2019.
25. Priority Mail Express Contract 73 (MC2019–121 and CP2019–130) (Order No. 5066), added April 23, 2019.
26. Priority Mail Contract 521 (MC2019–122 and CP2019–131) (Order No. 5067), added April 23, 2019.
27. Priority Mail Express Contract 74 (MC2019–123 and CP2019–132) (Order No. 5068), added April 24, 2019.
28. Priority Mail Express, Priority Mail & First-Class Package Service Contract 59 (MC2019–124 and CP2019–133) (Order No. 5069), added April 24, 2019.
29. Priority Mail Contract 522 (MC2019–125 and CP2019–134) (Order No. 5073), added April 29, 2019.
30. Priority Mail & First-Class Package Service Contract 99 (MC2019–126 and CP2019–135) (Order No. 5074), added April 29, 2019.
31. Priority Mail Contract 523 (MC2019–128 and CP2019–137) (Order No. 5075), added April 30, 2019.
32. Priority Mail Contract 524 (MC2019–129 and CP2019–138) (Order No. 5076), added April 30, 2019.
33. Priority Mail Express & Priority Mail Contract 92 (MC2019–127 and CP2019–136) (Order No. 5077), added April 30, 2019.
34. Priority Mail Contract 525 (MC2019–130 and CP2019–139) (Order No. 5078), added May 1, 2019.
35. GEPS 11 (MC2019–132 and CP2019–142) (Order No. 5082), added May 3, 2019.
36. Priority Mail Contract 526 (MC2019–133 and CP2019–143) (Order No. 5083), added May 3, 2019.
37. Parcel Return Service Contract 16 (MC2019–131 and CP2019–140) (Order No. 5089), added May 9, 2019.
38. Priority Mail Express, Priority Mail & First-Class Package Service Contract 60 (MC2019–134 and CP2019–146) (Order No. 5091), added May 15, 2019.
39. Priority Mail Contract 527 (MC2019–135 and CP2019–147) (Order No. 5092), added May 15, 2019.
40. Priority Mail Express Contract 75 (MC2019–136 and CP2019–149) (Order No. 5100), added May 21, 2019.
41. Priority Mail Contract 528 (MC2019–138 and CP2019–152) (Order No. 5106), added May 29, 2019.
42. Priority Mail & First-Class Package Service Contract 100 (MC2019–140 and CP2019–154) (Order No. 5107), added May 29, 2019.
43. Priority Mail Express, Priority Mail & First-Class Package Service Contract 61 (MC2019–137 and CP2019–150) (Order No. 5108), added May 29, 2019.
44. Priority Mail Express, Priority Mail & First-Class Package Service Contract 62 (MC2019–139 and CP2019–153) (Order No. 5109), added May 29, 2019.
45. Priority Mail & First-Class Package Service Contract 101 (MC2019–141 and CP2019–156) (Order No. 5110), added May 30, 2019.
46. Priority Mail Express Contract 76 (MC2019–142 and CP2019–157) (Order No. 5111), added June 3, 2019.
47. Priority Mail & First-Class Package Service Contract 102 (MC2019–143 and CP2019–158) (Order No. 5112), added June 3, 2019.
48. Priority Mail Contract 529 (MC2019–144 and CP2019–160) (Order No. 5116), added June 13, 2019.
49. Priority Mail Contract 530 (MC2019–145 and CP2019–161) (Order No. 5117), added June 13, 2019.
50. Priority Mail Express & Priority Mail Contract 93 (MC2019–146 and CP2019–162) (Order No. 5118), added June 17, 2019.
51. Priority Mail Contract 531 (MC2019–147 and CP2019–163) (Order No. 5119), added June 17, 2019.
52. First-Class Package Service Contract 99 (MC2019–148 and CP2019–165) (Order No. 5121), added June 18, 2019.
53. Priority Mail & First-Class Package Service Contract 103 (MC2019–150 and CP2019–167) (Order No. 5125), added June 19, 2019.
54. Priority Mail Contract 532 (MC2019–149 and CP2019–166) (Order No. 5126), added June 20, 2019.
55. Priority Mail Contract 533 (MC2019–151 and CP2019–168) (Order No. 5128), added June 24, 2019.
56. Priority Mail Contract 534 (MC2019–153 and CP2019–170) (Order No. 5129), added June 25, 2019.
57. Priority Mail & First-Class Package Service Contract 104 (MC2019–152 and CP2019–169) (Order No. 5130), added June 25, 2019.
58. Priority Mail Express & Priority Mail Contract 94 (MC2019–154 and CP2019–172) (Order No. 5138), added June 27, 2019.
59. Priority Mail Contract 535 (MC2019–155 and CP2019–173) (Order No. 5139), added June 27, 2019.
60. Priority Mail Express Contract 77 (MC2019–156 and CP2019–174) (Order No. 5141), added June 28, 2019.

The following negotiated service agreements have expired, or have been terminated early, and are being deleted from the Competitive Product List:

1. Parcel Return Service Contract 5 (MC2014–4 and CP2014–4) (Order No. 1867).
2. Parcel Select Contract 8 (MC2015–1 and CP2015–3) (Order No. 2242).
3. Priority Mail & First-Class Package Service Contract 4 (MC2015–48 and CP2015–60) (Order No. 2464).
4. Priority Mail Express & Priority Mail Contract 20 (MC2015–78 and CP2015–123) (Order No. 2670).
5. Priority Mail Express Contract 28 (MC2016–2 and CP2016–2) (Order No. 2761).
6. Priority Mail Contract 145 (MC2016–1 and CP2016–1) (Order No. 2762).
7. Priority Mail Contract 148 (MC2016–6 and CP2016–6) (Order No. 2777).
8. Priority Mail Express, Priority Mail & First-Class Package Service Contract 5 (MC2016–9 and CP2016–11) (Order No. 2796).
9. Priority Mail Contract 153 (MC2016–17 and CP2016–23) (Order No. 2846).

10. Priority Mail Contract 154 (MC2016–18 and CP2016–24) (Order No. 2849).
11. Priority Mail Express & Priority Mail Contract 24 (MC2016–27 and CP2016–33) (Order No. 2890).
12. First-Class Package Service Contract 39 (MC2016–38 and CP2016–47) (Order No. 2926).
13. Priority Mail Express & Priority Mail Contract 25 (MC2016–45 and CP2016–60) (Order No. 2966).
14. Priority Mail Contract 176 (MC2016–54 and CP2016–69) (Order No. 2981).
15. Priority Mail Contract 181 (MC2016–65 and CP2016–80) (Order No. 2992).
16. Priority Mail Express, Priority Mail & First-Class Package Service Contract 8 (MC2016–72 and CP2016–87) (Order No. 2997).
17. Priority Mail Contract 185 (MC2016–69 and CP2016–84) (Order No. 2999).
18. First-Class Package Service Contract 40 (MC2016–51 and CP2016–66) (Order No. 3007).
19. Priority Mail Contract 166 (MC2016–40 and CP2016–49) (Order No. 3070).
20. First-Class Package Service Contract 43 (MC2016–81 and CP2016–106) (Order No. 3110).
21. Priority Mail Contract 188 (MC2016–80 and CP2016–105) (Order No. 3111).
22. Priority Mail Express Contract 32 (MC2016–77 and CP2016–102) (Order No. 3116).
23. Priority Mail Contract 190 (MC2016–84 and CP2016–109) (Order No. 3138).
24. Priority Mail Contract 193 (MC2016–90 and CP2016–115) (Order No. 3153).
25. First-Class Package Service Contract 47 (MC2016–104 and CP2016–132) (Order No. 3198).
26. Priority Mail Contract 201 (MC2016–108 and CP2016–136) (Order No. 3215).
27. Priority Mail Contract 202 (MC2016–109 and CP2016–137) (Order No. 3217).
28. First-Class Package Service Contract 48 (MC2016–111 and CP2016–139) (Order No. 3218).
29. Priority Mail & Parcel Select Contract 1 (MC2016–113 and CP2016–141) (Order No. 3222).
30. Priority Mail Contract 205 (MC2016–115 and CP2016–146) (Order No. 3228).
31. First-Class Package Service Contract 50 (MC2016–117 and CP2016–148) (Order No. 3229).
32. Priority Mail Contract 204 (MC2016–114 and CP2016–145) (Order No. 3230).
33. First-Class Package Service Contract 49 (MC2016–116 and CP2016–147) (Order No. 3232).
34. Priority Mail Contract 206 (MC2016–121 and CP2016–154) (Order No. 3262).
35. Priority Mail Contract 211 (MC2016–126 and CP2016–160) (Order No. 3281).
36. Priority Mail Contract 213 (MC2016–128 and CP2016–162) (Order No. 3283).
37. Priority Mail Contract 209 (MC2016–124 and CP2016–158) (Order No. 3285).
38. Priority Mail Contract 212 (MC2016–127 and CP2016–161) (Order No. 3287).
39. Priority Mail & First-Class Package Service Contract 18 (MC2016–129 and CP2016–163) (Order No. 3288).
40. Priority Mail Contract 217 (MC2016–134 and CP2016–171) (Order No. 3336).
41. Priority Mail Contract 218 (MC2016–135 and CP2016–172) (Order No. 3337).
42. Priority Mail Contract 219 (MC2016–136 and CP2016–173) (Order No. 3338).
43. Priority Mail Express Contract 37 (MC2016–139 and CP2016–176) (Order No. 3343).
44. First-Class Package Service Contract 53 (MC2016–140 and CP2016–177) (Order No. 3344).
45. Priority Mail Contract 215 (MC2016–132 and CP2016–169) (Order No. 3345).
46. Priority Mail Express Contract 36 (MC2016–138 and CP2016–175) (Order No. 3346).
47. Priority Mail Contract 220 (MC2016–143 and CP2016–180) (Order No. 3353).
48. Parcel Select Contract 16 (MC2016–147 and CP2016–184) (Order No. 3355).
49. Parcel Select Contract 15 (MC2016–137 and CP2016–174) (Order No. 3363).
50. Priority Mail Contract 224 (MC2016–150 and CP2016–190) (Order No. 3367).
51. Priority Mail Contract 225 (MC2016–151 and CP2016–191) (Order No. 3368).
52. First-Class Package Service Contract 57 (MC2016–155 and CP2016–218) (Order No. 3390).
53. Priority Mail Contract 227 (MC2016–156 and CP2016–219) (Order No. 3397).
54. Priority Mail Express Contract 39 (MC2016–164 and CP2016–238) (Order No. 3438).
55. Priority Mail & First-Class Package Service Contract 22 (MC2016–166 and CP2016–240) (Order No. 3439).
56. Priority Mail Contract 240 (MC2016–201 and CP2016–290) (Order No. 3548).
57. Priority Mail & First-Class Package Service Contract 33 (MC2016–210 and CP2016–299) (Order No. 3556).
58. Priority Mail Contract 245 (MC2017–1 and CP2017–1) (Order No. 3569).
59. Priority Mail Contract 260 (MC2017–27 and CP2017–52) (Order No. 3661).
60. Priority Mail Contract 268 (MC2017–43 and CP2017–68) (Order No. 3687).
61. Priority Mail Contract 284 (MC2017–74 and CP2017–101) (Order No. 3738).
62. Priority Mail Contract 289 (MC2017–81 and CP2017–107) (Order No. 3774).
63. Parcel Select Contract 21 (MC2017–90 and CP2017–119) (Order No. 3786).
64. Priority Mail Contract 294 (MC2017–91 and CP2017–125) (Order No. 3801).
65. Priority Mail Contract 301 (MC2017–102 and CP2017–149) (Order No. 3845).
66. Priority Mail Contract 302 (MC2017–103 and CP2017–150) (Order No. 3846).
67. Priority Mail Contract 304 (MC2017–107 and CP2017–154) (Order No. 3855).
68. Priority Mail Express & Priority Mail Contract 46 (MC2017–114 and CP2017–165) (Order No. 3869).
69. Priority Mail Contract 309 (MC2017–116 and CP2017–167) (Order No. 3874).
70. Priority Mail Contract 315 (MC2017–127 and CP2017–180) (Order No. 3898).
71. Priority Mail & First-Class Package Service Contract 46 (MC2017–153 and CP2017–216) (Order No. 3987).
72. Priority Mail Contract 332 (MC2017–156 and CP2017–220) (Order No. 4007).
73. Priority Mail Express, Priority Mail & First-Class Package Service Contract 22 (MC2017–177 and CP2017–278) (Order No. 4082).
74. Priority Mail Contract 346 (MC2017–181 and CP2017–282) (Order No. 4093).
75. Priority Mail Contract 350 (MC2017–186 and CP2017–287) (Order No. 4100).
76. Priority Mail Express Contract 50 (MC2017–190 and CP2017–291) (Order No. 4106).
77. Priority Mail Express & Priority Mail Contract 50 (MC2017–191 and CP2017–292) (Order No. 4107).
78. First-Class Package Service Contract 84 (MC2018–2 and CP2018–2) (Order No. 4160).

79. Priority Mail Contract 369 (MC2018–8 and CP2018–15) (Order No. 4201).

80. Priority Mail Express & Priority Mail Contract 52 (MC2018–18 and CP2018–40) (Order No. 4212).

81. Priority Mail Contract 385 (MC2018–47 and CP2018–77) (Order No. 4281).

82. First-Class Package Service Contract 86 (MC2018–51 and CP2018–82) (Order No. 4289).

83. Priority Mail Contract 388 (MC2018–53 and CP2018–86) (Order No. 4299).

84. Priority Mail Contract 392 (MC2018–58 and CP2018–95) (Order No. 4307).

85. Priority Mail & First-Class Package Service Contract 68 (MC2018–83 and CP2018–125) (Order No. 4344).

86. Priority Mail Express Contract 58 (MC2018–91 and CP2018–133) (Order No. 4354).

87. Priority Mail Contract 407 (MC2018–102 and CP2018–144) (Order No. 4366).

88. Priority Mail Contract 409 (MC2018–104 and CP2018–146) (Order No. 4369).

89. Priority Mail Contract 417 (MC2018–112 and CP2018–154) (Order No. 4380).

90. Priority Mail Express & Priority Mail Contract 61 (MC2018–119 and CP2018–162) (Order No. 4384).

91. Priority Mail Contract 414 (MC2018–109 and CP2018–151) (Order No. 4389).

92. Priority Mail Express, Priority Mail & First-Class Package Service Contract 33 (MC2018–137 and CP2018–198) (Order No. 4581).

93. Priority Mail Contract 432 (MC2018–144 and CP2018–207) (Order No. 4597).

94. Priority Mail Contract 433 (MC2018–149 and CP2018–215) (Order No. 4626).

95. Priority Mail Contract 441 (MC2018–164 and CP2018–235) (Order No. 4651).

96. Priority Mail Contract 446 (MC2018–176 and CP2018–248) (Order No. 4674).

97. Parcel Select Contract 31 (MC2018–179 and CP2018–251) (Order No. 4676).

98. Priority Mail Contract 453 (MC2018–191 and CP2018–267) (Order No. 4716).

99. Priority Mail Express, Priority Mail & First-Class Package Service Contract 41 (MC2018–192 and CP2018–270) (Order No. 4729).

100. Priority Mail Contract 459 (MC2018–203 and CP2018–282) (Order No. 4760).

101. Priority Mail Contract 461 (MC2018–205 and CP2018–285) (Order No. 4768).

102. Parcel Select Contract 33 (MC2018–221 and CP2018–307) (Order No. 4841).

103. Priority Mail Contract 471 (MC2019–8 and CP2019–7) (Order No. 4863).

104. Priority Mail Contract 472 (MC2019–11 and CP2019–10) (Order No. 4880).

105. Priority Mail Contract 481 (MC2019–28 and CP2019–29) (Order No. 4907).

106. Priority Mail Contract 485 (MC2019–36 and CP2019–38) (Order No. 4920).

Updated product list. The referenced changes to the competitive product list is incorporated into 39 CFR Appendix B to Subpart A of Part 3020—Competitive Product List.

List of Subjects in 39 CFR Part 3020

Administrative practice and procedure, Postal Service.

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

PART 3020—PRODUCT LISTS

■ 1. The authority citation for part 3020 continues to read as follows:

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

■ 2. Revise Appendix B to Subpart A of Part 3020 to read as follows:

Appendix B to Subpart A of Part 3020—Competitive Product List

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

Domestic Products*

Priority Mail Express
Priority Mail
Parcel Select
Parcel Return Service
First-Class Package Service
USPS Retail Ground

International Products*

Outbound International Expedited Services
Inbound Parcel Post (at UPU rates)
Outbound Priority Mail International
International Priority Airmail (IPA)
International Surface Air List (ISAL)
International Direct Sacks—M-Bags
Outbound Single-Piece First-Class Package International Service

Negotiated Service Agreements*

Domestic*
Priority Mail Express Contract 35
Priority Mail Express Contract 40
Priority Mail Express Contract 41
Priority Mail Express Contract 42
Priority Mail Express Contract 43
Priority Mail Express Contract 44
Priority Mail Express Contract 45
Priority Mail Express Contract 46
Priority Mail Express Contract 47
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Priority Mail Express Contract 76
Priority Mail Express Contract 77
Parcel Return Service Contract 6
Parcel Return Service Contract 11
Parcel Return Service Contract 12
Parcel Return Service Contract 13
Parcel Return Service Contract 14
Parcel Return Service Contract 15
Parcel Return Service Contract 16
Priority Mail Contract 77
Priority Mail Contract 78
Priority Mail Contract 80
Priority Mail Contract 123
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Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2019–17273 Filed 8–13–19; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2018–0806; FRL–9998–04–Region 9]

Air Quality State Implementation Plans; Approval and Promulgations; Hawaii; Infrastructure SIP

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) submission from the State of Hawaii regarding certain Clean Air Act (CAA or ''Act'') requirements related to interstate transport for the 2008 ozone national ambient air quality standards (NAAQS). The interstate transport requirements consist of several elements; this approval pertains only to provisions requiring that SIPs prohibit sources or other types of emissions activity in one state from emitting any air pollutant in amounts that will contribute significantly to nonattainment and interference with maintenance of the 2008 ozone NAAQS in other states. The

EPA is approving Hawaii's August 6, 2015 SIP submittal on the basis that it addresses two requirements of CAA section 110(a)(2)(D)(i)(I), which we refer to as prong 1 (significant contribution to nonattainment of the NAAQS in any other state) and prong 2 (interference with maintenance of the NAAQS in any other state). The EPA refers to SIP revisions addressing the requirements of section 110(a)(2)(D)(i)(I) as ''good neighbor SIPs'' or ''interstate transport SIPs.''

DATES: This rule is effective on September 13, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2018–0806. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Wienke Tax, Air Planning Office (AIR–2), EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 947–4192, *tax.wienke@epa.gov.*

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

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I. Background Information
II. Public Comment
III. Final Action
IV. Statutory and Executive Order Reviews

I. Background Information

On February 28, 2019, the EPA published a notice of proposed rulemaking (NPRM) proposing to approve the Hawaii Department of Health's (DOH) August 6, 2015 submittal addressing two requirements of CAA section 110(a)(2)(D)(i)(I).[1] A detailed discussion of Hawaii's good neighbor SIP and the EPA's rationale for approving the SIP revision is provided in the NPRM and will not be restated here.

[1] 84 FR 6736.

II. Public Comment

The EPA's proposed action provided a 30-day public comment period that ended on April 1, 2019. During the comment period, we received one comment. We summarize the comment below and provide our response.

Comment 1: The commenter states that the EPA's preamble for its proposed action summarizes trajectory analyses submitted by Hawaii and that the EPA concludes that ''[a] very small fraction of emissions arrives in the continental United States (U.S.) more than two days after release and a slightly larger fraction arrives five days after release.'' The commenter states that it is unclear whether this factual assertion was made by the state or whether it is the EPA's own conclusion. The commenter goes on to assert that it is not possible to conclude from wind trajectories what fraction of emissions from Hawaii reach the continental U.S. The commenter concludes by stating that the EPA cannot base its approval of the good neighbor SIP on this factual assertion, as it is not supported by the cited evidence.

Response 1: This statement is the EPA's own conclusion. We agree with the commenter that it is not possible to precisely quantify the fraction of emissions from Hawaii that reaches the continental U.S. based on the trajectory analysis submitted by Hawaii. This analysis establishes the time to transport emissions to the continental U.S., but does not address the deposition, chemical transformation, and dispersion that would occur during transport. Quantifying these factors would require modeling, which, as explained in our proposal, we do not believe is necessary for an isolated state such as Hawaii. However, based on the time and distance of transport, as well as the fact that a certain degree of deposition, chemical transformation, and dispersion would necessarily occur over such time and distance, we believe it is reasonable to conclude that the fraction of emissions from Hawaii that would reach the continental U.S. would be relatively small. The commenter has provided no evidence to contradict this conclusion.

Furthermore, this conclusion was only one factor in the overall weight of evidence analysis that we used to assess Hawaii's interstate transport obligations with respect to the 2008 ozone NAAQS. Another key factor was that Hawaii's total emissions of ozone precursors are significantly lower than emissions of these pollutants from several continental states, including Colorado.[2] Based on modeling, the EPA has found that Colorado's emissions do not contribute significantly to nonattainment in downwind states.[3] Given that emissions from Colorado are over five times greater than those from Hawaii, and Colorado is more than 2,000 miles closer to nonattainment receptors than Hawaii, it is unlikely that Hawaii's emissions significantly contribute to nonattainment.

Comment 2: The commenter notes that the preamble to the EPA's proposed rule states that Hawaii's emissions are declining. The commenter asserts that the approval of a good neighbor SIP with respect to Prong 1 must be based on the effects that emissions from the upwind state are having on other states at this time, not on the effect of lower emissions projected to prevail in the future. The commenter states that the EPA's reference to future levels of emissions should not be part of the EPA's rationale for approving the SIP with respect to the Prong 1 requirement. The commenter acknowledges that the fact that future emissions are expected to be less than current emissions can be considered in evaluating whether the SIP satisfies Prong 2. The commenter requests that the EPA more logically state its rationale for approval of the SIP.

Response 2: The commenter is incorrect that an approval of a good neighbor SIP with respect to Prong 1 must be based solely on the effects emissions from the upwind state are having on other states at this time. Prong 1 requires SIPs to include adequate provisions prohibiting emission ''which will contribute significantly to nonattainment'' in another state.[4] The EPA has interpreted this phrase to refer to ''sources that presently and at some point in the future 'will' contribute to nonattainment'' and the D.C. Circuit Court has upheld this interpretation as reasonable in *North Carolina* v. *EPA* (''*North Carolina*'').[5]

Consistent with this interpretation, the EPA has routinely approved interstate transport SIPs that rely on future year modeling.[6] In particular, as

[2] 84 FR 6736, 6738.

[3] 80 FR 72937 (November 23, 2015) (proposed rule); 81 FR 7706 (February 16, 2016) (final rule).

[4] CAA section 110(a)(2)(D)(i)(I).

[5] *North Carolina* v. *EPA,* 531 F.3d 896, 914 (D.C. Cir. 2008).

[6] See, *e.g.,* 83 FR 65093 (Final approval of California's interstate transport SIP for ozone, fine particulate matter, and sulfur dioxide); Cf. 76 FR 48208 (Cross-State Air Pollution Rule (CSAPR), promulgating federal implementation plans (FIPs) addressing good neighbor obligations for ozone and fine particulate matter); 81 FR 74504 (CSAPR

Continued

noted in the preamble to the proposed action, the EPA's historical approach to addressing interstate transport under the good neighbor provision has been to evaluate states' obligations to address downwind contributions using a multistep process. This process involves identifying downwind air quality problems; identifying upwind states that impact those downwind air quality problems sufficiently such that they are considered ''linked'' and therefore warrant further review and analysis; identifying the emissions reductions necessary (if any), considering cost and air quality factors to prevent the linked upwind states from contributing significantly to nonattainment or interfering with maintenance of the NAAQS at the locations of the downwind air quality problems; and adopting permanent and enforceable measures needed to achieve those emissions reductions.

When the EPA identified downwind air quality problems as part of the 2016 Cross-State Air Pollution Rule (CSAPR) Update, we used air quality modeling projections for the (then) future analytic year of 2017,[7] consistent with the *North Carolina* decision.[8] The EPA also used a 2017 compliance deadline to ensure that the emissions reductions achieved through implementing the CSAPR Update would be made prior to the July 20, 2018 moderate attainment deadline,[9] again in conformance with *North Carolina.*[10]

Because Hawaii was not part of the EPA's air quality modeling analysis for the CSAPR Update, the EPA used a weight of evidence analysis to assess Hawaii's interstate transport obligations with respect to the 2008 ozone NAAQS. This approach included reviewing Hawaii's recent emissions history that showed emissions have decreased over time and are substantially lower than emissions from California, Arizona, Colorado, and Texas, as shown in Table 1 of our proposed rule,[11] and reviewing Hawaii's transport patterns using trajectory analysis. We then compared the emissions data and the distance between Hawaii and receptors in the continental U.S. with the much higher emissions levels and much smaller distances between upwind and downwind states with known, modeled linkages in the continental U.S. In other words, our analysis considered both the absolute level of recent emissions from Hawaii and the downward trend in these emissions. Based on this analysis, the EPA concludes that emissions from Hawaii will not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in any other state. Our approval of Hawaii's interstate transport SIP is based on this determination.

III. Final Action

For the reasons described in our responses to comments, the comments received do not alter our proposed determination that emissions from Hawaii will not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in any other state. Therefore, the EPA is approving Hawaii's 2008 ozone transport SIP, submitted by Hawaii DOH on August 6, 2015, as meeting the applicable requirements of CAA section 110(a)(2)(D)(i)(I) as a revision to the Hawaii SIP.

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**.

A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 15, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may

Update, promulgating FIPs addressing good neighbor obligations for ozone).

[7] 81 FR 74504, 74516. See 84 FR 6736 for additional details on the CSAPR Update.

[8] 531 F.3d 914.

[9] 81 FR 74504, 74516.

[10] 531 F.3d 911–12 (holding that the EPA must coordinate interstate transport compliance deadlines with downwind attainment deadlines).

[11] 84 FR 6736, 6738.

not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Infrastructure SIP, Interstate transport, Nitrogen oxides, Ozone, Volatile organic compounds.

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

Dated: July 30, 2019.

Deborah Jordan,

Acting Regional Administrator, EPA Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart M—Hawaii

■ 2. In § 52.620, amend the table in paragraph (e) by adding an entry for ''Hawaii State Implementation Plan Revision to Address CAA Section 110(a)(2)(D)(i)(I) for the 2008 Ozone National Ambient Air Quality Standard, excluding Attachment 3'' after the entry for ''Hawaii State Implementation Plan Revision, National Ambient Air Quality Standards for 2008 Ozone and 2010 Nitrogen Dioxide, Clean Air Act Section 110(a)(1) & (2), excluding attachment 3, and appendices A, B, and C.''

The revisions and additions read as follows:

§ 52.620 Identification of plan.

* * * * *

(e) * * *

EPA Approved Hawaii Nonregulatory Provisions and Quasi-Regulatory Measures

Name of SIP provision	Applicable geographic or non-attainment area	State submittal date	EPA approval date	Explanation
*	* *	*	*	* *
State of Hawaii Air Pollution Control Implementation Plans for Nitrogen Dioxide, Ozone, $PM_{2.5}$, and Lead				
*	* *	*	*	* *
Hawaii State Implementation Plan Revision to Address CAA Section 110(a)(2)(D)(i)(I) for the 2008 Ozone National Ambient Air Quality Standard, excluding Attachment 3.	Statewide	8/6/2015	[Insert **Federal Register** page number where the document begins, 8/14/19.	Approved SIP revision excludes Attachment 3 (''Summary of Public Participation Proceedings'').
*	* *	*	*	* *

[FR Doc. 2019–17125 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0641; FRL–9996–35]

Clonostachys rosea Strain CR–7; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Clonostachys rosea* strain CR–7 in or on all food commodities when used in accordance with label directions and good agricultural practices. Bee Vectoring Technology, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Clonostachys rosea* strain CR–7 in or on all food commodities under FFDCA.

DATES: This regulation is effective August 14, 2019. Objections and requests for hearings must be received on or before October 15, 2019 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0641, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0641 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 15, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0641, by one of the following methods:

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

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

II. Background

In the **Federal Register** of February 7, 2017 (82 FR 9555) (FRL–9956–86), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 6F8508) by Bee Vectoring Technology, Inc., 4160 Sladeview Crescent #7, Mississauga, Ontario L5L 0A1, Canada (c/o Technology Sciences Group, Inc., 1150 18th St. NW, Suite 1000, Washington, DC 20036). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the fungicide *Clonostachys rosea* strain CR–7 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner Bee Vectoring Technology, Inc. and available in the docket via *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit III.C.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.''

EPA evaluated the available toxicity and exposure data on *Clonostachys rosea* strain CR–7 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for *Clonostachys rosea* strain CR–7'' (Safety Determination). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The available data demonstrated that, with regard to humans, *Clonostachys rosea* strain CR–7 is not toxic via the pulmonary, oral, or dermal routes of exposure and is not pathogenic or infective via the pulmonary route of exposure. Although there may be some exposure to residues when *Clonostachys rosea* strain CR–7 is used on food commodities in accordance with label directions and good agricultural practices, dietary exposure to such residues presents no concern for adverse effects. EPA also determined that a Food Quality Protection Act safety factor (FQPA SF) was not necessary as part of the qualitative assessment conducted for *Clonostachys rosea* strain CR–7. These findings are discussed in more detail in the Safety Determination.

Based upon its evaluation in the Safety Determination, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Clonostachys rosea* strain CR–7. Therefore, an exemption from the requirement of a tolerance is established for residues of *Clonostachys rosea* strain CR–7 in or on all food commodities when used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

An analytical method is not required because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Response to Comments

Two comments were received in response to the notice of filing. EPA reviewed the comments and to the extent that they are relevant to the

tolerance exemption in this action, they asked EPA to ensure the public health against adverse effects of pesticides. EPA has evaluated the available information on *Clonostachys rosea* strain CR–7, including toxicological and potential exposure information, and concluded, in accordance with the statutory requirements of FFDCA, that the exemption would be safe. The commenters provided no basis for a different conclusion.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*).

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

V. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 31, 2019.

Richard Keigwin,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Add § 180.1368 CFR cite to subpart D to read as follows:

§ 180.1368 *Clonostachys rosea* strain CR–7; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Clonostachys rosea* strain CR–7 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2019–17309 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 18–214, GN Docket No. 12–268; FCC 19–21]

LPTV, TV Translator, and FM Broadcast Station Reimbursement

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, information collection requirements adopted in FCC 19–21. This document is consistent with the Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing the compliance date.

DATES:

Effective date: This rule is effective August 14, 2019.

Compliance Date: Compliance with 47 CFR 73.3701(c), published at 84 FR 11233 on March 26, 2019, shall commence as of August 14, 2019.

FOR FURTHER INFORMATION CONTACT: Cathy Williams by email at *Cathy.Williams@fcc.gov* and telephone at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that OMB approved the new information collection requirements contained in 47 CFR 73.3701, as adopted in the LPTV, TV Translator, and FM Reimbursement Report and Order, FCC 19–21, published at 84 FR 11233 (March 26, 2019). OMB approved OMB Control Number 3060–1178 on July 30, 2019. The Commission publishes this notice as an announcement of the effective date of the information collection requirements contained in 47 CFR 73.3701.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on July 30, 2019 for the new information collection requirements contained in 47 CFR 73.3701, as amended, in the LPTV, TV

Translator, and FM Reimbursement Report and Order, MB Dkt. No. 18–214, GN Docket No. 12–268, FCC 19–21 (rel. March 15, 2019). Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1178. The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1178.

Title: TV Broadcast Relocation Fund Reimbursement Form, FCC Form 2100, Schedule 399; Section 73.3700(e), Reimbursement Rules; Section 73.3701, Reimbursement Under the Reimbursement Expansion Act.

Form Number: FCC Form 2100, Schedule 399.

Respondents: Business or other for-profit entities; Not for profit institutions.

Number of Respondents and Responses: 4,400 respondents; 52,800 responses.

Estimated Hours per Response: 1–4 hours.

Frequency of Response: One-time reporting requirement; On occasion reporting requirement, Recordkeeping requirement.

Total Annual Burden: 98,800 hours.

Total Annual Cost: $15,000,000.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 154(j), 157 and 309(j) as amended; and Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, §§ 6402 (codified at 47 U.S.C. 309(j)(8)(G)), 6403 (codified at 47 U.S.C. 1452), 126 Stat. 156 (2012) (Spectrum Act).

Nature and Extent of Confidentiality: There is some need for confidentiality with this collection of information. Invoices, receipts, contracts, and other cost documentation submitted along with the form will be kept confidential in order to protect the identification of vendors and the terms of private contracts between parties. Vendor name and Employer Identification Numbers (EIN) or Tax Payer Identification Number (TIN) will not be disclosed to the public.

Privacy Impact Assessment: No impact(s).

Needs and Uses: This submission was made to the Office of Management and Budget (OMB) for the approval of new information collection requirements contained within the Commission's Report and Order, LPTV, TV Translator, and FM Reimbursement; Expanding the Economic and Innovation Opportunities Through Incentive Auction, MB Docket No. 18–214 and GN Docket No. 12–268, FCC 19–21, (March 15, 2019), 84 FR 11233 (March 26, 2019) (LPTV, TV Translator, and FM Reimbursement Report and Order). The LPTV, TV Translator, and FM Reimbursement Report and Order adopts rules to implement Congress' directive in the 2018 Reimbursement Expansion Act (REA) that the Commission reimburse certain Low Power Television and television translator stations and FM broadcast stations, for costs incurred as a result of the Commission's broadcast television spectrum incentive auction. In the REA, Congress provided additional funding for the TV Broadcaster Relocation Fund and expanded the list of entities eligible to receive reimbursement for costs reasonably incurred as a result of the reorganization of broadcast television spectrum to include LPTV/translator and FM stations. The LPTV, TV Translator, and FM Reimbursement Report and Order adopts rules relating to eligibility, expenses, and procedures the Commission will use to provide reimbursement to these entities and mandates the use of various measures designed to protect the Reimbursement Fund against waste, fraud, and abuse. This submission was made to implement the Commission's directive to add LPTV, TV Translators, and FM broadcast stations to this information collection.

In the LPTV, TV Translator, and FM Reimbursement Report and Order, the Commission delegated to the Media Bureau the authority to modify current FCC Form 2100, Schedule 399, TV Broadcaster Relocation Fund Reimbursement Form (Reimbursement Form), to add all newly eligible LPTV, TV Translator, and FM broadcast entities. The Media Bureau has, therefore, added questions and certifications to the Reimbursement Form to accommodate these newly eligible broadcast entities. Specifically, in order to protect the Reimbursement Fund against waste, fraud, and abuse, all newly eligible broadcast entities that propose to request reimbursement for eligible expenses must certify on the Reimbursement Form that they meet the specified eligibility criteria and provide information regarding their affected broadcasting equipment and the estimated costs eligible for reimbursement. This information collection is otherwise unchanged as already approved by OMB.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2019–17277 Filed 8–13–19; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 390

[Docket No. FMCSA–2012–0103]

RIN 2126–AC07 and 2126–AC22

Lease and Interchange of Vehicles; Motor Carriers of Passengers

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

ACTION: Final rule.

SUMMARY: FMCSA amends its May 27, 2015, final rule on *Lease and Interchange of Vehicles; Motor Carriers of Passengers* (2015 final rule) in response to petitions for rulemaking. This final rule narrows the applicability of the 2015 final rule by excluding certain contracts and other agreements between motor carriers of passengers that have active passenger carrier operating authority registrations with FMCSA from the definition of lease and the associated regulatory requirements. For passenger carriers that remain subject to the leasing and interchange requirements, FMCSA returns the bus marking requirement to its July 1, 2015, state with slight modifications to add references to leased vehicles; revises the exception for the delayed writing of a lease during certain emergencies; and removes the 24-hour lease notification requirement.

DATES: This final rule is effective October 15, 2019. *Compliance date:* As of October 15, 2019, the compliance date for the requirements in subpart G of 49 CFR part 390 (§§ 390.401 and 390.403) is January 1, 2021.

Comments sent to the Office of Management and Budget (OMB) on the collection of information must be received by OMB on or before September 13, 2019. OMB must receive your comments by this date in order to act quickly on the information collection request.

Petitions for reconsideration of this final rule must be submitted to the

FMCSA Administrator no later than September 13, 2019.

ADDRESSES: All comments on the collection of information should reference Federal Docket Management System (FDMS) Docket Number FMCSA–2012–0103. Interested persons are invited to submit written comments on information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/Federal Motor Carrier Safety Administration, and sent via:

- *Electronic mail: oira_submission@omb.eop.gov.*
- *Fax:* 1–202–395–6974.
- *Mail:* Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

To avoid duplication, please use only one of these three methods.

Petitions for reconsideration of this final rule must be submitted in accordance with 49 CFR 389.35 and submitted to the FMCSA Administrator, Federal Motor Carrier Safety Administration, 1200 New Jersey Ave. SE, Washington, DC 20590–0001.

FOR FURTHER INFORMATION CONTACT: Ms. Loretta Bitner, (202) 366–2400, *loretta.bitner@dot.gov,* Office of Enforcement and Compliance. FMCSA office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

This final rule is organized as follows:

I. Rulemaking Documents
  A. Availability of Rulemaking Documents
  B. Privacy Act
II. Executive Summary
  A. Purpose of the Final Rule
  B. Summary of the Major Provisions
  C. Costs and Benefits
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  A. Proposed Rulemaking
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VI. International Impacts
VII. Section-by-Section Description of the Rule
  A. Section 390.5 Definitions
  B. Section 390.21 Marking of Self-Propelled CMVs and Intermodal Equipment
  C. Part 390, Subpart F Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles
  D. Part 390, Subpart G Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles
  E. Section 390.401 Applicability
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VIII. Regulatory Analyses
  A. E.O. 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures
  B. E.O. 13771 (Reducing Regulation and Controlling Regulatory Costs)
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  E. Unfunded Mandates Reform Act of 1995
  F. Paperwork Reduction Act
  G. E.O. 13132 (Federalism)
  H. E.O. 12988 (Civil Justice Reform)
  I. E.O. 13045 (Protection of Children)
  J. E.O. 12630 (Taking of Private Property)
  K. Privacy
  L. E.O. 12372 (Intergovernmental Review)
  M. E.O. 13211 (Energy Supply, Distribution, or Use)
  N. E.O. 13783 (Promoting Energy Independence and Economic Growth)
  O. E.O. 13175 (Indian Tribal Governments)
  P. National Technology Transfer and Advancement Act (Technical Standards)
  Q. Environment (NEPA and CAA)

I. Rulemaking Documents

A. Availability of Rulemaking Documents

For access to docket FMCSA–2012–0103 to read background documents and comments received, go to *http://www.regulations.gov* at any time, or to Docket Services at U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Executive Summary

A. Purpose of the Final Rule

FMCSA revises its regulations governing the lease and interchange of passenger-carrying commercial motor vehicles (CMVs). This rule excludes from the lease and interchange requirements motor carriers that operate CMVs and have active operating authority registration [1] with FMCSA to transport passengers—hereafter called ''authorized carriers'' or ''carriers with operating authority'' for the sake of simplicity. This rule also excludes financial leases.[2] For leases between authorized carriers, the assignment of responsibility for regulatory compliance requires no additional regulatory obligations because FMCSA believes their identity can be determined by other means, principally because each authorized for-hire motor carrier must conduct the transportation in its own name, under its own authority, with its owned, leased, or borrowed vehicles, and is therefore responsible for compliance with the FMCSRs.

B. Summary of the Major Provisions

The rule (1) revises the definition of *lease* to exclude authorized carriers that grant the use of their vehicles to each other; (2) removes the May 27, 2015, final rule's marking requirements and reinstates the previous vehicle marking requirements with slight modifications; (3) revises the provision allowing a delay in the completion of a lease during certain emergencies; and (4) removes the requirement that motor carriers chartered for a trip who lease a CMV from another carrier to provide the transportation must notify the tour operator or group of passengers about the lease and the lessor.

C. Costs and Benefits

The Agency estimates that an annual average of 8,366 motor carriers of passengers and 547,034 passenger-carrying CMV trips will experience regulatory relief under this final rule. Approximately 75 percent of these passenger carriers and CMV trips will experience full regulatory relief and will no longer be subject to the lease and interchange requirements of the 2015 final rule. The remaining 25 percent of these passenger carriers and CMV trips will experience partial regulatory relief and remain subject to reduced lease and interchange requirements, compared to those of the 2015 final rule.

As presented in Table 1, the Agency estimates that the rule will result in a cost savings of $76.5 million on an

[1] Operating authority registration is defined in 49 CFR 390.5. The phrase ''means the registration required by 49 U.S.C. 13902 [*Registration of motor carriers*], 49 CFR part 365 [*Rules Governing Applications for Operating Authority*], 49 CFR part 368 [*Application for a Certificate of Registration to Operate in Municipalities in the United States on the United States-Mexico International Border or Within the Commercial Zones of Such Municipalities*], and 49 CFR 392.9a [*Operating authority*].'' ''Active'' in the context of *operating authority registration* means FMCSA has granted the motor carrier operating authority registration through issuance of a valid certificate, permit, or license as provided in §§ 365.115(b) or 368.6(d), and FMCSA has not suspended or revoked that certificate, permit, or license for various statutory or regulatory reasons.

[2] See § 390.301(b)(1) of the 2015 final rule and § 390.401(b)(2) of this final rule.

undiscounted basis, $67.7 million discounted at 3 percent, and $58.5 million discounted at 7 percent over the 10-year analysis period, expressed in 2016 dollars. On an annualized basis, this equates to a 10-year cost savings of $7.9 million at a 3 percent discount rate and $8.3 million at a 7 percent discount rate. This final rule has total costs less than zero, and is therefore a deregulatory action under Executive Order 13771.

TABLE 1—SUMMARY OF THE TOTAL COST OF THE RULE
[in thousands of 2016$]

Year	Passenger carriers experiencing regulatory relief under the rule	Passenger-carrying CMV trips experiencing regulatory relief under the rule	Undiscounted			Discounted	
			Lease and interchange costs [a]	Charter party notification costs	Total costs [b]	Discounted at 3%	Discounted at 7%
2021	8,046	526,111	($25,747)	($1,189)	($26,936)	($26,152)	($25,174)
2022	8,116	530,654	(4,114)	(1,199)	(5,315)	(5,009)	(4,642)
2023	8,186	535,237	(4,150)	(1,210)	(5,360)	(4,906)	(4,376)
2024	8,256	539,859	(4,187)	(1,220)	(5,407)	(4,804)	(4,125)
2025	8,328	544,521	(4,224)	(1,231)	(5,453)	(4,704)	(3,888)
2026	8,400	549,224	(4,260)	(1,241)	(5,500)	(4,607)	(3,665)
2027	8,472	553,967	(4,296)	(1,252)	(5,548)	(4,511)	(3,455)
2028	8,545	558,751	(4,333)	(1,263)	(5,596)	(4,417)	(3,257)
2029	8,619	563,576	(4,370)	(1,274)	(5,644)	(4,326)	(3,070)
2030	8,693	568,443	(4,409)	(1,285)	(5,693)	(4,236)	(2,894)
Total			(64,089)	(12,363)	(76,453)	(67,672)	(58,546)
Annualized					(7,645)	(7,933)	(8,336)

Notes:
[a] Values shown in parentheses are negative values (*i.e.,* less than zero) and represent a decrease in cost or a cost savings.
[b] Total cost values may not equal the sum of the components due to rounding. (The totals shown in this column are the rounded sum of unrounded components.)

The regulatory evaluation for the 2015 final rule addressed the potential safety benefits of lease and interchange requirements for motor carriers of passengers.[3] There was insufficient data and empirical evidence to demonstrate a measurable quantitative relationship between lease and interchange requirements for passenger-carrying CMVs and improved safety outcomes such as reduced frequency and/or severity of crashes or reduced frequency of violations. Therefore, FMCSA performed a threshold analysis, also referred to as a break-even analysis, estimating the reduction in crashes that would need to occur as a consequence of the 2015 final rule for the benefits of the rule to exactly offset the estimated costs of the rule.

In considering the potential impact to safety benefits from this final rule, the Agency notes that there remains insufficient data and empirical evidence to demonstrate a measurable quantitative relationship between lease and interchange requirements for passenger-carrying CMVs and improved safety outcomes. Lease and interchange requirements for motor carriers of passengers improve the ability of the Agency and our State partners to attribute inspection, compliance, enforcement, and safety data to the correct motor carrier and driver, allowing FMCSA and our State partners to more accurately identify unsafe carriers and initiate appropriate interventions. FMCSA believes that the lease and interchange requirements of this rule are a less costly and burdensome regulatory approach than the requirements of the 2015 final rule, yet still enable safety officials and the public to identify the passenger carrier responsible for safety because each authorized for-hire motor carrier must conduct the transportation in its own name, under its own authority, with its owned, leased, or borrowed vehicles, and is therefore responsible for compliance with the FMCSRs. The Agency does not anticipate any change to safety benefits as a result of the rule.

[3] U.S. Department of Transportation (DOT), FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Docket ID# FMCSA–2012–0103–0022. Available at: *https://www.regulations.gov/contentStreamer?documentId=FMCSA-2012-0103-0022&attachmentNumber=1&contentType=pdf* (accessed June 3, 2019).

III. Abbreviations

1935 Act	Motor Carrier Act of 1935.
1984 Act	Motor Carrier Safety Act of 1984.
2015 final rule.	May 27, 2015, *Lease and Interchange of Vehicles; Motor Carriers of Passengers* final rule, 80 FR 30164.
ABA	American Bus Association.
BLS	Bureau of Labor Statistics.
CMV	Commercial Motor Vehicle.
DART	Data Analysis and Reports Team.
DOL	United States Department of Labor.
DOT	United States Department of Transportation.
ECEC	Employer Costs for Employee Compensation.
E.O.	Executive Order.
FMCSA	Federal Motor Carrier Safety Administration.
FMCSRs	Federal Motor Carrier Safety Regulations, 49 CFR parts 350 through 399.
FR	**Federal Register**.
ICCTA	ICC [*Interstate Commerce Commission*] Termination Act of 1995.
L&I	Licensing and Insurance.
MCBOA	Minnesota Charter Bus Operators Association.
MAP–21	Moving Ahead for Progress in the 21st Century Act.
MCMIS	Motor Carrier Management Information System.
NPRM	Notice of Proposed Rulemaking.
NTSB	National Transportation Safety Board.
OMB	Office of Management and Budget.
PRA	Paperwork Reduction Act of 1995.
RFA	Regulatory Flexibility Act.
SBA	Small Business Administration.
SOC	Standard Occupational Classification.
UMA	United Motorcoach Association.
U.S.C.	United States Code.
VIN	Vehicle Identification Number.

IV. Legal Basis

This rule is based on the authority of the Motor Carrier Act of 1935 (1935 Act) and the Motor Carrier Safety Act of 1984 (1984 Act), as amended.

The 1935 Act authorizes DOT to ''prescribe requirements for—(1) qualifications and maximum hours of service of employees of, and safety of operation and equipment of, a motor carrier; and (2) qualifications and maximum hours of service of employees of, and standards of equipment of, a motor private carrier, when needed to promote safety of operation'' (49 U.S.C. 31502(b)).[4]

The 1984 Act confers on DOT authority to regulate drivers, motor carriers, and CMVs. ''At a minimum, the regulations shall ensure that—(1) commercial motor vehicles are

[4] See *https://www.gpo.gov/fdsys/pkg/USCODE-2017-title49/pdf/USCODE-2017-title49-subtitleVI-partB-chap315.pdf* (accessed June 3, 2019).

maintained, equipped, loaded, and operated safely; (2) the responsibilities imposed on operators of commercial motor vehicles do not impair their ability to operate the vehicles safely; (3) the physical condition of operators of commercial motor vehicles is adequate to enable them to operate the vehicles safely . . . ; and (4) the operation of commercial motor vehicles does not have a deleterious effect on the physical condition of the operators'' (49 U.S.C. 31136(a)). Section 32911 of the Moving Ahead for Progress in the 21st Century Act (MAP–21) [Pub. L. 112–141, 126 Stat. 405, 818, July 6, 2012] enacted a fifth requirement, *i.e.,* to ensure that ''(5) an operator of a commercial motor vehicle is not coerced by a motor carrier, shipper, receiver, or transportation intermediary to operate a commercial motor vehicle in violation of a regulation promulgated under this section, or chapter 51 or chapter 313 of this title'' [49 U.S.C. 31136(a)(5)].[5]

The 1984 Act also includes more general authority to ''(8) prescribe recordkeeping . . . requirements; . . . and (10) perform other acts the Secretary considers appropriate'' (49 U.S.C. 31133(a)).[6]

This rule imposes legal and recordkeeping requirements consistent with the 1935 and 1984 Acts on certain for-hire and private passenger carriers that operate CMVs, to enable safety officials and the public to identify the passenger carrier responsible for safety. Although the USDOT number serves a similar function, it does not assign responsibility when CMVs are exchanged between two or more parties, leaving an information gap filled by this rule. Currently, many passenger-carrying CMVs and drivers are rented, loaned, leased, interchanged, assigned, and reassigned with few records and little formality, thus obscuring the operational safety responsibility of certain industry participants. The more accurate, targeted enforcement allowed by this rule will help the Agency meet the mandate of 49 U.S.C. 31136(a)(1) to ensure that passenger-carrying CMVs, like other vehicles, are ''operated safely.'' The rule does not address the requirements of 49 U.S.C. 31136(a)(2)–(4). Because this rule has only indirect and minimal application to drivers of passenger-carrying CMVs—at most, their employers might require them to pick up a lease document and place it on the vehicle, though that task could also be assigned to other employees—FMCSA believes that coercion of drivers to violate the rule will not occur (49 U.S.C. 31136(a)(5)).

Before prescribing any regulations, FMCSA must also consider their ''costs and benefits'' (49 U.S.C. 31136(c)(2)(A) and 31502(d)). Those factors are discussed in this final rule.

V. Discussion of Proposed Rulemaking and Comments

A. Proposed Rulemaking

FMCSA published a notice of proposed rulemaking (NPRM) on September 20, 2018 (83 FR 47764) (2018 NPRM), that proposed several changes to the lease and interchange requirements added to 49 CFR part 390 by the 2015 final rule (80 FR 30164). The proposals included narrowing the applicability of the rule, excluding certain contracts and other agreements between motor carriers of passengers with operating authority from the definition of lease and the associated regulatory requirements, excluding financial leases,[7] and returning the § 390.21(e) marking requirement to its July 1, 2015, state with slight modifications to add references to leased vehicles. The NPRM also proposed to revise the delayed writing of a lease during certain emergencies; remove the 24-hour lease notification requirement; and extend the compliance date for the 2015 final rule to January 1, 2021, to give the Agency sufficient time to complete this final rule.

B. Comments and Responses

Eighteen comments to the 2018 NPRM were received from the following parties: American Bus Association (ABA), United Motorcoach Association (UMA), Greyhound Lines, Coach USA, Adirondack Trailways, Annett Bus Lines, Southern Tier Stages, Northwest Motorcoach Association, Peter Pan Bus Lines, Jefferson Bus Lines, Plymouth & Brockton Street Railway Company, Academy Bus, DeCamp Bus Lines, Burlington Trailways, FlixBus Inc., Pacific Coachways Charter Services, Thielen Bus Lines,[8] and a private citizen.

Extension of the Compliance Date

Extension of the compliance date was supported by ABA, Academy Bus, Coach USA, Adirondack Trailways, Annett Bus Lines, Southern Tier Stages, Inc., Northwest Motorcoach Association, Peter Pan Bus Lines, Jefferson Bus Lines, Plymouth & Brockton, DeCamp Bus Lines, Burlington Trailways, UMA, Greyhound, Thielen Bus Lines, and Pacific Coachways Charter Services.

FMCSA Response

On December 4, 2018, FMCSA published a final rule extending the compliance date for the 2015 final rule to January 1, 2021 (83 FR 62505). This final rule will use the January 1, 2021 compliance date set by the December 2018 final rule.

General Applicability

The NPRM proposed revising the general applicability section to add two exceptions to the applicability requirements of the lease and interchange rule. Under the NPRM, section 390.401(b) would be modified in several ways. First, a new exception in paragraph (b)(1) would exclude from the rule contracts and agreements between passenger carriers with active passenger carrier operating authority registration [9] when one such carrier acquires transportation services from another such carrier. Second, the 2015 exception for financial leases would be revised to remove the requirement that the bank or similar financial organization, manufacturer, or dealer must be a motor carrier to utilize the exception from the rule. This is because such entities are motor carriers if they move their vehicle inventory between business locations before purchases. Third, as proposed, the limited exception for passenger-carrying CMVs exchanged or interchanged between or among commonly owned and controlled motor carriers would be removed.

Fourth, as proposed, the limited exception for passenger-carrying CMVs exchanged or interchanged between or among motor carriers that are a party to a revenue pooling agreement approved by the STB in accordance with 49 U.S.C

[5] See *https://www.gpo.gov/fdsys/pkg/USCODE-2017-title49/pdf/USCODE-2017-title49-subtitleVI-partB-chap311-subchapIII-sec31136.pdf* (accessed June 3, 2019).

[6] See *https://www.gpo.gov/fdsys/pkg/USCODE-2017-title49/pdf/USCODE-2017-title49-subtitleVI-partB-chap311-subchapIII-sec31133.pdf* (accessed June 3, 2019).

[7] *Financial lease* (however designated, *e.g.,* lease, closed-end lease, hire purchase, lease purchase, purchase agreement, installment plan, demonstration or loaner vehicle, etc.) as defined in § 390.401(b)(2) means a contract between a motor carrier and a bank or similar financial organization or a manufacturer or dealer of passenger-carrying CMVs.

[8] The commenter states he is a board member of the Minnesota Charter Bus Operators Association (MCBOA). He submitted comments on his own behalf, and as a representative of the other 32 members of the MCBOA.

[9] Operating authority registration means the registration required by 49 U.S.C. 13902, 49 CFR part 365, 49 CFR part 368, and 49 CFR 392.9a as defined in 49 CFR 390.5. ''Active'' in the context of *operating authority registration* means FMCSA has granted the motor carrier operating authority registration through issuance of a valid certificate, permit, or license as provided in §§ 365.115(b) or 368.6(d), and FMCSA has not suspended or revoked that certificate, permit, or license for various statutory or regulatory reasons.

14302 would be removed. All passenger carriers that are commonly owned and controlled or participate in STB-approved revenue pooling agreements operate in interstate commerce and should have operating authority. Under the NPRM, an authorized carrier that obtains a vehicle from another commonly owned and controlled authorized carrier or another authorized participant in an STB-approved pooling agreement, would not be subject to the lease and interchange requirement. Accordingly, a separate exception for carriers operating under an STB-approved pooling agreement would no longer be necessary.

Greyhound Lines, Coach USA, Adirondack Trailways, Annett Bus Lines, Southern Tier Stages, Northwest Motorcoach Association, Peter Pan Bus Lines, Jefferson Bus Lines, Plymouth & Brockton Street Railway Company, Academy Bus, DeCamp Bus Lines, Burlington Trailways, FlixBus Inc., Pacific Coachways Charter Services, Thielen Bus Lines, ABA, and UMA supported the proposed general applicability section, including the proposed active operating authority registration exception, maintaining the financial lease exception, and the removal of the two limited exceptions for commonly owned and controlled authorized carriers and STB-approved pooling agreements.

The UMA commented that the rule should not compel two or more carriers, all possessing the requisite valid Federal operating authority, to enter a lease they would not otherwise enter when engaging each other's services. UMA believes that inspections and crashes should be attributed to the chartered, contracted, or subcontracted carrier that possesses the sole, direct responsibility for compliance and control of vehicle maintenance and driver qualifications and behavior.

Academy Bus adds this ''is a key issue to allow legally operating carriers to utilize the services of other legally operating carriers to meet demand fluctuations. Other carriers provide their buses and drivers to complete sub-contracted work. The recipient maintains their own operating authority, own insurance program and manage their own operations. The carrier sub-contracting the work has no input into the sub-contracted (recipient) carrier's operations. There is no ambiguity as to what buses on the road are operated by which company and/or authority. This is not a lease issue as there is no control over the other carrier's equipment or drivers.''

FMCSA Response

The Agency adopts without change the proposed general applicability section to the leasing requirements for passenger carriers, including the proposed exception for passenger carriers with active operating authority registration, maintaining the financial lease exception, and the removal of the two limited exceptions for commonly owned and controlled authorized carriers and STB-approved pooling agreements. The lease and interchange regulations do not directly affect safety. Rather, they help FMCSA, the National Transportation Safety Board (NTSB), and State safety officials to identify the passenger carrier responsible for safety and to assign inspection, compliance, crash, and enforcement data to the correct carrier and driver, allowing the Agency, NTSB, and the States to more accurately identify unsafe and high risk carriers and to take appropriate action. The changes made by this rule will not adversely affect safety because authorized carriers involved in chartering (or subcontracting) with each other assume responsibility for their own regulatory compliance, and are readily identifiable. In addition, banks or similar financial organizations, manufacturers, or dealers: (a) Must not be a motor carrier in order to use the exception from this leasing rule; (b) will be deemed a private motor carriers of property when moving its empty passenger vehicle inventory between business locations before purchases; and (c) will have to comply fully with all 49 CFR parts 300 to 399 regulations during these moves of empty passenger vehicle inventory between business locations.

Definitions

The Agency proposed to revise the definition of *lease* in § 390.5 to include only contracts and agreements in which a motor carrier grants the use of a passenger-carrying CMV to another motor carrier when at least one of the motor carriers is not an authorized carrier.[10] Authorized carriers of passengers routinely assist one another by providing transportation services during demand surges, emergencies, or events that require more than their available capacity. These common agreements, some of which amount to subcontracting, will not meet the regulatory definition of a *lease* in this final rule. Authorized carriers or passengers that are hired by another authorized carrier of passengers have traditionally assumed responsibility for their own regulatory compliance and liability. This practice has long been acceptable to the insurance industry. Furthermore, authorized carriers of passengers are readily identifiable to enforcement personnel, making a separate lease agreement assigning regulatory responsibility unnecessary.

The definition of *lease* was proposed to be narrowed by including only contracts and agreements granting the use of a passenger-carrying CMV between motor carriers when one (or more) such carrier does not have active operating authority registration. The term *lease* also has been revised as proposed with added language to include circumstances when no compensation is specified. The terms *lessee* and *lessor* have both been revised slightly to specify that the granting of passenger-carrying CMV usage is through a *lease.*

The ABA, UMA, Jefferson Bus Lines, Plymouth & Brockton, Academy Bus LLC, DeCamp Bus Lines, Burlington Trailways, Thielen Bus Lines, and Coach USA support the Agency's proposal to exclude from the definition of lease chartering between or among authorized passenger carriers. ABA writes ''This change is consistent with the Agency's stated goal of ensuring a lessor relinquishes all control of a passenger carrying commercial motor vehicle (CMV) for the full term of a lease. In the case of chartering or subcontracting, there is no surrender of the vehicle and thus these types of operations do not fit within definition of a lease. During a charter transaction, the vehicles remain within the control of the respective charter parties, each party is responsible for dispatching and maintaining its respective vehicles, and each party is responsible for regulatory compliance. Thus, in-line with FMCSA's underlying oversight philosophy, each carrier in a charter transaction is held accountable for maintaining its own respective operating authority. This is the fundamental basis by which FMCSA conducts enforcement and can ensure carriers remain compliant. Alternatively, applying the same logic, for carriers with no operating authority, a lease requirement demonstrating the full surrender of the vehicle for the entire term of the lease also supports FMCSA's oversight philosophy by ensuring a responsible carrier with operating authority is always controlling the vehicles operating on the road, thereby limiting opportunities to circumvent the law.''

[10] This rulemaking does not change the definition of *lease* in the context of property-carrying vehicles in 49 CFR 376.2.

FMCSA Response

The Agency adopts without change the proposed exception to the leasing requirements for passenger carriers with active operating authority.

Marking of Self-Propelled CMVs and Intermodal Equipment

Before the 2015 rule, a motor carrier operating a CMV under a rental agreement having a term of not more than 30 calendar days could mark the CMV with either (1) the name and USDOT identification number of the lessee, or (2) the name and USDOT identification number of the lessor if, in the latter case, a fully complete lease is carried on the rented CMV during the full term of the lease. The 2015 final rule required that a motor carrier operating a passenger-carrying CMV under a lease must add an additional marking device on the CMV temporarily on the right (curb) side of the vehicle on or near the front passenger door. The 2015 rule's temporary device would show the legal or trade name and USDOT number of the carrier operating the vehicle, preceded by the words ''operated by.''

Industry commenters to the 2016 NOI and the 2017 proposal argued that the 2015 final rule imposes burdensome marking requirements that are impractical, and that there are less burdensome ways to address the Agency's concerns.

The 2018 NPRM proposed to eliminate the cost of additional marking of the vehicles while maintaining all of the information necessary for enforcement officials to identify the carrier for regulatory compliance. FMCSA also proposed to add paragraph (e)(2)(v) to allow a passenger-carrying CMV operating under the 48-hour emergency exception pursuant to § 390.403(a)(2) to be excepted from paragraphs (e)(2)(iii) and (iv) regarding a lease document with required information being carried on the vehicle, provided the lessor and lessee comply with the requirements of the provision in § 390.403(a)(2).

The ABA, UMA, Jefferson Bus Lines, Plymouth & Brockton, Academy Bus LLC, DeCamp Bus Lines, Burlington Trailways, Thielen Bus Lines, and Coach USA support removing the 2015 final rule's CMV marking requirements and restoring the previous § 390.21(e) with slight modifications to comport with the leasing requirements proposed under the 2018 NPRM. ABA noted that ''This change addresses the industry's concerns with the impracticality of the 2015 final rule requirements while still providing enforcement officials with sufficient information to identify carriers for regulatory compliance. By restoring the marking requirements of the pre-2015 final rule, the Agency is addressing a major industry concern that threatened to severely restrict current operations, particularly at high-volume periods, leading to a reduction of capacity in the system without providing any additional safety benefit. As well, FMCSA's proposed modifications to 49 CFR 390.21(e), to address operations under a lease agreement, are sufficiently tailored to ensure enforcement officials continue to have access to appropriate information in those circumstances.''

FMCSA Response

The Agency agrees with these comments and implements the marking revision as proposed. Enforcement officials will be able to use the markings on the sides of the passenger CMV and the lease or the § 390.403(a)(2) summary document to determine the identity of the carrier responsible for safety and to assign inspection, compliance, crash, and enforcement data to the correct carrier and driver. FMCSA has therefore concluded that this change will not adversely affect safety.

Section 390.21 in this final rule is similar to the text in effect before the May 27, 2015, final rule. FMCSA removes the special marking regulations for leased and interchanged passenger-carrying CMVs in paragraph (f). Section 390.21 has been revised to treat leased passenger-carrying CMVs like all other rented CMVs. For a lease of 30 calendar days or less, the lessee can opt to mark the vehicle with either the lessee's information or the lessor's information. However, the latter would require a fully executed copy of the lease be carried on the vehicle, unless the CMV is being operated for up to 48 hours under the emergency related provisions of § 390.403(a)(2).

If the motor carrier is operating a passenger-carrying CMV under a lease or rental agreement for more than 30 calendar days, the CMV must be marked with the lessee's identification information. In a lease situation, the operating motor carrier is the lessee. These revised regulations address petitioners' concerns that there is no easy way to display a temporary marking on certain passenger-carrying motor vehicles for short term leases. FMCSA sets a compliance date of January 1, 2021, for passenger-carrying CMVs subject to the lease and interchange rules, which is identical to the compliance date for the rules themselves. To be clear, a transaction involving a motor carrier operating a passenger-carrying CMV financed by a bank or similar financial organization, or provided by a manufacturer or dealership for demonstration purposes or to replace a vehicle being serviced or repaired, is not subject to the lease and interchange requirements in 49 CFR part 390 subpart G as provided by the 2015 final rule and retained in § 390.401(b)(2) *Financial leases.* None of these *financial lease* arrangements is considered to be a lease, interchange, or rental of a CMV under the definition of lease in § 390.5 because banks and other similar financial organizations do not operate passenger-carrying CMVs as a motor carrier. In these cases, the motor carrier that is granted use of the passenger-carrying CMV has full responsibility for the operation of such vehicle and compliance with the vehicle marking requirements in § 390.21 for the duration of the arrangement. However, it should also be noted that a motor carrier that obtained a passenger-carrying CMV through a loan from a bank or similar financial organization, may be responsible for compliance if it leases that vehicle to another motor carrier of passengers.

Customer Notification

The 2018 NPRM proposed to remove the requirement in the 2015 rule's § 390.305 to notify the passenger group or their representative within 24 hours after the primary contractor reassigns the transportation to a subcontractor.

The ABA, UMA, Jefferson Bus Lines, Plymouth & Brockton, Academy Bus LLC, DeCamp Bus Lines, Burlington Trailways, Thielen Bus Lines, and Coach USA support FMCSA's proposal to remove the 24-hour lease notification requirement for subcontracted charter arrangements. Multiple commenters said that if this requirement remained in place it would be very difficult for motorcoach operators to maintain the flexibility required to address emergency situations and public necessity. They wrote that it would be impractical in terms of meeting customer needs when time schedules for charter customers often restrict motor carriers' ability to notify tour operators, unduly burdening the operator. Further, they wrote that such notifications would not necessarily provide any added safety benefit. Instead, they believe that FMCSA ensures a greater safety benefit when all carriers providing charter service have operating authority, either under their own USDOT number or established under a formal lease arrangement as proposed under the 2018 NPRM. UMA commented that ''This provision was one of the least objectionable of the

2015 final rule by passenger carriers, indicative of the fact that most passenger carriers advise their customers and/or passengers of changes.''

FMCSA Response

The Agency removes the customer notification requirements, as proposed. The Agency agrees with the comments received that the notifications would have imposed burdens on the passenger carrier industry and is more about customer protection than directly linked to safety.

48-Hour Lease Delay Exception

When passengers are on a CMV and an emergency occurs that requires a replacement vehicle from another motor carrier, the 2015 rule allows the two carriers to postpone writing a lease or other written agreement for up to 48 hours. The Agency believed the 48-hour window would provide ample time for the parties to document the transaction.

One of the issues listed in the 2016 NOI was that FMCSA would reconsider expanding applicability of the 48-hour delay provision for preparing a lease to include emergencies when passengers are not actually on board a bus (81 FR 59952, Aug. 31, 2016). FMCSA provided examples of events that might require a motor carrier to obtain a replacement vehicle immediately:

- Buses might be needed to transport stranded passengers in the event that Amtrak or airline service was suspended or disrupted. A bus operator contracted to provide emergency service might need to obtain additional drivers and vehicles without delay;
- Last minute maintenance or mechanical issues, or driver illness, might arise late in the evening or during the night (such as on a multi-day charter or tour trip), or just prior to picking up a group for a charter or scheduled service run.

In the 2017 proposal, FMCSA explained that it intended to broaden the emergency 48-hour delay provision for preparing a lease authorized by 49 CFR 390.303(a)(2) and remove the requirement that passengers actually be on board a bus when the exception occurs.

Based on comments to the 2016 NOI and 2017 proposal, the 2018 NPRM adopted the petitioners' recommendation to expand the regulatory exception that permits the delayed writing of a lease during certain emergencies (*e.g.,* a crash, the vehicle is disabled) including when no passengers are on the vehicle. FMCSA proposed to move the exception in 49 CFR 390.303(a)(2) to 49 CFR 390.403(a)(2). If a motor carrier obtains a replacement vehicle from, or subcontracts for service with, another motor carrier, the motor carriers may delay writing of a lease during these emergency situations. However, a summary document signed and dated by the lessee's driver or available company official must state: ''[Carrier A, USDOT number, telephone number] has leased this vehicle to [Carrier B, USDOT number, telephone number] pursuant to 49 CFR 390.403(a)(2)'' and the summary document must be carried on the replacement vehicle for the duration of the lease. Enforcement officials will be able to use this summary document to determine the identity of the carrier responsible for regulatory compliance.

ABA, UMA, Jefferson Bus Lines, Plymouth & Brockton, Academy Bus LLC, DeCamp Bus Lines, Burlington Trailways, Thielen Bus Lines, and Coach USA support the 2018 NPRM's proposal. ABA writes, ''this is a sound change that properly captures emergency situations for when passengers are and are not on a vehicle. It also provides added flexibility to address unexpected situations that have little lead time and require short-term replacement vehicles. Additional flexibility, when needing to meet customer needs both in the interest of safety and comfort, is critical in terms of successfully conducting passenger operations.''

UMA requested clarification in this final rule that ''. . . the caveat that two or more passenger carriers possessing operating authority are not compelled to enter into a lease continues to apply.'' UMA believes that the general exception from the leasing requirements for passenger carriers with active operating authority in proposed § 390.401(b)(1) supersedes the delayed-lease provision in proposed § 390.403(a)(2) when both carriers in a replacement vehicle scenario have operating authority.

FMCSA Response

FMCSA implements the delayed-lease provision as proposed. UMA's understanding is correct; an authorized carrier hiring a replacement CMV from another authorized carrier is not subject to the delayed-lease provision of § 390.403(a)(2). As stated above, enforcement officials will be able to use the 48-hour lease delay exception summary document to determine the identity of the carrier responsible for safety and to assign inspection, compliance, crash, and enforcement data to the correct carrier and driver. This will allow the Agency to identify unsafe and high risk carriers and to take appropriate action. Because the exception's summary document must be signed and dated by the lessee's driver or available company official and carried on the replacement vehicle for the duration of the lease, the vehicle will be readily identifiable. FMCSA has concluded that this change will not adversely affect safety.

Lease and Interchange Requirements

The lease and interchange requirements have been revised, as proposed, by moving § 390.303(a)(1)(iii), which covers written agreements governing the renting, borrowing, loaning, or similar transfer of a passenger-carrying CMV from another party, to § 390.403(a)(1), which makes paragraph (a)(1)(iii) unnecessary.

Section 390.403(b) specifies the contents of lease and interchange documents. This paragraph requires the lease, interchange agreement, or other agreement to contain: (1) The name of the vehicle manufacturer, the year of manufacture, and the last 6 digits of the Vehicle Identification Number; (2) the legal names, contact information, and signatures [11] of both parties; (3) the time and date when the lease begins and ends; and (4) a statement that the lessee has exclusive possession and control of the leased vehicle and is responsible for regulatory compliance.

Previous § 390.303(b)(4)(i)–(iii) was a slightly revised version of 49 CFR 376.12(c)(1), (2) and (4). Paragraph (b)(4)(i) is essential because it sets forth the basic reason for a lease from FMCSA's point of view, namely to assign full responsibility for regulatory compliance to the lessee. As proposed in the 2018 NPRM, FMCSA makes this paragraph more concise, moves paragraph (b)(3)(ii) to § 390.403(b)(4)(ii), and retains only the last sentence of that provision. Paragraph (b)(4)(iii) in the 2015 final rule is a useful disclaimer, should questions arise about the status of the lessor (contractor or employee) in a tax context, but FMCSA does not believe it is essential. Therefore, FMCSA has shortened paragraphs (b)(4)(i) and (b)(4)(ii) and has removed paragraph (b)(4)(iii).

FMCSA removes the requirement in previous § 390.303(b)(5) that the lease contain a statement that the lessee is responsible for compliance with the insurance requirements of 49 CFR part 387.

[11] FMCSA allows the use of electronic signatures in accordance with the Government Paperwork Elimination Act (Pub. L. 105–277, Sec. 1703, 112 Stat. 2681–749, Oct. 21, 1998). See FMCSA's ''Regulatory Guidance Concerning Electronic Signatures and Documents (76 FR 411, Jan. 4, 2011) and the Electronic Signature final rule's §§ 390.5, 390.5T, and 390.32, April 16, 2018 (83 FR 16210, 16226–7).

Previous § 390.303(c) and (d) have been merged and made more concise and transferred to § 390.403(c), which states that a copy of the lease must be carried in the passenger-carrying CMV during the period of the lease or interchange agreement. Both the lessee and lessor retain the lease or interchange agreement for 1 year afterwards.

Previous § 390.303(e) regarding receipts has been removed. FMCSA has decided it does not need receipts when vehicles are surrendered to the lessee and returned to the lessor. If FMCSA or another government enforcement agency sought to assign a safety incident to the lessee or the lessor based on a lease or other agreement that had already been terminated, the former parties to the lease would have to decide how to document that premature termination.As proposed, FMCSA removes the requirements of § 390.303(f) for additional temporary markings of leased and interchanged passenger-carrying CMVs, and returns to the text of the marking rule in § 390.21(e) that was effective on July 1, 2015, with slight modifications. The modifications add references to leased passenger-carrying CMVs in paragraph (e) to provide an option similar to that for rented CMVs. This modification would eliminate the cost of additional marking of the vehicles while maintaining all of the information necessary for enforcement officials to identify the carrier for regulatory compliance.

No comments were received about these lease and interchange requirements in § 390.403 covering written agreements governing the renting, borrowing, loaning, or similar transfer of a passenger-carrying CMV from another party.

FMCSA Response

As the Agency received no comments about the proposed § 390.403 lease and interchange requirements for passenger carriers, the requirements are adopted with a reference to the compliance date. FMCSA adds a January 1, 2021, compliance date for passenger-carrying CMVs subject to the lease and interchange rules to § 390.401's introductory phrase.

This final rule helps FMCSA, NTSB, and State safety officials to identify the passenger carrier responsible for safety and to assign inspection, compliance, crash, and enforcement data to the correct carrier and driver, allowing the Agency, NTSB, and other enforcement officials to more accurately identify the carrier for regulatory compliance, identify unsafe and high risk carriers, and to take appropriate action. FMCSA has concluded that the changes in the lease and interchange requirements of this final rule will not adversely affect safety.

Example of Proposed Rule Implementation

A private citizen, Lawrence F. Hughes, requested clarification of the implementation example for ''Subcontracting Among Regular Route Authorized Carriers'' [83 FR 47764, at 47773] and restated below under section VII. B. In the example, authorized carrier A hires authorized carrier B to continue authorized carrier A's regular-route transportation service to carrier A's regular-route trip destination. Mr. Hughes argues that the example lacks necessary details to be sufficiently clear as to the circumstances when it applies, and that the example fails to note when it does not apply and the rules for leases must be followed. He suggested either clarification of the example or a change in the method by which FMCSA registers motor carriers of passengers.

FMCSA Response

First, changing the method by which FMCSA registers motor carriers of passengers is outside the scope of the 2018 NPRM.

Second, regardless of whether the active operating authority registration is of the subtype ''regular route'' or ''charter and special transportation,'' each authorized for-hire motor carrier must conduct the transportation in its own name, under its own authority, with its owned, leased, or borrowed vehicles, and is therefore responsible for compliance with the FMCSRs.

Third, the ICC Termination Act of 1995 (ICCTA) [Pub. L. 104–88, 109 Stat. 803, 880, Dec. 29, 1995, codified at 49 U.S.C. 13902] eliminated ''regular route'' or ''charter and special transportation'' limitations when registering most motor carriers of passengers. Before ICCTA, the statute required all for-hire motor carrier of passengers to administratively register with the ICC as subtype ''regular route'' or ''charter and special transportation'' motor passenger carrier, and generally prohibited that motor carrier from doing the other subtypes of passenger transportation service, unless granted additional operating authority to do so. The ICCTA eliminated these administrative labels, except for registrations for motor carriers that are ''public recipients of governmental assistance.'' [12] Thus, a motor carrier of passengers previously issued ''regular route'' operating authority has general authority to perform ''charter and special transportation,'' whatever its certificate, permit, or license may say. Similarly, a motor carrier of passengers previously issued ''charter and special transportation'' operating authority also has general authority to perform ''regular route'' service. This elimination of administrative service terminology is similar to the ICCTA's removal of the registration labels and transportation service limitations of ''common'' and ''contract'' motor carriers.[13]

However, if carrier A hires carrier B to conduct a regular-route passenger transportation service and at least one of the two carriers does not have active operating authority registraton, then the lease and interchange requirements of this final rule apply.

Out-of-Scope Comment

Greyhound, Coach USA, and Adirondack Trailways asked FMCSA (1) to clarify that entities that lease buses or drivers and control their operations to the extent of control exercised by FlixBus, OurBus, and similar technology entities, are bound by the requirements of the rule; and (2) to determine that the services of these entities make them motor carriers ''providing motor vehicle transportation for compensation''—not brokers—and subject them to the full range of FMCSA regulations. They argue that there is undisputed evidence FlixBus, OurBus, and similar entities should be subject to the 2018 NPRM and this final rule.

FlixBus, Inc. argued that the Agency should reject requests to make it subject to the 2018 NPRM's proposed requirements and other FMCSA regulations as a ''motor carrier.'' FlixBus claims it is a transportation technology company that does not own, lease, or operate passenger-carrying CMVs. It does not employ drivers. It provides a consumer-facing platform travelers can use to purchase transportation provided by one of its bus partners.

[12] See 49 U.S.C. 13902(b)(1) and (2), and 49 CFR 365.101(e).

[13] Many instances of the terms ''common'' and ''contract'' were removed in the Unified Registration System (URS) final rules published in 2013, 2015, and 2016 (Final Rule, Unified Registration System, 78 FR 52608 (Aug. 23, 2013), amendments, corrections, and delayed effective and compliance dates published at 80 FR 63703, October 21, 2015, and 81 FR 49553, July 28, 2016.), and in the 2016 General Technical, Organizational, Conforming, and Correcting Amendments to the Federal Motor Carrier Safety Regulations final rule published at 81 FR 68336 (Oct. 4, 2016) many instances of the terms ''regular route'' and ''irregular route,'' as well as ''common'' and ''contract'' were also removed. See also Elimination of Route Designation Requirement for Motor Carriers Transporting Passengers Over Regular Routes final rule published at 74 FR 2895 (Jan. 16, 2009).

FlixBus also argues FMCSA should disregard the Greyhound, Coach USA, and Adirondack Trailways requests because their comments are beyond the scope of this rulemaking. FlixBus argues this rulemaking addresses rules that will apply to motor carriers of passengers that lease and interchange vehicles; it does not attempt to address which entities are or should be regulated as ''motor carriers.'' ''Petitioners cannot unilaterally expand the scope of this rulemaking through their comments, nor are those comments entitled to a substantive response.''

FMCSA Response

FMCSA agrees with FlixBus that this issue is outside the scope of the 2018 NPRM. FMCSA reviewed FlixBus, OneBus, and other similar operations. At the time, these operations were not found to be motor carriers of passengers that lease or interchange vehicles. Thus, FlixBus and OneBus are not required to comply with the terms of this final rule. Changed operations or other business models may subject companies to this rule.

Additional Out-of-Scope Comment

Adirondack Trailways requested that its businesses be exempt from the marking requirements in § 390.21(b)(3).

FMCSA Response

FMCSA did not propose any changes to § 390.21(b)(3) and this comment is thus outside the scope of the 2018 NPRM.

C. Examples of Final Rule Implementation

The following examples were published in the NPRM and remain applicable to this final rule.

Complete Contract Transfer Example

Authorized carrier A is contracted to transport a tour or travel group on a trip, but finds itself without the capacity to accommodate the group. Carrier A completely transfers the contract to authorized carrier B that has the necessary capacity. Carrier A may or may not pay a fee to carrier B for taking over the contract. A complete transfer would require carrier A to cancel its contract with the customer and carrier B to create a new contract with the customer. The final rule does not apply to these transactions because these transactions do not qualify as a ''lease'' (or interchange), as defined in § 390.5, of a passenger-carrying CMV.

Complete Subcontracting Among Authorized Carriers

Authorized carrier A lacks the capacity to execute a contracted trip and hires authorized carrier B to make the trip while maintaining its contract with the customer. This arrangement is documented by a charter contract between carriers A and B. Carrier A pays carrier B for the trip. This arrangement is not a lease, first because carrier B is not granting the use of a passenger-carrying CMV to carrier A, and second because both carriers are authorized carriers. Instead, carrier B is making the trip in its own name, on its own authority, with its own vehicles and is therefore responsible for compliance with the FMCSRs. This final rule therefore does not apply to this arrangement.

Partial Subcontracting Among Authorized Carriers

Assuming the same facts as described above, except that authorized carrier A provides some of the transportation service while contracting with authorized carrier B for the remainder, this arrangement is not a lease, first because carrier B is not granting the use of a passenger-carrying CMV to carrier A, and second because both carriers are authorized carriers. Carrier A pays carrier B for the transportation service as part of a charter contract. Carrier B is not surrendering control of a passenger-carrying CMV to carrier A for its own use. Both carriers are authorized carriers providing transportation in their own name, on their own authority, with their own vehicles, and each is independently responsible for compliance with the FMCSRs.

Subcontracting Among Regular Route Authorized Carriers

Authorized carrier A, which provides regular route passenger transportation services according to a fixed schedule, finds itself without the capacity to execute a route. Carrier A hires authorized carrier B to continue this service. This arrangement is documented by a charter contract between carriers A and B. Carrier A pays carrier B for the transportation service. This arrangement is not a lease, first because carrier B is not granting the use of a passenger-carrying CMV to carrier A, and second because both carriers are authorized carriers. This arrangement is also not an interchange because carriers A and B are not conducting a through movement. The final rule does not apply to this arrangement. Carrier B will conduct the transportation in its own name, on its own authority, with its own vehicle(s), and is therefore responsible for compliance with the FMCSRs.

Other Business Arrangements Between Passenger Carriers

Example 1

Carrier A is exempt under 49 U.S.C. 13506 from the requirement for operating authority—for example, because of the hotel exemption in section 13506(a)(3) [14]—but finds itself without the capacity to accommodate a group that it originally intended to transport. When this occurs, carrier A hires authorized carrier B to provide charter passenger transportation of the group in whole or in part. This arrangement is documented by a charter contract between carriers A and B. Carrier A pays carrier B for the transportation service, but is not a lessee of carrier B's vehicle. Therefore, this arrangement is not a lease. Carrier B does not claim the exemption in section 13506(a)(3) but conducts the transportation in its own name, on its own authority, with its own vehicle(s) and is therefore responsible for compliance with the FMCSRs. This final rule does not apply to this arrangement.

Example 2

Private motor carrier of passengers A finds itself without the capacity to transport the members of its organization. Carrier A therefore hires authorized carrier B to provide charter passenger transportation of the group in whole or in part. This arrangement is documented by a charter contract between carriers A and B. Carrier A pays carrier B for the transportation service. Carrier A is not a lessee and the arrangement is not a lease or interchange because carrier B conducts the transportation in its own name, on its own authority, with its own vehicle(s) and is therefore responsible for compliance with the FMCSRs. The final rule does not apply to this arrangement.

Example 3

Carrier A is an exempt for-hire motor carrier of passengers (under 49 U.S.C. 13506) that finds itself without the capacity to accommodate a group it originally intended to transport. Carrier A uses a passenger-carrying CMV owned by authorized carrier B. This transaction is a lease under the final rule and is subject to its requirements

[14] Section 13506 lists the miscellaneous motor carrier transportation exemptions. Under section 13506(a)(3), neither the Secretary nor the Board has jurisdiction over a motor vehicle owned or operated by or for hotel patrons between the hotel and the local station of a carrier.

because carrier A is not authorized to operate for-hire in interstate commerce. In this case, carrier B is a lessor that is surrendering control of a passenger-carrying CMVs to carrier A for the use of that carrier. Carrier A will conduct the transportation in its own name under its own safety registration (*i.e.,* USDOT number) with the CMV leased from carrier B, with or without drivers provided by carrier B, and is therefore responsible for compliance with the FMCSRs.

Example 4

Private motor carrier of passengers A finds itself without the capacity to accommodate a group it originally intended to transport. Carrier A uses a passenger-carrying CMV owned by authorized carrier B. This transaction is a lease under this final rule and is subject to its requirements because carrier A is not authorized to operate for-hire in interstate commerce. In this case, carrier B is a lessor that is surrendering control of a passenger-carrying CMVs to carrier A for the use of that carrier. Carrier A will conduct the transportation in its own name under its own safety registration (*i.e.,* USDOT number) with the CMV leased from carrier B, with or without drivers provided by carrier B, and is therefore responsible for compliance with the applicable FMCSRs.

Example 5

Authorized carrier A lacks the capacity to execute a contracted trip and uses a passenger-carrying CMV owned by private motor carrier of passengers, carrier B. This transaction is a lease under the final rule and is subject to its requirements because private carrier B is not authorized to operate for-hire in interstate commerce and cannot be hired to provide transportation. In this case, carrier B is a lessor that is surrendering control of its passenger-carrying CMV to carrier A. Carrier A will conduct the transportation in its own name, under its own authority, with the CMV leased from the private motor carrier of passengers, with or without drivers provided by carrier B, and is therefore responsible for compliance with the FMCSRs.

Example 6

Private motor carrier of passengers A finds itself without the capacity to transport the members of its organization and uses a passenger-carrying CMV owned by private motor carrier of passengers B. This transaction is a lease under the final rule and is subject to the requirements of this rule because neither carrier has the authority to conduct for-hire operations in interstate commerce. In this case, carrier B is a lessor that is surrendering control of its passenger-carrying CMV to carrier A for the use of that carrier. Carrier A will conduct the transportation in its own name, under its own safety registration (*i.e.,* USDOT number), with the CMV leased from carrier B, with or without drivers provided by carrier B, and is therefore responsible for compliance with the applicable FMCSRs.

Example 7

For-hire passenger carrier A had its operating authority revoked for lack of adequate insurance coverage. Carrier A wishes to generate revenue from its otherwise idle CMVs. It therefore negotiates an arrangement with authorized carrier B to surrender control of its passenger-carrying CMVs to carrier B for a fee. This arrangement is a lease under the final rule and would be subject to its requirements because carrier A is not authorized to operate for-hire in interstate commerce. In this case, carrier A is simply a lessor. Carrier B would conduct the transportation in its own name, under its own authority, with the CMVs leased from carrier A, with or without drivers provided by carrier A, and is therefore responsible for compliance with the FMCSRs.

VI. International Impacts

The FMCSRs, and any exceptions to the FMCSRs, apply only within the United States (and, in some cases, United States territories). Motor carriers and drivers are subject to the laws and regulations of the countries in which they operate, unless an international agreement states otherwise. Drivers and carriers should be aware of the regulatory differences among nations.

VII. Section-By-Section Description of the Rule

A. Section 390.5 Definitions

Section 390.5 is amended to revise the definitions of *lease, lessee,* and *lessor* and these terms apply specifically to motor carriers of passengers.

B. Section 390.21 Marking of Self-Propelled CMVs and Intermodal Equipment

Section 390.21 is returned nearly to the form before the May 27, 2015, final rule's effective date. In the paragraph (e) header, FMCSA replaces ''Rented property-carrying commercial motor vehicles'' with the phrase ''*Rented CMVs and leased passenger-carrying CMVs.*'' Throughout paragraph (e), the Agency adds the phrase ''or lease'' after the term ''rental agreement.'' When referring to a ''renting motor carrier,'' the Agency adds the phrase ''or lessee'' immediately after it. In paragraph (e)(2)(iv), in addition to the cross reference to the property-carrying leasing regulations in 49 CFR part 376, FMCSA adds a cross reference to the passenger-carrying leasing regulations in subpart G of part 390 so that the revised sentence reads ''See the property-carrying leasing regulations at 49 CFR part 376 and the passenger-carrying leasing regulations at subpart G of this part for information that should be included in all leasing documents.'' FMCSA adds paragraph (e)(2)(v)(A) to § 390.21 to allow the passenger-carrying CMV operating under the 48-hour emergency exception pursuant to § 390.403(a)(2) to be excepted from paragraphs § 390.21(e)(2)(iii) and (iv), provided the lessor and lessee comply with the requirements of the provision in § 390.403(a)(2). FMCSA adds § 390.21(e)(2)(v)(B) to set a January 1, 2021, compliance date for the paragraph (e) requirements for passenger-carrying CMVs subject to the lease and interchange rules under subpart G (§§ 390.401 and 390.403). This date is identical to the compliance date in §§ 390.401 and 390.403.

FMCSA removes § 390.21(f) and redesignates paragraphs (g) and (h) as paragraphs (f) and (g), respectively, as they were on July 1, 2015.[15]

C. Part 390, Subpart F Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles

Subpart F, including §§ 390.300T, 390.301, 390.303, and 390.305, is removed and reserved.

D. Part 390, Subpart G Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles

Subpart G, consisting of §§ 390.401 and 390.403, is added. These sections include the applicability of the final rule, the two general exceptions, the civil penalties for failure to meet applicable requirements, and the requirements for every lease or interchange.

E. Section 390.401 Applicability

Paragraph (a) explains the general applicability of Subpart G. The compliance date of this section is January 1, 2021.

Paragraph (b) provides two exceptions to the general rule. Paragraph (b)(1) makes the rules in §§ 390.401 and 390.403 inapplicable to contracts and

[15] See *https://www.ecfr.gov/cgi-bin/text-idx?SID=b9ddca68b462ed0f3d5758839de97752&pitd=20150701&node=pt49.5.390&rgn=div5#se49.5.390_121* (accessed June 3, 2019).

agreements between motor carriers of passengers that have active FMCSA operating authority. This exception is applicable when one such motor carrier acquires transportation service(s) from another such motor carrier(s), whether those agreements are designated sub-charters, farm-out charters, subcontracts, pooling agreements approved by the U.S. Surface Transportation Board, or through-service [16] agreements.

Paragraph (b)(2) makes the rules in §§ 390.401 and 390.403 inapplicable to *Financial leases* (however designated, *e.g.,* lease, closed-end lease, hire purchase, lease purchase, purchase agreement, installment plan, demonstration or loaner vehicle, etc.) between a motor carrier and a bank or similar financial organization or a manufacturer or dealer of passenger-carrying CMVs. This provision repromulgates the same section of the 2015 final rule.

Paragraph (c) provides that if the use of a passenger-carrying CMV is arranged between motor carriers subject to both rules in §§ 390.401 and 390.403 and either carrier fails to meet all applicable requirements of subpart G, both motor carriers are subject to a civil penalty.

F. Section 390.403 Lease and Interchange Requirements

Paragraph (a)(1) sets out the two instances in which a lease or other agreement is required (and the lease or agreement must then meet the conditions of paragraphs (b) and (c) of this section) beginning on the compliance date of this rule, January 1, 2021. Paragraph (a)(2) allows the delayed writing of a lease or agreement after an emergency, such as a disabled vehicle, that disrupts or delays a trip, and, unlike the previous rule, does not limit the exception to times when passengers are on the bus.

Paragraph (b) specifies the four required items of any lease, sublease, or interchange document required by this rule: (1) *Vehicle identification information;* (2) *Parties;* (3) *Specific duration;* and (4) *Exclusive possession and responsibilities.*

Paragraph (c) explains when a copy of the lease or agreement must be on the passenger-carrying CMV and how long both the lessor and lessee must retain copies of the lease or agreement.

[16] A through-service agreement involves a change in the operating provider of the transportation at a specified boundary on a regular schedule. This is usually accomplished at specific locations where equipment, drivers, or motor carriers are changed.

VIII. Regulatory Analyses

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

FMCSA performed an analysis of the impacts of the rule and determined it is not a significant regulatory action under section 3(f) of E.O. 12866 (58 FR 51735, October 4, 1993), Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, January 21, 2011), Improving Regulation and Regulatory Review. Accordingly, the Office of Management and Budget (OMB) has not reviewed it under that Order. It is also not significant within the meaning of DOT regulatory policies and procedures (DOT Order 2100.5 dated May 22, 1980; 44 FR 11034 (February 26, 1979) [17]). This rule is not a major rule as defined under the Congressional Review Act (5 U.S.C. 801–808).

The Agency received eighteen comments on the 2018 NPRM. None specifically addressed the regulatory analyses that were presented in the NPRM. The only substantive change made to the regulatory evaluation from the NPRM to this final rule is that the analysis time period has been updated to reflect the December 4, 2018, extension of the compliance date for the May 2015 final rule from January 1, 2019, to January 1, 2021 (83 FR 62505). Because this rule revises the regulations established in the 2015 final rule, that rule serves as the baseline against which the effects of this rule are evaluated. When the regulatory evaluation for the NPRM was performed, the compliance date for the 2015 final rule was January 1, 2019, and therefore the analysis period likewise began as of 2019. As noted, on December 4, 2018, the Agency extended the compliance date for the 2015 final rule to January 1, 2021. Therefore, the analysis period for this rule now begins as of 2021. The primary result of this change is a less than 2 percent increase in the annualized cost savings. This small increase is primarily a reflection of the slightly larger number of passenger carriers and CMV trips that experience regulatory relief in future years under the new analysis time period, consistent with the modest baseline annual industry growth rate projections used in the analysis.

As described earlier, the rule reduces the scope of the lease and interchange requirements for motor carriers of passengers. Furthermore, those passenger carriers and passenger-carrying CMV trips for which the rule remains applicable are subject to lease and interchange requirements that are reduced in comparison to those of the 2015 final rule. At the same time, FMCSA believes that the lease and interchange requirements of the rule still enable safety officials and the public to sufficiently identify the passenger carrier responsible for safety because each authorized for-hire motor carrier must conduct the transportation in its own name, under its own authority, with its owned, leased, or borrowed vehicles, and is therefore responsible for compliance with the FMCSRs. Therefore, FMCSA estimates that the rule results in a cost savings, but will not result in any change to safety benefits.

The Agency estimates that the rule will result in a cost savings of $76.5 million on an undiscounted basis, $67.7 million discounted at 3 percent, and $58.5 million discounted at 7 percent over the 10-year analysis period, expressed in 2016 dollars. On an annualized basis, this equates to a 10-year cost savings of $7.9 million at a 3 percent discount rate and $8.3 million at a 7 percent discount rate.

Key Inputs to the Analysis

The rule revises regulations established in the 2015 final rule, therefore the 2015 final rule serves as the baseline against which the effects of this rule are evaluated. Many of the key inputs to this analysis of the rule are based on the same data sources and methods as those developed and used in the evaluation of the 2015 final rule, with various updates made as needed to reflect more recently available data and information. Therefore, a copy of the regulatory evaluation for the 2015 final rule is available in the docket for this final rule, and, where applicable, the Agency cites that document in the analysis below.[18] The analysis of this final rule utilizes a 10-year analysis period of 2021 to 2030, and all monetary values are expressed in 2016 dollars.

[17] Although the recent DOT Order 2100.6 (Policies and Procedures for Rulemakings) that was published December 20, 2018, cancels and supersedes this DOT Order 2100.5, the newer DOT Order 2100.6 specifically notes that it ''does not apply to any rulemaking in which a notice of proposed rulemaking was issued before the effective date of this Order,'' which was December 20, 2018. Therefore, because the NPRM for this final rule was published September 20, 2018 (83 FR 47764), the newer DOT Order 2100.6 does not apply and therefore is not cited here.

[18] U.S. Department of Transportation (DOT), FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Docket ID# FMCSA–2012–0103–0022. Available at: *https://www.regulations.gov/contentStreamer?documentId=FMCSA-2012-0103-0022&attachmentNumber=1&contentType=pdf* (accessed June 3, 2019).

Number of Passenger Carriers Experiencing Regulatory Relief Under the Rule

The Agency estimates that an annual average of 8,366 motor carriers of passengers will experience regulatory relief under the rule, as discussed below. This represents the average over the 10-year analysis period of the individual annual estimates of the total number of passenger carriers experiencing regulatory relief under the rule, which are presented in Table 2. As also shown in Table 2, the Agency estimates that approximately 75 percent of this total number of passenger carriers will experience full regulatory relief and are no longer subject to the lease and interchange requirements for passenger-carrying CMVs because of the rule. The remaining 25 percent of these passenger carriers will experience partial regulatory relief and remain subject to reduced lease and interchange requirements compared to those of the 2015 final rule.

TABLE 2—ESTIMATED NUMBER OF PASSENGER CARRIERS EXPERIENCING REGULATORY RELIEF UNDER THE RULE

Year	Passenger carriers experiencing full regulatory relief under the rule	Passenger carriers experiencing partial regulatory relief under the rule	Total passenger carriers experiencing regulatory relief under the rule [a]
2021	6,035	2,012	8,046
2022	6,087	2,029	8,116
2023	6,139	2,046	8,186
2024	6,192	2,064	8,256
2025	6,246	2,082	8,328
2026	6,300	2,100	8,400
2027	6,354	2,118	8,472
2028	6,409	2,136	8,545
2029	6,464	2,155	8,619
2030	6,520	2,173	8,693
Annual average	6,275	2,092	8,366

Notes:
[a] Values may not equal the sum of the components due to rounding.

To derive the estimates presented in Table 2 of the number of passenger carriers experiencing regulatory relief under the rule, FMCSA first estimated the number of passenger carriers that, in the absence of the rule, would be affected by the lease and interchange requirements of the 2015 final rule. This estimate is based on the same data sources and methods as those developed and used in the evaluation of the 2015 final rule [19] but updated to reflect more recently available data and information. The Agency used data from the FMCSA Motor Carrier Management Information System (MCMIS) and the FMCSA Licensing and Insurance (L&I) system to develop a new baseline value for the reported number of all active interstate passenger carriers operating in the U.S. as of the end of calendar year 2017, namely 13,386 carriers.[20] [21]

Of this total population, the Agency estimates that, in the absence of this rule, 7,774 of these passenger carriers would be subject to the May 2015 final rule. This estimate is based on the same methods as those developed and used in the evaluation of the 2015 final rule, and assumes that under that rule 100 percent of authorized for-hire carriers, 100 percent of exempt for-hire carriers, and 10 percent of private passenger carriers would be subject to the lease and interchange requirements for passenger-carrying CMVs.[22]

TABLE 3—REPORTED NUMBER OF ACTIVE INTERSTATE PASSENGER CARRIERS OPERATING IN THE U.S. (AS OF DECEMBER 29, 2017) AND ESTIMATED NUMBER THAT WOULD BE SUBJECT TO THE MAY 2015 FINAL RULE IN THE ABSENCE OF THE RULE

Type of passenger carrier operation	Total number of carriers	Number (and percent) estimated to be subject to the May 2015 final rule in the absence of the rule
Authorized For-Hire [a]	6,629	6,629 (100% of total).
Exempt For-Hire (9+) [b]	340	340 (100% of total).
Exempt For-Hire (16+) [c]	181	181 (100% of total).
Private (business) [d]	2,599	260 (10% of total).

[19] Further details regarding the specific data sources and methods can be found in U.S. DOT, FMCSA, ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Pages 9 to 12.

[20] U.S. DOT, FMCSA. Motor Carrier Management Information System (MCMIS), and Licensing and Insurance (L&I) system. Snapshots as of December 29, 2017 (Data Analysis and Reports Team (DART) request ID # 38883).

[21] The total number of 13,386 passenger carriers as of the end of 2017 represents 11,705 unique carriers, because some carriers provide passenger service in more than one of the operation classifications shown. Consistent with the approach used in the regulatory evaluation for the May 2015 final rule, the larger number was used here to not risk underestimating the number of affected passenger carriers and the corresponding cost of the lease and interchange requirements of the May 2015 final rule.

[22] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Pages 9 to 12.

TABLE 3—REPORTED NUMBER OF ACTIVE INTERSTATE PASSENGER CARRIERS OPERATING IN THE U.S. (AS OF DECEMBER 29, 2017) AND ESTIMATED NUMBER THAT WOULD BE SUBJECT TO THE MAY 2015 FINAL RULE IN THE ABSENCE OF THE RULE—Continued

Type of passenger carrier operation	Total number of carriers	Number (and percent) estimated to be subject to the May 2015 final rule in the absence of the rule
Private (non-business) [e]	3,637	364 (10% of total).
Total [f]	13,386	7,774.

Notes:

[a] A commercial entity whose primary business activity is the transportation of passengers by motor vehicle for compensation.

[b] A for-hire entity that is exempt under 49 U.S.C. 13506, and operates at least one passenger vehicle designed or used to accommodate 9 or more passengers including the driver.

[c] A for-hire entity that is exempt under 49 U.S.C. 13506, and operates at least one passenger vehicle designed or used to accommodate 16 or more passengers including the driver.

[d] A private entity engaged in the interstate transportation of passengers which is provided in the furtherance of a commercial enterprise and is not available to the public at large.

[e] A private entity involved in the interstate transportation of passengers that does not otherwise meet the definition of a ''private (business)'' motor carrier of passengers as noted above.

[f] The total number of 13,386 passenger carriers shown represents 11,705 unique carriers, because some carriers provide passenger service in more than one of the operation classifications shown. Consistent with the approach used in the regulatory evaluation for the May 2015 final rule, the larger number was used here to not risk underestimating the number of affected passenger carriers and the corresponding cost of the lease and interchange requirements of the May 2015 final rule.

The 2017 value of 7,774 passenger carriers that would be subject to the 2015 final rule was then used as the basis to develop future projections over the 2021 to 2030 analysis period. The Agency developed these projections by increasing the baseline 2017 value of 7,774 passenger carriers consistent with the occupation-specific employment growth projections for Standard Occupational Classification (SOC) Code 53–3021 (Bus drivers, transit and intercity) obtained from the U.S Department of Labor (DOL) Bureau of Labor Statistics (BLS) Employment Projections Program which, from 2016 to 2026, is forecast to grow by 0.86 percent annually.[23] This results in a projection of the number of passenger carriers that, in the absence of this rule, would be subject to the 2015 rule each year over the 2021 to 2030 analysis period. In the absence of the rule, these passenger carriers would be subject to the 2015 rule. As discussed earlier, under the rule a large portion of these passenger carriers will no longer be subject to lease and interchange requirements, and the remaining carriers will be subject to reduced requirements. In Table 2, the column on the far right shows the projected number of passenger carriers that will experience regulatory relief under the rule over the 10-year analysis period of 2021 to 2030, which equals an annual average of 8,366 passenger carriers.

Table 2 also shows the subset of those 8,366 passenger carriers that under the rule will experience full regulatory relief and will no longer be subject to lease and interchange requirements. Over the 10-year analysis period, the Agency estimates that an annual average of 6,275 passenger carriers, or approximately 75 percent of the total number of carriers that will experience regulatory relief, will experience full regulatory relief. The Agency estimated this value by assuming that approximately 10 percent of authorized for-hire carriers will be subject to the lease and interchange requirements under this rule, rather than 100 percent as assumed previously under the 2015 final rule and as shown in Table 3.

For exempt for-hire carriers and private passenger carriers, the analysis assumes that 100 percent and 10 percent, respectively, of these carriers will continue to be subject to the lease and interchange requirements under the rule, the same percentages as under the 2015 final rule and as shown in Table 3. Combined, these changes result in an estimated overall reduction of approximately 75 percent in the number of passenger carriers subject to lease and interchange requirements under the rule.[24] This reduction is consistent with the comments and petitions for reconsideration that the Agency received, a number of which suggested that the scope of the 2015 final rule likely encompassed a relatively large proportion of passenger-carrying CMV trips in which both the lessor and the lessee were authorized carriers. Petitioners generally argued that such carriers should not be subject to lease and interchange requirements.

Finally, Table 2 also presents an estimate of the remaining subset of the annual average of 8,366 passenger carriers that will experience partial regulatory relief and remain subject to reduced lease and interchange requirements compared to those of the 2015 rule. Over the 10-year analysis period, the Agency estimates that an annual average of 2,092 passenger carriers, or approximately 25 percent of the total, will experience partial regulatory relief. As noted earlier, however, these carriers will be subject to reduced requirements compared to those of the 2015 final rule.

[23] U.S. DOL BLS. ''Occupational Employment Projections. Table 1.2: Employment by detailed occupation, 2016 and projected 2026.'' Available at: *https://www.bls.gov/emp/ep_data_occupational_data.htm* (accessed June 3, 2019).

[24] As shown in Table 3, in 2017 an estimated 7,774 passenger carriers would be subject to the lease and interchange requirements of passenger-carrying CMVs under the May 2015 final rule. Under this rule, as noted, the analysis assumes that only 10 percent of authorized for-hire carriers will be subject to the lease and interchange requirements of passenger-carrying CMVs, or 10 percent of 6,629, which equals 663 authorized for-hire passenger carriers. The analysis also assumes that 100 percent of exempt for-hire carriers and 10 percent of private passenger carriers will continue to be subject to the lease and interchange requirements for passenger-carrying CMVs under the rule, which equals 100 percent of 340 and 181 exempt for-hire carriers (totaling 521 exempt for-hire carriers), and 10 percent of 2,599 and 3,637 private carriers (totaling 624 private carriers). Therefore, the Agency estimates that 1,808 passenger carriers will be subject to the lease and interchange requirements of passenger-carrying CMVs in 2017 under this final rule, or 23.3 percent of those subject to the requirements under the 2015 final rule, which is rounded to 25 percent for purposes of developing the future projections of affected passenger carriers presented in Table 2. Therefore, as a consequence of this final rule, there will be a 75 percent reduction in the number of passenger carriers subject to lease and interchange requirements.

Number of CMV Trips Experiencing Regulatory Relief Under the Rule

The Agency estimates that an annual average of 547,034 passenger-carrying CMV trips will experience regulatory relief under the rule over the 10-year analysis period, as presented in Table 4 and discussed below. This estimate is based on the same methods as those developed and used in the evaluation of the 2015 final rule.[25] The estimated number of passenger carriers that will experience regulatory relief under the rule (see Table 2) serves as the primary basis for the estimate of the number of trips that will experience regulatory relief under the rule. For each of the carriers in Table 2, the Agency assumed an estimated average of 64 trips per year would be operated with vehicles that would be considered leased or interchanged vehicles under the 2015 final rule. This is consistent with the assumptions used in the regulatory evaluation for the 2015 final rule.[26] The estimated number of trips that will experience regulatory relief under the rule (see Table 4) also incorporates a modest upward adjustment to reflect an annual average of 11,400 trips operated by Greyhound, one of the largest U.S. interstate passenger carriers. This adjustment is consistent with the methods used in the evaluation of the 2015 final rule,[27] and is based on data that Greyhound provided to FMCSA regarding trips with leased and interchanged vehicles in 2012.[28]

The Agency estimates that approximately 75 percent of these passenger-carrying CMV trips will experience full regulatory relief and will no longer be subject to the lease and interchange requirements of the 2015 final rule. The remaining 25 percent of these trips will experience partial regulatory relief and remain subject to reduced lease and interchange requirements compared to those of the 2015 final rule.

TABLE 4—ESTIMATED NUMBER OF PASSENGER-CARRYING CMV TRIPS EXPERIENCING REGULATORY RELIEF UNDER THE RULE

Year	Passenger-carrying CMV trips experiencing full regulatory relief under the rule	Passenger-carrying CMV trips experiencing partial regulatory relief under the rule	Total CMV trips experiencing regulatory relief under the rule [(a)]
2021	394,583	131,528	526,111
2022	397,990	132,663	530,654
2023	401,427	133,809	535,237
2024	404,894	134,965	539,859
2025	408,391	136,130	544,521
2026	411,918	137,306	549,224
2027	415,475	138,492	553,967
2028	419,063	139,688	558,751
2029	422,682	140,894	563,576
2030	426,332	142,111	568,443
Annual average	410,276	136,759	547,034

Notes:
[(a)] Values may not equal the sum of the components due to rounding.

Other Key Inputs to the Analysis

The opportunity cost of the time employees of passenger carriers spend complying with the lease and interchange requirements represents approximately 95 percent of the total cost of the 2015 final rule. The cost savings from this rule are likewise heavily influenced by aggregate changes in the opportunity cost of employee time.

The Agency evaluates changes in employee opportunity cost by using their labor costs. Labor costs comprise wages, fringe benefits, and overhead. Fringe benefits include paid leave, bonuses and overtime pay, health and other types of insurance, retirement plans, and legally required benefits (Social Security, Medicare, unemployment insurance, and workers' compensation insurance). Overhead includes any expenses to a firm associated with labor that are not part of employees' compensation, and typically includes many types of fixed costs of managing a body of employees, such as management and human resource staff salaries or payroll services. The economic costs of labor to a firm, in this case a passenger carrier, include all forms of compensation and labor related expenses. For this regulatory evaluation, the costs of labor to the firm are calculated to include base wages and fringe benefits, plus overhead.

For the regulatory evaluation of both the 2015 final rule and this rule, the median hourly base wage rate for the BLS SOC code 53–1031, ''First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators,'' is used as the basis for calculating the relevant cost of labor. For 2016, BLS reports an hourly base

[25] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Page 21, Table 6.

[26] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Page 21, Table 6.

[27] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Pages 12 to 13.

[28] ''Lease and Interchange of Vehicles; Motor Carriers of Passengers. NPRM.'' September 20, 2013. Comments of Greyhound Lines, Inc., Docket ID number FMCSA–2012–0103–0010. Page 2. November 12, 2013. Available at: *https://www.regulations.gov/contentStreamer?documentId=FMCSA-2012-0103-0010&attachmentNumber=1&contentType=pdf* (accessed June 3, 2019). Greyhound reported 10,263 passenger-carrying CMV trips performed in 2012 by vehicles leased and interchanged. This 2012 value was then adjusted to reflect observed industry growth from 2012 to 2016 as represented by growth in employment for SOC Code 53–3021 (Bus drivers, transit and intercity), and then further adjusted to reflect employment growth projections for SOC Code 53–3021 (Bus drivers, transit and intercity).

wage rate of $27.54 for this occupation.[29]

BLS does not publish data on fringe benefits for specific occupations, but it does do so for broad industry groups in its Employer Costs for Employee Compensation (ECEC) publication. A fringe benefit rate of 57 percent (*i.e.,* equal to 57 percent of the base wage rate) is used. This is based on information from the June 2016 BLS ECEC data, which for the ''Transportation and warehousing'' segment of private industry reports a benefits cost of $14.09 per hour worked, which represents 57 percent of wages and salaries in that industry segment of $24.73 per hour.[30]

Finally, for estimating overhead rates, the Agency used industry data gathered for the Truck Costing Model developed by the Upper Great Plains Transportation Institute, North Dakota State University.[31] Research conducted for this model found an average cost of $0.107 per mile of CMV operation for management and overhead, and $0.39 per mile for labor, indicating an overhead rate of 27 percent (27% = $0.107 ÷ $0.39 (rounded to the nearest whole percent)).

Combined, the overall relevant cost of labor, including base wage rate, fringe benefits, and overhead, for passenger carriers that will experience regulatory relief under the rule is $54.91 per hour.

Costs

The rule will not result in any increase in costs. It revises the 2015 final rule, which serves as the baseline against which the effects of this rule are evaluated. Absent this rule, the Agency estimates that the baseline costs of the 2015 final rule over the 10-year analysis period of 2021 to 2030 would be $10.6 million on an annualized basis at a 7 percent discount rate, expressed in 2016 dollars.[32] As noted earlier, the Agency estimates that the rule will result in a cost savings of $8.3 million at a 7 percent discount rate relative to the 2015 baseline, representing a 79 percent overall reduction in cost.

The estimated reduction of approximately 75 percent in the number of passenger carriers and CMV trips under the rule is responsible for most of the annualized cost savings. The remaining cost savings are the result of reduced requirements for those approximately 25 percent of passenger carriers and CMV trips that will remain subject to the lease and interchange rules.

Under both the 2015 rule and this rule, costs are organized into six major categories. Five are related to the requirements under § 390.303 of the 2015 rule, and include: One-time costs of lease negotiation; lease documentation costs; lease copying costs; lease receipt costs; and vehicle marking costs. The sixth cost category is related to the charter party notification requirement under § 390.305 of the 2015 rule.

One-time costs of lease negotiation under this rule are calculated based on the number of CMV trips that will experience regulatory relief under the rule for this cost category, the time expended by employees in negotiating the lease and developing the lease document, and the total labor cost of these employees. The number of trips that will experience regulatory relief under the rule for this cost category are the trips that will no longer be subject to the lease and interchange requirements. As presented earlier in Table 4, the Agency estimates that an annual average of 410,276 passenger-carrying CMV trips will no longer be subject to the lease and interchange requirements. Consistent with the approach used in the 2015 regulatory evaluation, for each of these trips it is assumed that 30 minutes of employee time is saved, for both the lessor and the lessee, for a total time savings of one hour for each such trip.[33] This savings is valued at the total labor cost of $54.91 per hour, described earlier. The resulting savings in one-time costs of lease negotiation under the rule will be $21.7 million on an undiscounted basis over the 10-year analysis period, and $2.9 million on an annualized basis at a 7 percent discount rate. For the remaining passenger carriers and passenger-carrying CMV trips that are still subject to the leasing and interchange requirements, the provision in § 390.303(b)(5), that the lease contain a statement that the lessee is responsible for compliance with the insurance requirements of 49 CFR part 387, is removed. Although in theory this change may result in a modest incremental reduction in the amount of time passenger carrier employees expend in negotiating the lease and developing the lease document for carriers still subject to the leasing and interchange requirements, there is no empirical basis upon which to estimate such a possible impact. Therefore, the Agency has chosen not to make any such incremental reduction in its analysis. Also, not quantifying such a potential impact is a conservative approach that helps to avoid overestimating the cost savings of the rule.

Lease documentation costs under the rule are calculated based on the number of CMV trips that will experience regulatory relief under the rule for this cost category, the time spent by carrier employees verifying the information and signing the lease, and the total labor cost of these employees. The number of trips that will experience regulatory relief under the rule for this cost category are the same as above, an annual average of 410,276 trips that will no longer be subject to the lease and interchange requirements. Consistent with the 2015 regulatory evaluation, for each trip that will experience regulatory relief under the rule for this cost category this analysis assumes that both the lessor and the lessee save 5 minutes of employee time, for a total savings of 10 minutes for each such trip.[34] This is valued at the total labor cost of $54.91 per hour. The resulting savings in lease documentation costs under the rule will be $37.6 million on an undiscounted basis over the 10-year analysis period, and $3.7 million on an annualized basis at a 7 percent discount rate.

Lease copying cost savings under the rule are calculated based on the number of CMV trips that will experience regulatory relief under the rule for this cost category, and an estimated cost per copy. The number of trips that will experience regulatory relief under the rule for this cost category are the same as above, an annual average of 410,276

[29] U.S. DOL BLS. ''Occupational Employment Statistics (OES). National.'' May 2016. March 31, 2017. Available at: *https://www.bls.gov/oes/special.requests/oesm16nat.zip* (accessed June 3, 2019). The May 2017 BLS OES published in March 2018 did not report data for this BLS SOC code 53–1031. Therefore, the May 2016 data used in the analysis for the NPRM is used again here in the analysis for this final rule.

[30] U.S. DOL BLS. ''Table 10: Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by industry group, June 2016.'' Available at: *https://www.bls.gov/news.release/archives/ecec_09082016.pdf* (accessed June 3, 2019).

[31] Berwick, Farooq. ''Truck Costing Model for Transportation Managers.'' North Dakota State University. Upper Great Plains Transportation Institute. August 2003. Appendix A, pp. 42–47. Available at: *http://www.mountain-plains.org/pubs/pdf/MPC03-152.pdf* (accessed June 3, 2019).

[32] This annualized cost estimate of $10.6 million differs somewhat from the value of $8.0 million that was presented in the regulatory evaluation for the 2015 final rule primarily due to various real and nominal updates made to reflect more recently available data and information, as well as the different time frames covered by the 10-year analysis period for each respective analysis (previously 2017 to 2026, and now 2021 to 2030).

[33] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Pages 16 to 17.

[34] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Page 17.

such trips. As in the 2015 regulatory evaluation, it assumed that for each trip one copy of the lease is made for the lessor and another for the lessee, each at a cost of $0.15, for a total cost of $0.30 per trip.[35] The resulting lease copying cost savings under the rule will be $1.2 million on an undiscounted basis over the 10-year analysis period, and $0.123 million on an annualized basis at a 7 percent discount rate.

The remaining three cost categories (lease receipts, vehicle marking, and charter party notification) will be eliminated for all passenger carriers and passenger-carrying trips, including those that would still be subject to the lease and interchange requirements under the rule.

Lease receipt cost savings under the rule are calculated based on the number of CMV trips that will experience regulatory relief under the rule for this cost category, with two receipts assumed per trip (one for obtaining, the other for surrendering, the vehicle), and both the lessor and lessee requiring copies of each, for a total of four receipts per trip. Because the rule will remove the receipt provision in its entirety, the cost savings will apply to all trips listed in Table 4, an annual average of 547,034 trips. Consistent with the 2015 regulatory evaluation, each receipt is assumed to cost $0.15, with four receipts required for a total of $0.60 per trip.[36] The resulting lease receipt cost savings under the rule will be $3.3 million on an undiscounted basis over the 10-year analysis period, and $0.327 million on an annualized basis at a 7 percent discount rate.

Vehicle marking cost savings under the rule are calculated based on the number of CMV trips that will experience regulatory relief under the rule for this cost category, and marking costs per vehicle that include two sheets of letter size paper per trip at $0.014 per sheet, plus $0.04 for adhesive tape. Because the rule will remove the marking provision in its entirety, the cost savings will apply to all trips listed in Table 4, an annual average of 547,034 trips. The resulting vehicle marking cost savings under the rule will be $0.361 million on an undiscounted basis over the 10-year analysis period, and $0.036 million on an annualized basis at a 7 percent discount rate.

Charter party notification cost savings under the rule are calculated based on the number of CMV trips that will experience regulatory relief under the rule for this cost category, and an estimated expenditure by passenger carrier employees of 5 minutes per notification.[37] Because the rule will remove the notification provision in its entirety, the resulting cost savings will apply to all trips in which notification would otherwise have been necessary, which are assumed to be 50 percent of the total annual average of 547,034 passenger-carrying CMV trips listed in Table 4.[38] The resulting savings in charter party notification costs under the rule will be $12.4 million on an undiscounted basis over the 10-year analysis period, and $1.23 million on an annualized basis at a 7 percent discount rate.

In summary, and as presented in Table 5, the Agency estimates that the rule will result in a cost savings of $76.5 million on an undiscounted basis, $67.7 million discounted at 3 percent, and $58.5 million discounted at 7 percent over the 10-year analysis period, expressed in 2016 dollars. On an annualized basis, this equates to a 10-year cost savings of $7.9 million at a 3 percent discount rate and $8.3 million at a 7 percent discount rate.

TABLE 5—TOTAL COST OF THE RULE

[In thousands of 2016]

Year	Undiscounted					Discounted	
	Lease and interchange costs			Charter party notification costs	Total cost [b]	Discounted at 3%	Discounted at 7%
	Lease negotiation costs [a]	Lease documentation, copying, and lease receipt costs	Vehicle marking costs				
2021	($21,667)	($4,045)	($35)	($1,189)	($26,936)	($26,152)	($25,174)
2022	0	(4,079)	(35)	(1,199)	(5,315)	(5,009)	(4,642)
2023	0	(4,115)	(35)	(1,210)	(5,360)	(4,906)	(4,376)
2024	0	(4,151)	(36)	(1,220)	(5,407)	(4,804)	(4,125)
2025	0	(4,188)	(36)	(1,231)	(5,453)	(4,704)	(3,888)
2026	0	(4,224)	(36)	(1,241)	(5,500)	(4,607)	(3,665)
2027	0	(4,259)	(37)	(1,252)	(5,548)	(4,511)	(3,455)
2028	0	(4,296)	(37)	(1,263)	(5,596)	(4,417)	(3,257)
2029	0	(4,333)	(37)	(1,274)	(5,644)	(4,326)	(3,070)
2030	0	(4,371)	(38)	(1,285)	(5,693)	(4,236)	(2,894)
Total	(21,667)	(42,061)	(361)	(12,363)	(76,453)	(67,672)	(58,546)
Annualized					(7,645)	(7,933)	(8,336)

Notes:

[a] Values shown in parentheses are negative values (*i.e.,* less than zero) and represent a decrease in cost or a cost savings.

[b] Total cost values may not equal the sum of the components due to rounding. (The totals shown in this column are the rounded sum of unrounded components.)

[35] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Page 17.

[36] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Pages 17 to 18.

[37] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Pages 24 to 26.

[38] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Pages 24 to 26.

Benefits

The regulatory evaluation for the 2015 final rule attempted to estimate the potential safety benefits of lease and interchange requirements,[39] but there were insufficient data and empirical evidence to demonstrate a measurable quantitative relationship between lease and interchange requirements and improved safety outcomes, such as reduced frequency and/or severity of crashes or reduced frequency of violations. Therefore, FMCSA followed the guidance of the Office of Management and Budget (OMB) in its Circular A–4 and performed a threshold analysis.[40] Also referred to as a break-even analysis, a threshold analysis attempts to determine the amount of safety benefits (*e.g.,* reduced crashes and corresponding reductions in fatalities, injuries, and property damage) that would need to occur as a consequence of a rule in order for the rule to yield zero net benefits (*i.e.,* for the benefits of the rule to equal, or exactly to offset, the estimated costs of the rule).

The problem of insufficient data and empirical evidence noted in 2015 is still present today. Unlike regulations dealing with vehicle equipment or driver behaviors that can be clearly linked to reduced crashes and improved safety, both the 2015 final rule and this rule affect safety less directly and immediately. Lease and interchange requirements for motor carriers of passengers improve the ability of the Agency to attribute the inspection, compliance, enforcement, and safety data collected by the Agency and its State partners to the correct motor carrier and driver, allowing FMCSA to more accurately identify unsafe carriers and initiate appropriate interventions. FMCSA believes that this rule will be a less costly and burdensome regulatory approach than the 2015 final rule, yet will still enable safety officials and the public to sufficiently identify the passenger carrier responsible for safety because each authorized for-hire motor carrier must conduct the transportation in its own name, under its own authority, with its owned, leased, or borrowed vehicles, and is therefore responsible for compliance with the FMCSRs. Therefore, the Agency does not anticipate any change to safety benefits because of the rule.

B. E.O. 13771 (Reducing Regulation and Controlling Regulatory Costs)

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 (82 FR 9339, Feb. 3, 2017). E.O. 13771 requires that for every one new regulation issued by an Agency, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.[41] Final implementation guidance addressing the requirements of E.O. 13771 was issued by the Office of Management and Budget (OMB) on April 5, 2017.[42] The OMB guidance defines what is an E.O. 13771 regulatory action and what is an E.O. 13771 deregulatory action, provides procedures for how agencies should account for the costs and cost savings of such actions, and outlines various other details regarding implementation of E.O. 13771.

This final rule has total costs less than zero, and is therefore an E.O. 13771 deregulatory action.[43] The present value of the cost savings of this rule, measured on an infinite time horizon at a 7 percent discount rate, expressed in 2016 dollars, and discounted to 2021 (the year that cost savings would first be realized), is $104.4 million. On an annualized basis, these cost savings are $7.3 million.

For the purpose of E.O. 13771 accounting, the April 5, 2017, OMB guidance requires that agencies also calculate the costs and cost savings discounted to year 2016.[44] In accordance with this requirement, the present value of the cost savings of this rule, measured on an infinite time horizon at a 7 percent discount rate, expressed in 2016 dollars, and discounted to 2016, is $74.4 million. On an annualized basis, these cost savings are $5.2 million.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121, 110 Stat. 857), requires Federal agencies to consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment. The term ''small entities'' means small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000.[45] Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these entities. Section 605 of the RFA allows an Agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

In the 2018 NPRM, in lieu of preparing an Initial Regulatory Flexibility Analysis under section 603(a) of the RFA to assess the impact of the rule, FMCSA performed a certification analysis under section 605(b) of the RFA. The threshold economic analysis that was performed determined that, although the rule will have an impact on a substantial number of small entities, the impact on these small entities will not be significant, and furthermore will be entirely beneficial. Therefore, FMCSA certified that the rule will not have a significant economic impact on a substantial number of small entities.

The Agency received eighteen comments on the 2018 NPRM, eight of which were from motor carriers of passengers that are classified as small entities.[46] All eight of these small entities expressed support for the 2018 NPRM. None of them, nor any of the other submissions received to the 2018 NPRM, specifically commented on the certification or its underlying threshold economic analysis that were presented in the NPRM. The Chief Counsel for Advocacy of the Small Business

[39] U.S. DOT, FMCSA. ''Final Rule. Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' May 2015. Page 35 to 36.

[40] OMB. ''Circular A–4. Regulatory Analysis.'' September 17, 2003. Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf* (accessed June 3, 2019).

[41] Executive Office of the President. ''Executive Order 13771 of January 30, 2017. Reducing Regulation and Controlling Regulatory Costs.'' 82 FR 9339. Feb. 3, 2017. Section 1 (Purpose).

[42] Executive Office of the President. Office of Management and Budget. ''Memorandum M–17–21. Guidance Implementing Executive Order 13771.'' April 5, 2017.

[43] Executive Office of the President. Office of Management and Budget. ''Memorandum M–17–21. Guidance Implementing Executive Order 13771.'' April 5, 2017. Q4 on page 4.

[44] Executive Office of the President. Office of Management and Budget. ''Memorandum M–17–21. Guidance Implementing Executive Order 13771.'' April 5, 2017. Q25 on page 11.

[45] Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601 *et seq.*).

[46] The eight motor carriers of passengers classified as small entities that submitted comments to the 2018 NPRM include Adirondack Trailways, Annett Bus Lines, Southern Tier Stages, Inc., Plymouth & Brockton Street Railway Company, DeCamp Bus Lines, Burlington Trailways, Pacific Coachways Charter Services, Inc., and Thielen Bus Lines (the comment from Thielen Bus Lines (Docket ID# FMCSA–2012–0103–0162) was also submitted in representation of the more than 30 other passenger carriers that comprise the membership of the Minnesota Charter Bus Operators Association (MCBOA)).

Administration did not file comments in response to the proposed rule.

As noted earlier in the Regulatory Analyses section, the only substantive change made to the regulatory evaluation from the NPRM to this final rule is that the analysis time period has been updated to reflect the December 4, 2018, extension of the compliance date for the May 2015 final rule from January 1, 2019, to January 1, 2021 (83 FR 62505). Because this rule revises the regulations established in the 2015 final rule, the 2015 final rule serves as the baseline against which the effects of this rule are evaluated. Therefore, the analysis period for this rule now begins as of 2021. As noted earlier in the Regulatory Analyses section, the primary result of this change in the analysis time period is a less than 2 percent increase in the annualized cost savings from this rule. This result has no substantive impact upon the certification or its underlying threshold economic analysis that were presented in the NPRM. Therefore, as also determined in the 2018 NPRM, although FMCSA determines that this rule will have an impact on a substantial number of small entities, the Agency determines that the impact on these small entities will not be significant. Therefore, there is no change to the Agency's certification that this final rule will not have a significant economic impact on a substantial number of small entities. The threshold economic analysis is presented again below, now incorporating modest revisions where necessary resulting from the change in the analysis period, to again clearly demonstrate the Agency's reasoning and assumptions underlying its certification.

This rule will not result in any increase in costs or any increase in burden. The rule will reduce the applicability of the lease and interchange requirements for motor carriers of passengers, resulting in a substantial reduction in the number of entities that will be subject to these requirements, and a commensurate reduction in costs and burden experienced by these entities. Furthermore, for those motor carriers of passengers that will continue to be subject to the lease and interchange requirements under the rule, the requirements will be reduced in comparison to the existing requirements. This will also result in a reduction in costs and burden experienced by these entities.

The regulated entities that will experience regulatory relief under this rule include all the passenger carriers that are subject to the existing lease and interchange requirements. Approximately 75 percent of this total number of passenger carriers will experience full regulatory relief, and will no longer be subject to lease and interchange requirements. The remaining 25 percent of these passenger carriers will experience partial regulatory relief and remain subject to reduced lease and interchange requirements compared to those of the 2015 final rule.

As presented earlier in Table 3 of the Regulatory Analyses section, as of 2017 there were an estimated 7,774 passenger carriers subject to the existing lease and interchange requirements, representing approximately 58 percent of all active interstate passenger carriers. As presented in Table 2, this population of passenger carriers is projected to increase slightly, due to general baseline industry growth, to 8,046 passenger carriers in 2021, the first year that the rule is anticipated to be in effect. Therefore, the Agency estimates that 8,046 passenger carriers will experience regulatory relief under the rule. The number of these 8,046 passenger carriers that are small entities is not directly known by FMCSA, and is therefore estimated below.

The U.S. Small Business Administration (SBA) defines the size standards used to classify entities as small. SBA establishes separate standards for each industry, as defined by the North American Industry Classification System (NAICS).[47] The Agency estimates that the passenger carriers that will experience regulatory relief under the rule will be in industries within Subsector 485 (Transit and Ground Passenger Transportation). All eleven 6-digit NAICS industries within Subsector 485 have an SBA size standard based on annual revenue of $15.0 million. Three of the eleven 6-digit NAICS industries within Subsector 485 are likely to encompass most of the passenger carriers that will experience regulatory relief under the rule, and details regarding the SBA size standards for those three industries are presented in Table 6.

TABLE 6—SBA SIZE STANDARDS FOR SELECTED INDUSTRIES [(a)]

NAICS code	NAICS industry description	SBA size standard (annual revenue in millions of dollars)	SBA size standard (number of employees)
485113	Bus and Other Motor Vehicle Transit Systems	$15.0	(none).
485210	Interurban and Rural Bus Transportation	15.0	(none).
485510	Charter Bus Industry	15.0	(none).

Notes:
[(a)] U.S. Small Business Administration (SBA). ''Table of Small Business Size Standards.'' October 1, 2017. Available at: *https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.xlsx* (accessed June 3, 2019).

[47] OMB. ''North American Industry Classification System.'' 2017. Available at: *https://www.census.gov/eos/www/naics/2017NAICS/2017_NAICS_Manual.pdf* (accessed June 3, 2019).

Data regarding the annual revenue earned by the estimated 8,046 passenger carriers that will experience regulatory relief under the rule is not collected by FMCSA and is not otherwise available from other sources. Therefore, the SBA size standard of $15.0 million in annual revenue cannot be directly applied to determine how many of these passenger carriers are small entities. FMCSA does, however, collect information regarding the number of passenger-carrying vehicles operated by these carriers. As of the end of 2017, of the active interstate passenger carriers operating in the U.S. as presented earlier in Table 3, approximately 81 percent operated six or fewer passenger vehicles, and approximately 93 percent operated 19 or fewer passenger vehicles.[48] We estimate that in the passenger carrier industry, the average annual revenue earned per motorcoach is approximately $200,000.[49] [50] [51] This means that the SBA size standard of $15.0 million in annual revenue equates to a carrier size of 75 passenger vehicles. Therefore, carriers operating 75 passenger vehicles or fewer are classified as small, consistent with the SBA size standard of $15.0 million. As of the end of 2017, of the active interstate passenger carriers operating in the U.S. as presented earlier in Table 3, approximately 98 percent operated 75 or fewer passenger vehicles. The Agency does not believe that the rule will disproportionately apply to either larger or smaller passenger carriers, and we therefore estimate that a similar 98 percent of the 8,046 passenger carriers that will experience regulatory relief under the rule, or approximately 7,885 passenger carriers, will be small entities. Therefore, as also determined in the 2018 NPRM, this rule will have an impact on a substantial number of small entities.

Although FMCSA has determined that this rule will have an impact on a substantial number of small entities, the Agency has determined that the impact on the small entities that will experience regulatory relief under the rule will not be significant. The rule will not result in any increase in costs or any increase in burden for passenger carriers that are small entities. The effect of the rule will be a reduction in costs and burden, and will be entirely beneficial to the passenger carriers that are small entities. As discussed in the Regulatory Analyses section, the Agency estimates that the rule will result in a total cost savings of $76.5 million on an undiscounted basis over the 10-year analysis period used for the regulatory evaluation, or $7.65 million on an annualized basis, expressed in 2016 dollars. As presented in Table 2, an annual average of approximately 8,366 passenger carriers will experience regulatory relief under the rule over the same 10-year analysis period, 98 percent of which are estimated to be small entities. The annual average cost savings per small carrier will therefore be at most $914 (potentially even somewhat less, given that approximately 2 percent of passenger carriers that will experience regulatory relief under the rule are not small entities and therefore may represent a disproportionately larger share of the overall absolute cost savings because of the larger scale of their operations). For even the smallest of the small entities, those operating only one passenger vehicle, this $914 in annual savings represents only about one half of one percent of the estimated total annual revenues of $200,000 for a carrier with just one motorcoach. Therefore, as also determined in the 2018 NPRM, although FMCSA has determined that this rule will have an impact on a substantial number of small entities, the Agency has also determined that the impact on these small entities will not be significant, and furthermore will be entirely beneficial.

Accordingly, pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), I hereby certify that this final rule will not have a significant economic impact on a substantial number of small entities.

D. Assistance for Small Entities

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

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). The DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.[52]

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. The Act requires agencies to prepare a comprehensive written statement for any final rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $161 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2017 levels) or more in any one year. Because this rule does not result in such an expenditure, a written statement is not required. However, the Agency does discuss the costs and benefits of this rule elsewhere in this preamble.

[48] U.S. DOT, FMCSA. Motor Carrier Management Information System (MCMIS), and Licensing and Insurance (L&I) system. Snapshots as of December 29, 2017 (DART request ID # 38883).

[49] The information available regarding revenue for the passenger carrier industry is limited. The American Bus Associated reported that for 2004, revenue per motorcoach was approximately $160,000. Inflated from 2004 dollars to 2016 dollars using either the CPI–U or the Implicit Price Deflator for GDP, this value becomes approximately $200,000 per vehicle.

[50] American Bus Association (ABA). ''Motorcoach Census 2005.'' September 2006. Page 19, Table 3–5 (Carrier Revenue per Motorcoach, Averages, 2004). Available at: *https://www.iru.org/apps/cms-filesystem-action?file=events_2007_busandcoach/Motorcoach%20Census%202005%2009-21-20061.pdf* (accessed June 3, 2019).

[51] Greyhound, one of the largest interstate passenger carriers operating in the U.S., reported total revenue for 2017 of $894 million, with 78 percent of that total, or $697 million, being passenger revenue. With a fleet size reported to consist of 1,600 buses for the same year, this equals an average passenger revenue per motorcoach of $435,000. We believe that substantially higher levels of per vehicle revenue such as this are not representative of the smaller passenger carriers that make up most of the industry, and therefore the lesser estimate of $200,000 revenue per motorcoach described above was used here so as not to risk underestimating the number of small entities in the passenger carrier industry when used to compare against the SBA size standard of $15.0 million in annual revenue. Greyhound data is from ''FirstGroup plc, Annual Report and Accounts, 2017'', pages 18–19, available at *https://www.firstgroupplc.com/~/media/Files/F/Firstgroup-Plc/indexed-pdfs/2017%20ARA/2017%20FirstGroup%20plc%20Annual%20Report%20and%20Accounts.pdf* (accessed June 3, 2019).

[52] U.S. DOT. ''The Rights of Small Entities To Enforcement Fairness and Policy Against Retaliation.'' Available at: *https://www.transportation.gov/sites/dot.gov/files/docs/SBREFAnotice2.pdf* (accessed June 3, 2019).

F. Paperwork Reduction Act

This final rule amends two OMB-approved information collections under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB Control No. 2126–0054, ''Commercial Motor Vehicle Marking Requirements,'' and OMB Control No. 2126–0056, ''Lease and Interchange of Vehicles.'' As defined in 5 CFR 1320.3(c), ''collection of information'' includes reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

OMB Control No. 2126–0054 (Commercial Motor Vehicle Marking Requirements)

The Agency's CMV marking regulations require freight-carrying commercial motor carriers, passenger-carrying commercial motor carriers, and intermodal equipment providers to display the USDOT number and the legal name or a single trade name of the carrier or intermodal equipment provider on their vehicles. The USDOT number is used to identify all motor carriers in FMCSA's registration and information systems. It is also used by States as the key identifier in the Performance and Registration Information Systems Management (PRISM) system, a cooperative Federal/State program that makes motor carrier safety a requirement for obtaining and maintaining CMV registration and privileges. Vehicle marking requirements are intended to ensure that FMCSA, NTSB, and State safety officials can identify motor carriers and correctly assign responsibility for regulatory violations during inspections, investigations, compliance reviews, and crash studies. These marking requirements also provide the public with beneficial information that could assist in identifying carriers for the purposes of commerce, complaints, or emergency notification.

The final rule will eliminate the existing requirement under 49 CFR 390.303(f) for the temporary marking of leased commercial passenger vehicles. The final rule will therefore amend the OMB-approved information collection titled ''Commercial Motor Vehicle Marking Requirements,'' OMB No. 2126–0054. In the currently approved information collection, the temporary marking of leased passenger-carrying CMVs was assumed to have *de minimis* time burden, and therefore no separate time burden was estimated for that element of the passenger-carrying CMV marking requirements. Because of this, in the revision to this information collection, there is no change in time burden due to program change, and the estimated changes in time burden from the currently approved information collection are due to adjustments related to factors such as revised estimates of the population of passenger-carrying motor carriers and industry growth rate. There is a small reduction in the annual cost burden, however, related to the elimination of the cost of materials (paper and adhesive tape) estimated to be used for the temporary vehicle markings that are to be eliminated.

Title: Commercial Motor Vehicle Marking Requirements

OMB Control Number: 2126–0054

Summary of the Collection of Information: Under the information collection, freight-carrying commercial motor carriers, passenger-carrying commercial motor carriers, and intermodal equipment providers mark their vehicles to display the USDOT number and the legal name or a single trade name of the carrier or intermodal equipment provider. This vehicle marking occurs when a new vehicle is purchased, when a used vehicle is purchased and requires re-marking, and when a vehicle is retained by the owner but the existing label reaches the end of its useful life.

Need for Information: Vehicle marking requirements are needed to ensure that FMCSA, the NTSB, and State safety officials can identify motor carriers and correctly assign responsibility for regulatory violations during inspections, investigations, compliance reviews, and crash studies. These marking requirements also provide the public with beneficial information that could assist in identifying carriers for the purposes of commerce, complaints, or emergency notification.

Proposed Use of Information: The USDOT number is used to identify all motor carriers in FMCSA's registration and information systems, is used as the key identifier in the PRISM system, and is used by the public to assist in identifying carriers for the purposes of commerce, complaints, or emergency notification.

Description of the Respondents: Freight-carrying commercial motor carriers, passenger-carrying commercial motor carriers, and intermodal equipment providers.

Number of Respondents:

IC–1 (freight carriers) number of respondents: 317,041

IC–2 (passenger carriers) number of respondents: 7,816

IC–3 (intermodal equipment providers) number of respondents: 11

Total number of respondents: 324,868

Frequency of Response:

IC–1 (freight carriers) frequency of response: 7.9 responses per year, per respondent.

IC–2 (passenger carriers) frequency of response: 20.4 responses per year, per respondent.

IC–3 (intermodal equipment providers) frequency of response: 3,962 responses per year, per respondent.

Overall average frequency of response: 8.3 responses per year, per respondent

Burden per Response:

IC–1 (freight carriers) burden per response: 0.43 hours

IC–2 (passenger carriers) burden per response: 0.43 hours

IC–3 (intermodal equipment providers) burden per response: 0.43 hours

Overall average burden per response: 0.43 hours

Estimate of Total Annual Burden:

IC–1 (freight carriers) burden: 1,085,658 hours

IC–2 (passenger carriers) burden: 69,151 hours

IC–3 (intermodal equipment providers) burden: 18,886 hours

Total annual burden: 1,173,695 hours

OMB Control No. 2126–0056 (Lease and Interchange of Vehicles)

The Agency's lease and interchange of vehicles regulations ensure that truck and bus carriers are identified (and in some cases protected) when they agree to lease their equipment and drivers to other carriers. These regulations also ensure that the government and members of the public can determine who is responsible for a CMV. Prior to these regulations, some equipment was leased without written agreements, leading to disputes and confusion over which party to the lease was responsible for charges and actions and, at times, who was legally responsible for the vehicle. These recordkeeping requirements enable the public and investigators to identify the passenger carrier responsible for safety, and ensure that FMCSA, our State partners, and the NTSB are better able to identify the responsible motor carrier and therefore correctly assign regulatory violations to the appropriate carrier during inspections, investigations, compliance reviews, and crash studies.

The final rule reduces the scope of the lease and interchange requirements for

motor carriers of passengers. Furthermore, those passenger carriers and passenger-carrying CMV trips for which lease and interchange requirements remain applicable are subject to reduced requirements. The applicability of the existing lease and interchange requirements for motor carriers of passengers under 49 CFR 390.301 are revised and moved to § 390.401, resulting in a substantial reduction of approximately 75 percent in the number of passenger carriers and passenger-carrying CMV trips that will be subject to the lease and interchange requirement for motor carriers of passengers. For those motor carriers of passengers that remain subject to lease and interchange requirements, the existing requirements under 49 CFR 390.303(e) for lease receipt copies will be eliminated, and the existing requirements under 49 CFR 390.305 for charter party notification will also be eliminated.

The final rule therefore amends the OMB-approved information collection titled ''Lease and Interchange of Vehicles,'' OMB No. 2126–0056. In the revision to this information collection, there is substantial reduction in time burden due to program change from the currently approved information collection because of the rule.

Title: Lease and Interchange of Vehicles

OMB Control Number: 2126–0056

Summary of the Collection of Information: Under the information collection, freight-carrying commercial motor carriers and passenger-carrying commercial motor carriers negotiate leases, prepare and sign lease documents, and produce copies of lease documents.

Need for Information: The Agency's lease and interchange of vehicles regulations ensure that truck and bus carriers are identified (and in some cases protected) when they agree to lease their equipment and drivers to other carriers. These regulations also ensure that the government and members of the public can determine who is responsible for a CMV. These recordkeeping requirements enable the public and investigators to identify the passenger carrier responsible for safety.

Proposed Use of Information: The government generally collects little information with this ICR. The leases and other agreements are developed and held by the lessor (*e.g.,* those granting use of equipment) and lessee (*e.g.,* party acquiring equipment). They are used to assign duties and responsibilities. The information may also be used by law enforcement to determine legal responsibility if a leased vehicle is in violation of the regulations or is involved in a crash.

Description of the Respondents: Freight-carrying commercial motor carriers, and passenger-carrying commercial motor carriers.

Number of Respondents:

IC–1 (property-carrying CMVs) number of respondents: 36,001

IC–2 (passenger-carrying CMVs) number of respondents: 6,729

Total number of respondents: 42,730

Frequency of Response:

IC–1 (property-carrying CMVs) frequency of response: 19.9 responses per year, per respondent.

IC–2 (passenger-carrying CMVs) frequency of response: 65.4 responses per year, per respondent.

Overall average frequency of response: 27.1 responses per year, per respondent

Burden per Response:

IC–1 (property-carrying CMVs) burden per response: 0.11 hours

IC–2 (passenger-carrying CMVs) burden per response: 0.13 hours

Overall average burden per response: 0.12 hours

Estimate of Total Annual Burden:

IC–1 (property-carrying CMVs) burden: 77,767 hours

IC–2 (passenger-carrying CMVs) burden: 58,520 hours

Total annual burden: 136,287 hours

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), FMCSA will submit a copy of this rule to OMB for its review of the collection of information.

FMCSA asked for public comment on the collection of information in the 2018 NPRM. No comments addressed the collection of information analysis to the NPRM.

G. E.O. 13132 (Federalism)

A rule has implications for Federalism under Section 1(a) of E.O. 13132 if it has ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' FMCSA has determined that this rule will not have substantial direct costs on or for States, nor will it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. No comments received addressed Federalism implications. Therefore, this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Impact Statement.

H. E.O. 12988 (Civil Justice Reform)

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. E.O. 13045 (Protection of Children)

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), requires agencies issuing ''economically significant'' rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. The Agency determined this rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, the Agency does not anticipate that this regulatory action could in any respect present an environmental or safety risk that could disproportionately affect children.

J. E.O. 12630 (Taking of Private Property)

FMCSA reviewed this final rule in accordance with E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it will not effect a taking of private property or otherwise have taking implications.

K. Privacy

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a Privacy Impact Assessment (PIA) of a regulation that will affect the privacy of individuals. This rule does not require the collection of any personally identifiable information.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program. FMCSA has determined that this rule would not result in a new or revised Privacy Act System of Records for FMCSA.

The E-Government Act of 2002, Public Law 107–347, sec. 208, 116 Stat. 2899, 2921 (December 17, 2002), requires Federal agencies to conduct a PIA for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology would collect, maintain, or disseminate

information as a result of this rule. Accordingly, FMCSA has not conducted a privacy impact assessment.

L. E.O. 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

M. E.O. 13211 (Energy Supply, Distribution, or Use)

FMCSA has analyzed this rule under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, it does not require a Statement of Energy Effects under E.O. 13211.

N. E.O. 13783 (Promoting Energy Independence and Economic Growth)

Executive Order 13783 directs executive departments and agencies to review existing regulations that potentially burden the development or use of domestically produced energy resources, and to appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources. In accordance with E.O. 13783, the DOT prepared and submitted a report to the Director of OMB providing specific recommendations that, to the extent permitted by law, could alleviate or eliminate aspects of agency action that burden domestic energy production. The DOT has not identified this rule as potentially alleviating unnecessary burdens on domestic energy production under E.O. 13783.

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

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

P. National Technology Transfer and Advancement Act (Technical Standards)

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) are standards developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, FMCSA did not consider the use of voluntary consensus standards.

Q. Environment (NEPA and CAA)

FMCSA analyzed this rule for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680, March 1, 2004), Appendix 2, paragraphs (6)(y)(2) and (6)(y)(7). The Categorical Exclusion (CE) in paragraph (6)(y)(2) covers regulations implementing motor carrier identification and registration reports. The Categorical Exclusion (CE) in paragraph (6)(y)(7) covers regulations implementing prohibitions on motor carriers, agents, officers, representatives, and employees from making fraudulent or intentionally false statements on any application, certificate, report, or record required by FMCSA. The requirements in this rule are covered by these CEs, and the action does not have the potential to significantly affect the quality of the environment. The CE determination is available for inspection or copying in the *regulations.gov* website listed under **ADDRESSES**.

FMCSA also analyzed this rule under section 176(c) of the Clean Air Act, as amended (CAA) (42 U.S.C. 7401 *et seq.*), and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA's general conformity requirement since it does not affect direct or indirect emissions of criteria pollutants.

List of Subjects in 49 CFR Part 390

Highway safety, Intermodal transportation, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, FMCSA amends 49 CFR chapter III, subchapter B, part 390 to read as follows:

PART 390—FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

■ 1. The authority citation for part 390 continues to read as follows:

Authority: 49 U.S.C. 504, 508, 31132, 31133, 31134, 31136, 31137, 31144, 31149, 31151, 31502; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 212 and 217, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 229, Pub. L. 106–159 (as added and transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743; sec. 4136, Pub. L. 109–59, 119 Stat. 1144, 1745; secs. 32101(d) and 32934, Pub. L. 112–141, 126 Stat. 405, 778, 830; sec. 2, Pub. L. 113–125, 128 Stat. 1388; secs. 5403, 5518, and 5524, Pub. L. 114–94, 129 Stat. 1312, 1548, 1558, 1560; sec. 2, Pub. L. 115–105, 131 Stat. 2263; and 49 CFR 1.81. 1.81a, 1.87.

■ 2. Amend § 390.5 as follows:

■ a. Lift the suspension of the section;

■ b. Revise the definition of ''*Lease,*'' ''*Lessee,*'' and ''*Lessor*'''';

■ c. Suspend § 390.5 indefinitely.

The revised text reads as follows:

§ 390.5 Definitions.

* * * * *

Lease, as used in subpart G of this part, means a contract or agreement in which a motor carrier of passengers grants the use of a passenger-carrying commercial motor vehicle to another motor carrier, with or without a driver, for a specified period for the transportation of passengers, whether or not compensation for such use is specified or required, when one or more of the motor carriers of passengers is not authorized to operate in interstate commerce pursuant to 49 U.S.C. 13901–13902. The term *lease* includes an interchange, as defined in this section, or other agreement granting the use of a passenger-carrying commercial motor vehicle for a specified period, with or without a driver, whether or not compensation for such use is specified or required. For a definition of *lease* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

Lessee, as used in subpart G of this part, means the motor carrier obtaining the use of a passenger-carrying commercial motor vehicle, with or without the driver, from another motor carrier, through a *lease* as defined in this section. The term *lessee* includes a motor carrier obtaining the use of a passenger-carrying commercial motor vehicle from another motor carrier under an interchange or other agreement, with or without a driver, whether or not compensation for such use is specified. For a definition of *lessee* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

Lessor, as used in subpart G of this part, means the motor carrier granting the use of a passenger-carrying commercial motor vehicle, with or without the driver, to another motor carrier, through a *lease* as defined in this section. The term *lessor* includes a motor carrier granting the use of a passenger-carrying commercial motor vehicle, with or without the driver, to another motor carrier under an interchange or other agreement, whether or not compensation for such use is specified. For a definition of *lessor* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

* * * * *

■ 3. Amend § 390.5T by revising the definitions of ''Lease,'' ''Lessee,'' and ''Lessor'' to read as follows:

§ 390.5T Definitions.

* * * * *

Lease, as used in subpart G of this part, means a contract or agreement in which a motor carrier of passengers grants the use of a passenger-carrying commercial motor vehicle, with or without the driver, to another motor carrier, for a specified period for the transportation of passengers, whether or not compensation for such use is specified or required, when one or more of the motor carriers of passengers is not authorized to operate in interstate commerce pursuant to 49 U.S.C. 13901–13902. The term *lease* includes an interchange, as defined in this section, or other agreement granting the use of a passenger-carrying commercial motor vehicle, with or without the driver, for a specified period, whether or not compensation for such use is specified or required. For a definition of *lease* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

Lessee, as used in subpart G of this part, means the motor carrier obtaining the use of a passenger-carrying commercial motor vehicle, with or without the driver, from another motor carrier, through a *lease* as defined in this section. The term *lessee* includes a motor carrier obtaining the use of a passenger-carrying commercial motor vehicle, with or without the driver, from another motor carrier under an interchange or other agreement, whether or not compensation for such use is specified. For a definition of *lessee* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

Lessor, as used in subpart G of this part, means the motor carrier granting the use of a passenger-carrying commercial motor vehicle, with or without the driver, to another motor carrier, through a *lease* as defined in this section. The term *lessor* includes a motor carrier granting the use of a passenger-carrying commercial motor vehicle, with or without the driver, to another motor carrier under an interchange or other agreement, whether or not compensation for such use is specified. For a definition of *lessor* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

* * * * *

■ 4. Amend § 390.21 as follows:
■ a. Lift the suspension of the section;
■ b. Revise paragraph (e);
■ c. Remove paragraph (f);
■ d. Redesignate paragraphs (g) and (h) as paragraphs (f) and (g), respectively;
■ e. Suspend § 390.21 indefinitely.

The revised text reads as follows:

§ 390.21 Marking of self-propelled CMVs and intermodal equipment.

* * * * *

(e) *Rented CMVs and leased passenger-carrying CMVs.* A motor carrier operating a self-propelled CMV under a rental agreement or a passenger-carrying CMV under a lease, when the rental agreement or lease has a term not in excess of 30 calendar days, meets the requirements of this section if:

(1) The CMV is marked in accordance with the provisions of paragraphs (b) through (d) of this section; or

(2) Except as provided in paragraph (e)(2)(v) of this section, the CMV is marked as set forth in paragraph (e)(2)(i) through (iv) of this section:

(i) The legal name or a single trade name of the lessor is displayed in accordance with paragraphs (c) and (d) of this section.

(ii) The lessor's identification number preceded by the letters ''USDOT'' is displayed in accordance with paragraphs (c) and (d) of this section; and

(iii) The rental agreement or lease as applicable entered into by the lessor and the renting motor carrier or lessee conspicuously contains the following information:

(A) The name and complete physical address of the principal place of business of the renting motor carrier or lessee;

(B) The identification number issued to the renting motor carrier or lessee by FMCSA, preceded by the letters ''USDOT,'' if the motor carrier has been issued such a number. In lieu of the identification number required in this paragraph, the following information may be shown in a rental agreement:

(*1*) Whether the motor carrier is engaged in ''interstate'' or ''intrastate'' commerce; and

(*2*) Whether the renting motor carrier is transporting hazardous materials in the rented CMV;

(C) The sentence: ''This lessor cooperates with all Federal, State, and local law enforcement officials nationwide to provide the identity of customers who operate this rental CMV''; and

(iv) The rental agreement or lease as applicable entered into by the lessor and the renting motor carrier or lessee is carried on the rental CMV or leased passenger-carrying CMV during the full term of the rental agreement or lease. See the property-carrying leasing regulations at 49 CFR part 376 and the passenger-carrying leasing regulations at subpart G of this part for information that should be included in all leasing documents.

(v) *Exception.* (A) The passenger-carrying CMV operating under the 48-hour emergency exception pursuant to § 390.403(a)(2) of this part does not need to comply with paragraphs (e)(2)(iii) and (iv) of this section, provided the lessor and lessee comply with the requirements of § 390.403(a)(2).

(B) A motor carrier operating a self-propelled CMV under a lease subject to subpart G of this part (§§ 390.401 and 390.403) must begin complying with this paragraph (e) on January 1, 2021.

* * * * *

■ 5. Amend § 390.21T by
■ a. Revising paragraph (e);
■ b. Removing paragraph (f);
■ c. Redesignating paragraphs (g) and (h) as paragraphs (f) and (g), respectively.

The revision to read as follows:

§ 390.21T Marking of self-propelled CMVs and intermodal equipment.

* * * * *

(e) *Rented CMVs and leased passenger-carrying CMVs.* A motor carrier operating a self-propelled CMV under a rental agreement or a passenger-carrying CMV under a lease, when the rental agreement or lease has a term not in excess of 30 calendar days, meets the requirements of this section if:

(1) The CMV is marked in accordance with the provisions of paragraphs (b) through (d) of this section; or

(2) Except as provided in paragraph (e)(2)(v) of this section, the CMV is marked as set forth in paragraph (e)(2)(i) through (iv) of this section:

(i) The legal name or a single trade name of the lessor is displayed in accordance with paragraphs (c) and (d) of this section.

(ii) The lessor's identification number preceded by the letters ''USDOT'' is displayed in accordance with paragraphs (c) and (d) of this section; and

(iii) The rental agreement or lease as applicable entered into by the lessor and

the renting motor carrier or lessee conspicuously contains the following information:

(A) The name and complete physical address of the principal place of business of the renting motor carrier or lessee;

(B) The identification number issued to the renting motor carrier or lessee by FMCSA, preceded by the letters ''USDOT,'' if the motor carrier has been issued such a number. In lieu of the identification number required in this paragraph, the following information may be shown in a rental agreement:

(*1*) Whether the motor carrier is engaged in ''interstate'' or ''intrastate'' commerce; and

(*2*) Whether the renting motor carrier or lessee is transporting hazardous materials in the rented or leased CMV;

(C) The sentence: ''This lessor cooperates with all Federal, State, and local law enforcement officials nationwide to provide the identity of customers who operate this rental or leased CMV''; and

(iv) The rental agreement or lease as applicable entered into by the lessor and the renting motor carrier or lessee is carried on the rental CMV or leased passenger-carrying CMV during the full term of the rental agreement or lease. See the property-carrying leasing regulations at 49 CFR part 376 and the passenger-carrying leasing regulations at subpart G of this part for information that should be included in all leasing documents.

(v) *Exception.* (A) A passenger-carrying CMV operating under the 48-hour emergency exception pursuant to § 390.403(a)(2) of this part does not need to comply with paragraphs (e)(2)(iii) and (iv) of this section, provided the lessor and lessee comply with the requirements of § 390.403(a)(2).

(B) A motor carrier operating a self-propelled CMV under a lease subject to subpart G of this part (§§ 390.401 and 390.403) must begin complying with this paragraph (e) on January 1, 2021.

* * * * *

Subpart F—[Removed and Reserved]

■ 6. Remove and reserve subpart F of part 390, consisting of §§ 390.300T through 390.305.

■ 5. Add subpart G, consisting of §§ 390.401 and 390.403, to read as follows:

Subpart G—Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles

Sec.

390.401 Applicability.
390.403 Lease and interchange requirements.

Subpart G—Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles

§ 390.401 Applicability.

(a) *General.* Beginning on January 1, 2021, and except as provided in paragraphs (b)(1) and (2) of this section, this subpart applies to the following actions, irrespective of duration, or the presence or absence of compensation, by motor carriers operating commercial motor vehicles to transport passengers:

(1) The lease of passenger-carrying commercial motor vehicles; and

(2) The interchange of passenger-carrying commercial motor vehicles between motor carriers.

(b) *Exceptions*—(1) *Contracts and agreements between motor carriers of passengers with active passenger carrier operating authority registrations.* This subpart does not apply to contracts and agreements between motor carriers of passengers that have active passenger carrier operating authority registrations with the Federal Motor Carrier Safety Administration when one such motor carrier acquires transportation service(s) from another such motor carrier(s).

(2) *Financial leases.* This subpart does not apply to a contract (however designated, *e.g.,* lease, closed-end lease, hire purchase, lease purchase, purchase agreement, installment plan, demonstration or loaner vehicle, etc.) between a motor carrier and a bank or similar financial organization or a manufacturer or dealer of passenger-carrying commercial motor vehicles allowing the motor carrier to use the passenger-carrying commercial motor vehicle.

(c) *Penalties.* If the use of a passenger-carrying commercial motor vehicle is conferred on one motor carrier subject to this subpart by another such motor carrier without a lease or interchange agreement, or pursuant to a lease or interchange agreement that fails to meet all applicable requirements of subpart G, both motor carriers shall be subject to a civil penalty.

§ 390.403 Lease and interchange requirements.

Beginning on January 1, 2021, and except as provided in § 390.401(b) of this section, a motor carrier may transport passengers in a leased or interchanged commercial motor vehicle only under the following conditions:

(a) *In general*—(1) *Lease or agreement required.* There shall be in effect either:

(i) A lease granting the use of the passenger-carrying commercial motor vehicle and meeting the conditions of paragraphs (b) and (c) of this section. The provisions of the lease shall be adhered to and performed by the lessee; or

(ii) An agreement meeting the conditions of paragraphs (b) and (c) of this section and governing the interchange of passenger-carrying commercial motor vehicles between motor carriers of passengers conducting service on a route or series of routes. The provisions of the interchange agreement shall be adhered to and performed by the lessee.

(2) *Exception.* When an event occurs (*e.g.,* a crash, the vehicle is disabled) that requires a motor carrier of passengers immediately to obtain a replacement vehicle from another motor carrier of passengers, the two carriers may postpone the writing of the lease or written agreement for the replacement vehicle for up to 48 hours after the time the lessee takes exclusive possession and control of the replacement vehicle. However, during that 48-hour period, until the lease or agreement is written and provided to the driver, the driver must carry, and produce upon demand of an enforcement official, a document signed and dated by the lessee's driver or available company official stating: ''[Carrier A, USDOT number, telephone number] has leased this vehicle to [Carrier B, USDOT number, telephone number] pursuant to 49 CFR 390.403(a)(2).''

(b) *Contents of the lease.* The lease or interchange agreement required by paragraph (a) of this section shall contain:

(1) *Vehicle identification information.* The name of the vehicle manufacturer, the year of manufacture, and at least the last 6 digits of the Vehicle Identification Number (VIN) of each passenger-carrying commercial motor vehicle transferred between motor carriers pursuant to the lease or interchange agreement.

(2) *Parties.* The legal name, USDOT number, and telephone number of the motor carrier providing passenger transportation in a commercial motor vehicle (lessee) and the legal name, USDOT number, and telephone number of the motor carrier providing the equipment (lessor), and signatures of both parties or their authorized representatives.

(3) *Specific duration.* The time and date when, and the location where, the lease or interchange agreement begins and ends.

(4) *Exclusive possession and responsibilities.* (i) A clear statement that the motor carrier obtaining the passenger-carrying commercial motor vehicle (the lessee) has exclusive possession, control, and use of the passenger-carrying commercial motor

vehicle for the duration of the agreement, and assumes complete responsibility for operation of the vehicle and compliance with all applicable Federal regulations for the duration of the agreement.

(ii) In the event of a sublease between motor carriers, all of the requirements of this section shall apply to a sublease.

(c) *Copies of the lease.* A copy shall be on the passenger-carrying commercial motor vehicle during the period of the lease or interchange agreement, and both the lessee and lessor shall retain a copy of the lease or interchange agreement for 1 year after the expiration date.

Issued under the authority delegated in 49 CFR 1.87.

Dated: August 8, 2019.

Raymond P. Martinez,

Administrator.

[FR Doc. 2019–17342 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

RIN 0648–XG660

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Amendment 17 to the Coastal Pelagic Species Fishery Management Plan

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

ACTION: Notice of agency decision.

SUMMARY: NMFS announces the approval of Amendment 17 to the Coastal Pelagic Species Fishery Management Plan. On June 10, 2019, the Regional Administrator of the West Coast Region, NMFS, with the concurrence of the Assistant Administrator for Fisheries, approved Amendment 17 to the Coastal Pelagic Species Fishery Management Plan. The intent of Amendment 17 is to allow the Pacific Fishery Management Council flexibility in recommending restrictions on the live bait portion of the fishery when a stock is overfished.

DATES: The amendment was approved on June 10, 2019.

ADDRESSES: Copies of the Coastal Pelagic Species Fishery Management Plan as amended through Amendment 17, are available at the Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384, or at this URL: *https://www.pcouncil.org/coastal-pelagic-species/fishery-management-plan-and-amendments/.*

FOR FURTHER INFORMATION CONTACT: Lynn Massey, Sustainable Fisheries Division, NMFS West Coast Region, at 562–436–2462; or Kerry Griffin, Pacific Fishery Management Council, at 503–820–2280.

SUPPLEMENTARY INFORMATION: Amendment 17 removed the pre-specified incidental landing limit for overfished stocks for vessels fishing for live bait. Prior to Amendment 17, if a Coastal Pelagic Species stock were to become overfished, and even prior to adoption of a rebuilding plan, the Fishery Management Plan automatically limited retention in the live bait fishery of that stock to only incidentally caught fish with no more than 15 percent of any load being from the overfished stock.

NMFS published a Notice Availability for Amendment 17 on March 22, 2019 (84 FR 10768), and solicited public comments through May 21, 2019. NMFS received three public comments from industry representatives in support of Amendment 17. The industry representatives included the American Albacore Fishing Associations, the Sportfishing Association of California, and a private fisherman from southern California.

There are no implementing regulations associated with Amendment 17; therefore, NMFS did not promulgate a proposed and final rule to implement this amendment.

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

Dated: August 9, 2019.

Samuel D. Rauch III,

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

[FR Doc. 2019–17465 Filed 8–13–19; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 157
Wednesday, August 14, 2019

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AN87

Prevailing Rate Systems; Redefinition of Certain Appropriated Fund Federal Wage System Wage Areas

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing a proposed rule that would redefine the geographic boundaries of several appropriated fund Federal Wage System (FWS) wage areas for pay-setting purposes. Based on recent reviews of Metropolitan Statistical Area (MSA) boundaries in a number of wage areas, OPM proposes redefinitions affecting the following wage areas: Washington, DC; Hagerstown-Martinsburg-Chambersburg, MD; Detroit, MI; Jackson, MS; Meridian, MS; and Cleveland, OH.

DATES: Send comments on or before September 13, 2019.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Madeline Gonzalez, by telephone at (202) 606–2838 or by email at *pay-leave-policy@opm.gov.*

SUPPLEMENTARY INFORMATION: OPM is issuing a proposed rule to redefine the geographic boundaries of several appropriated fund FWS wage areas. These changes are based on recommendations of the Federal Prevailing Rate Advisory Committee (FPRAC), the statutory national labor-management committee responsible for advising OPM on matters affecting the pay of FWS employees. From time to time, FPRAC reviews the boundaries of wage areas and provides OPM with recommendations for changes if the Committee finds that changes are warranted.

OPM considers the following regulatory criteria under 5 CFR 532.211 when defining FWS wage area boundaries:

(i) Distance, transportation facilities, and geographic features;

(ii) Commuting patterns; and

(iii) Similarities in overall population, employment, and the kinds and sizes of private industrial establishments.

In addition, OPM regulations at 5 CFR 532.211 do not permit splitting MSAs for the purpose of defining a wage area, except in very unusual circumstances.

The Office of Management and Budget (OMB) defines MSAs and maintains and periodically updates the definitions of MSA boundaries. MSAs are composed of counties and are defined on the basis of a central urbanized area—a contiguous area of relatively high population density. Additional surrounding counties are included in MSAs if they have strong social and economic ties to central counties.

When the boundaries of wage areas were first established in the 1960s, there were fewer MSAs than there are today and the boundaries of the then existing MSAs were much smaller. Most MSAs were contained within the boundaries of a wage area. With each OMB update, MSAs have expanded and in some cases now extend beyond the boundaries of the wage area.

FPRAC recently reviewed several wage areas where boundaries subdivide certain MSAs and has recommended by consensus that OPM implement the changes described in this proposed rule. These changes would be effective on the first day of the first applicable pay period beginning on or after 30 days following publication of the final regulations.

Washington-Arlington-Alexandria, DC-VA-MD-WV MSA

Washington, DC; Calvert, Charles, Frederick, Montgomery, and Prince George's Counties, MD; Alexandria, Fairfax, Falls Church, Fredericksburg, Manassas, and Manassas Park Cities, VA; Arlington, Clarke, Culpeper, Fairfax, Fauquier, Loudoun, Madison, Prince William, Rappahannock, Spotsylvania, Stafford, and Warren Counties, VA; and Jefferson County, WV, comprise the Washington-Arlington-Alexandria, DC-MD-VA-WV MSA.

The Washington-Arlington-Alexandria MSA is split between the Washington, DC, wage area and the Hagerstown-Martinsburg-Chambersburg, MD, wage area. Washington, DC; Charles, Frederick, Montgomery, and Prince George's Counties, MD; Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park Cities, VA; and Arlington, Fairfax, Loudoun, and Prince William Counties, VA, are part of the Washington, DC, survey area. Calvert County, MD; Fredericksburg City, VA; Clarke, Culpeper, Fauquier, Rappahannock, Spotsylvania, Stafford, and Warren Counties, VA; and Jefferson County, WV, are part of the Washington, DC, area of application. Madison County, VA, is part of the Hagerstown-Martinsburg-Chambersburg area of application.

OPM proposes to redefine Madison County to the Washington, DC, area of application so that the entire Washington-Arlington-Alexandria, DC-VA-MD-WV MSA is in one wage area. There are currently 44 FWS employees working in Madison County.

Toledo, OH MSA

Fulton, Lucas, Ottawa, and Wood Counties, OH, comprise the Toledo, OH MSA.

The Toledo MSA is split between the Cleveland, OH, wage area and the Detroit, MI, wage area. Ottawa County is part of the Cleveland area of application while Fulton, Lucas, and Wood Counties are part of the Detroit area of application.

OPM proposes to redefine Ottawa County to the Detroit area of application so that the entire Toledo, OH MSA is in one wage area. There are currently 38 FWS employees working in Ottawa County.

Hattiesburg, MS MSA

Covington, Forrest, Lamar, and Perry Counties, MS, comprise the Hattiesburg, MS MSA.

The Hattiesburg MSA is split between the Jackson, MS, wage area and the Meridian, MS, wage area. Covington County is part of the Jackson area of application. Forrest and Lamar Counties are part of the Meridian survey area while Perry County is part of the Meridian area of application.

OPM proposes to redefine Covington County to the Meridian area of application so that the entire Hattiesburg, MS MSA is in one wage area. There are currently no FWS employees working in Covington County.

Regulatory Impact Analysis

This action is not a ''significant regulatory action'' under the terms of Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under E.O. 12866 and 13563 (76 FR 3821, January 21, 2011).

Reducing Regulation and Controlling Regulatory Costs

This rule is not an Executive Order 13771 regulatory action because this rule is not significant under E.O. 12866.

Regulatory Flexibility Act

OPM certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

Civil Justice Reform

This regulation meets the applicable standard set forth in Executive Order 12988.

Unfunded Mandates Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of nonagency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act (Subtitle E of the Small Business ''Regulatory Enforcement Fairness Act of 1996 (SBREFA)). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

Office of Personnel Management.

Stephen Hickman,

Regulatory Affairs.

Accordingly, OPM is proposing to amend 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

■ 1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

■ 2. Appendix C to subpart B is amended by revising the wage area listings for the Washington, DC; Hagerstown-Martinsburg-Chambersburg, MD; Detroit, MI; Jackson, MS; Meridian, MS; and, Cleveland, OH, wage areas to read as follows:

Appendix C to Subpart B of Part 532—Appropriated Fund Wage and Survey Areas

* * * * *

DISTRICT OF COLUMBIA

Washington, DC

Survey Area

District of Columbia:
  Washington, DC
Maryland:
  Charles
  Frederick
  Montgomery
  Prince George's
Virginia (cities):
  Alexandria
  Fairfax
  Falls Church
  Manassas
  Manassas Park
Virginia (counties):
  Arlington
  Fairfax
  Loudoun
  Prince William

Area of Application. Survey area plus:

Maryland:
  Calvert
  St. Mary's
Virginia (city):
  Fredericksburg
Virginia (counties):
  Clarke
  Culpeper
  Fauquier
  King George
  Madison
  Rappahannock
  Spotsylvania
  Stafford
  Warren
West Virginia:
  Jefferson

* * * * *

MARYLAND

* * * * *

Hagerstown-Martinsburg-Chambersburg

Survey Area

Maryland:
  Washington
Pennsylvania:
  Franklin
West Virginia:
  Berkeley

Area of Application. Survey area.

Maryland:
  Allegany
  Garrett
Pennsylvania:
  Fulton
Virginia (cities):
  Harrisonburg
  Winchester
Virginia (counties):
  Frederick
  Page
  Rockingham
  Shenandoah
West Virginia:
  Hampshire
  Hardy
  Mineral
  Morgan

* * * * *

MICHIGAN

Detroit

Survey Area

Michigan:
  Lapeer
  Livingston
  Macomb
  Oakland
  St. Clair
  Wayne

Area of Application. Survey area.

Michigan:
  Arenac
  Bay
  Clare
  Clinton
  Eaton
  Genesee
  Gladwin
  Gratiot
  Huron

Ingham
Isabella
Lenawee
Midland
Monroe
Saginaw
Sanilac
Shiawassee
Tuscola
Washtenaw
Ohio:
Fulton
Lucas
Ottawa
Wood
* * * * *

MISSISSIPPI

* * * * *

Jackson

Survey Area

Mississippi:
Hinds
Rankin
Warren
Area of Application. Survey area.
Mississippi:
Adams
Amite
Attala
Claiborne
Copiah
Franklin
Holmes
Humphreys
Issaquena
Jefferson
Jefferson Davis
Lawrence
Lincoln
Madison
Marion
Pike
Scott
Sharkey
Simpson
Smith
Walthall
Wilkinson
Yazoo

Meridian

Survey Area

Alabama:
Choctaw
Mississippi:
Forrest
Lamar
Lauderdale
Area of Application. Survey area plus:
Alabama:
Sumter
Mississippi:
Clarke
Covington
Greene
Jasper
Jones
Kemper
Leake
Neshoba
Newton
Perry
Wayne
* * * * *

OHIO

* * * * *

Cleveland

Survey Area

Ohio:
Cuyahoga
Geauga
Lake
Medina
Area of Application. Survey area plus:
Ohio:
Ashland
Ashtabula
Carroll
Columbiana
Erie
Huron
Lorain
Mahoning
Portage
Sandusky
Seneca
Stark
Summit
Trumbull
Wayne
Pennsylvania:
Mercer
* * * * *

[FR Doc. 2019–17413 Filed 8–13–19; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0466; Airspace Docket No. 19–ACE–8]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Marshalltown, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface at Marshalltown Municipal Airport, Marshalltown, IA. The FAA is proposing this action as the result of an airspace review caused by the decommissioning of the Elmwood VHF omnidirectional range (VOR) navigation aid, which provided navigation guidance for the instrument procedures at these airports, as part of the VOR Minimum Operational Network (MON) Program. Airspace redesign is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Comments must be received on or before September 30, 2019.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2019–0466; Airspace Docket No. 19–ACE–8, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

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

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

amend Class E airspace extending upward from 700 feet above the surface at Marshalltown Municipal Airport, Marshalltown, IA, to support IFR operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2019–0466; Airspace Docket No. 19–ACE–8.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

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

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

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E airspace extending upward from 700 feet above the surface to within a 6.5-mile radius (increased from a 6.4-mile radius) of Marshalltown Municipal Airport, Marshalltown, IA.

This action is necessary due to an airspace review caused by the decommissioning of the Elmwood VOR, which provided guidance information for the instrument procedures at these airports, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

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

* * * * *

ACE IA E5 Marshalltown, IA [Amended]

Marshalltown Municipal Airport, IA
(Lat. 42°06′46″ N, long. 92°55′04″ W)

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

Issued in Fort Worth, Texas, on August 7, 2019.

John Witucki,

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

[FR Doc. 2019–17368 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0591; Airspace Docket No. 19–ASO–15]

RIN 2120–AA66

Proposed Establishment of Class E Airspace, St Simons, GA, and Brunswick, GA; Proposed Revocation of Class E Airspace, Brunswick, GA, and Proposed Amendment of Class E Airspace, Brunswick, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E surface airspace for St Simons Island Airport, St Simons, GA, and for Brunswick Golden Isles Airport, Brunswick, GA, and amend Class E airspace extending upward from 700 feet above the surface in Brunswick, GA, to accommodate airspace reconfiguration due to the airport's names and cities requiring updates. Also, this action proposes to remove Class E surface airspace listed as Brunswick Glynco Jetport, GA, and Brunswick Malcolm-McKinnon Airport, GA in the FAA's 7400.11C. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at these airports. This action also would update the geographic coordinates of St Simons Island Airport, (formally Brunswick Malcolm-McKinnon Airport). In addition, this action proposes to amend Class E airspace extending upward from 700 feet above the surface in the Brunswick area by updating the name and geographic coordinates of St Simons Island Airport and Brunswick Golden Isles Airport.

DATES: Comments must be received on or before September 30, 2019.

ADDRESSES: Send comments on this proposal to: the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2019–0591; Airspace Docket No. 19–ASO–15, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

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

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace at St Simons Island Airport, St Simons, GA, and Brunswick Golden Isles Airport, Brunswick, GA, as well as amend Class E airspace in Brunswick, GA to support IFR operations in the area. Also, this action would remove outdated airspace in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2019–0591 and Airspace Docket No. 19–ASO–15) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number.) You may also submit comments through the internet at *http://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2019–0591; Airspace Docket No. 19–ASO–15.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed

in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to establish Class E surface airspace at St Simons Island Airport, St Simons, GA, and Brunswick Golden Isle Airport, Brunswick, GA. Also, this action proposes to amend Class E airspace extending upward from 700 feet or more above the surface at Brunswick, GA, by updating the airport names to St Simons Island Airport (previously Brunswick/Malcolm-McKinnon Airport), and Brunswick Golden Isles Airport (previously Glynco Jetport Airport). Also, the geographic coordinates of St Simons Island Airport would be adjusted to coincide with the FAA's aeronautical database.

Class E airspace designations are published in Paragraph 6005, of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6002 Class E Surface Area Airspace.

* * * * *

ASO GA E2 St Simons, GA [New]

St Simons Island Airport, GA
(Lat. 31°09′07″ N, long. 81°23′28″ W)

That airspace extending upward from the surface within a 4.1-mile radius of St Simons Island Airport.

* * * * *

ASO GA E2 Brunswick, GA [New]

Brunswick Golden Isles Airport, GA
(Lat. 31°15′33″ N, long. 81°27′59″ W)

That airspace extending upward from the surface within a 4.2-mile radius of Brunswick Golden Isles Airport.

* * * * *

ASO GA E2 Brunswick Glynco Jetport, GA [Removed]

* * * * *

ASO GA E2 Brunswick Malcolm-McKinnon Airport, GA [Removed]

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

* * * * *

ASO GA E5 Brunswick, GA [Amended]

St Simons Island Airport, GA
(Lat. 31°09′07″ N, long. 81°23′28″ W)
Brunswick Golden Isles Airport, GA
(Lat. 31°15′33″ N, long. 81°27′59″ W)
Jekyll Island Airport, GA
(Lat. 31°04′28″ N, long. 81°25′40″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the St Simons Island Airport, and within a 7-mile radius of Brunswick Golden Isles Airport, and within a 9-mile radius of Jekyll Island Airport.

Issued in College Park, Georgia, on August 7, 2019.

Matthew Cathcart,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2019–17369 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Part 111

[USCBP–2019–0024]

RIN 1651–AB17

Customs Broker Verification of an Importer's Identity

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

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes to amend the U.S. Customs and Border Protection (CBP) regulations to require customs brokers to collect certain information from importers to enable the customs brokers to verify the identity of importers, including nonresident importers. CBP proposes these amendments, pursuant to section 116 of the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA), which directs CBP to promulgate regulations to require brokers to verify the identity of the importers who are their clients.

DATES: Comments must be received on or before October 15, 2019.

ADDRESSES: You may submit comments, identified by *docket number,* by *one* of the following methods:

- Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments via Docket No. USCBP–2019–0024.
- *Mail:* Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the

SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Submitted comments may be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE, 10th Floor, Washington, DC 20229–1177. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325–0118.

FOR FURTHER INFORMATION CONTACT: Randy Mitchell, Director, Commercial Operations Revenue Entry Division, Office of Trade, U.S. Customs and Border Protection, 202–325–6532, *Randy.mitchell@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this proposed rule. U.S. Customs and Border Protection (CBP) also invites comments that relate to the economic, environmental, or federalism effects that might result from this regulatory change. Comments that will provide the most assistance to CBP will reference a specific portion of the rule, explain the reason for any recommended change, and include data, information or authority that support such recommended change. *See* **ADDRESSES** above for information on how to submit comments.

II. Background

Section 641 of the Tariff Act of 1930, as amended (19 U.S.C. 1641), provides that individuals and business entities must hold a valid customs broker's license and permit in order to transact customs business on behalf of others. The statute also sets forth standards for the issuance of broker's licenses and permits, provides for disciplinary action against brokers in the form of suspension or revocation of such licenses and permits or assessment of monetary penalties, and provides for the assessment of monetary penalties against other persons for conducting customs business without the required broker's license. Section 641 authorizes the Secretary of the Treasury to prescribe rules and regulations relating to the customs business of brokers as may be necessary to protect importers and the revenue of the United States and to carry out the provisions of section 641.[1]

The regulations issued under the authority of section 641 are set forth in part 111 of title 19 of the Code of Federal Regulations (CFR) (19 CFR part 111). Customs brokers serve many functions when acting on behalf of their clients, which include resident and nonresident importers. Customs brokers file information about their clients' merchandise and transactions with CBP. Customs brokers also track shipments, pay duties and fees to CBP, and keep current documents and records about the business they transact on behalf of their clients, all to help their clients comply with Federal import and export laws. *See* 19 CFR part 111 subpart C.

However, before a customs broker may transact customs business on behalf of a client, the broker must obtain a valid power of attorney (POA). 19 CFR 141.46. A POA authorizes the customs broker to become that client's agent and to prepare and file the necessary customs documents on their behalf.

A. Current POA Regulations

In the customs broker context, a valid POA is the written appointment of the broker as the true and lawful agent of the principal (*i.e.,* client) allowed to transact customs business on behalf of the principal. The regulations governing POAs are set forth in 19 CFR part 141 subpart C.

A POA may be executed for a specified part of the principal's business (limited power of attorney) or all of the principal's customs business (general power of attorney). *See* 19 CFR 141.31(a). Pursuant to 19 CFR 141.32, POAs can be executed through various means. CBP Form 5291 may be used to establish a power of attorney. If CBP Form 5291 is not used, a limited POA must be executed in the same manner and as explicit in its terms as CBP Form 5291. 19 CFR 141.32. A general POA with unlimited authority may be executed in any format. *See* 19 CFR 141.32.

A POA issued by a partnership is limited to a period not to exceed two years from the date of execution. 19 CFR 141.34. All other POAs may be granted for an unlimited period of time. 19 CFR 141.34.

A valid POA requires the principal to provide only limited information. The principal is required to provide:

(1) A statement from the principal authorizing the customs broker to act as the principal's agent and for the customs broker to file entry/entry summary in the principal's name for a shipment;

(2) The name of the individual or the authorized representative of the sole proprietorship, partnership, or corporation executing the POA; and

(3) The name and address of the individual or business on whose behalf the POA is being executed.

See 19 CFR 141.32; 141.36–.39.

B. Customs Brokers' Current Practice for Verifying Importer's Identity

While only a limited amount of information is required for a valid POA, the majority of customs brokers currently require additional information when a POA is obtained from an importer, which is used by the broker to verify the importer's existence and identity. Brokers require this additional information and have initiated processes and procedures to validate an importer's identity in order to protect the broker's business interests, reduce identity theft, and help to prevent the use of shell [2] or shelf [3] companies to further a business fraud scheme. Additional information that a broker might request includes, but is not limited to, the registration of the importer's business with a state government and the Articles of Incorporation under which that business is formed.

CBP provides non-binding guidance on how brokers can validate importers when they obtain a POA. For example, CBP recommends that a broker should, whenever possible, do the following: [4]

[1] The Homeland Security Act of 2002 generally transferred the functions of the U.S. Customs Service from the Treasury Department to the Secretary of the Department of Homeland Security (DHS). *See* Pub. L. 107–296, 116 Stat. 2142. The Act provides that the Secretary of the Treasury retains customs revenue functions unless delegated to the Secretary of DHS. The regulation of customs brokers is encompassed within the customs revenue functions set forth in section 412 of the Homeland Security Act. On May 15, 2003, the Secretary of the Treasury delegated authority related to the customs revenue functions to the Secretary of DHS subject to certain exceptions. *See* Treasury Order No. 100–16 (Appendix to 19 CFR part 0). Since the authority to prescribe the rules and regulations related to customs brokers is not listed as one of the exceptions, this authority now resides with the Secretary of DHS.

[2] A shell company is a company without active business operations or significant assets, which may be used illegitimately to disguise business ownership or operations.

[3] A shelf company is a company which was created and maintained by legal means, but is left dormant for a period of time before its sale to a buyer, which may serve to conceal the buyer's identity and history of business transactions so as not to appear as a new business entity.

[4] *See* U.S. Customs and Border Protection, ''Validating the Power of Attorney'' for comprehensive list of recommendations. Last published May 25, 2018. Available at *https://*

Continued

(1) Complete POAs in-person and review personal identification (driver's license, passport, etc.);

(2) Check applicable websites to verify the business registration with State authorities;

(3) Confirm business's trade or fictitious names that may appear on the POA;

(4) Verify that the importer's name, importer number, and Employer Identification Number (EIN) (also known as the Federal Tax Identification Number) on the POA match what is in CBP's Automated Commercial Environment (ACE);

(5) Check whether an importer is named as a sanctioned or restricted person or entity by the U.S. Government.

Since the collection and verification of any additional information from the importer is voluntary, certain brokers do not require any additional information. As a result, an atmosphere of ''broker shopping'' has been created where an importer that does not wish to provide this additional information might refuse to provide the information to one broker in the hopes that another broker will not ask for that information. If the second broker does not request the additional information, that broker, with minimal knowledge about the importer, transacts customs business on the importer's behalf leading to the possible use of shell or shelf companies, revenue loss, increased security risks with the goods being imported into the United States, and an uneven playing field for brokers.

C. Section 116 of TFTEA

On February 24, 2016, Congress enacted the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA), Section 116, Public Law 114–125, 130 Stat. 122 (19 U.S.C. 4301 note), which amended section 641 of the Tariff Act of 1930 (19 U.S.C. 1641). Section 116 of TFTEA, *Customs Broker Identification of Importers,* specifically requires the Secretary to promulgate regulations setting minimum standards to: (1) Identify the information that an importer, including a nonresident importer, is required to submit to a customs broker and that a broker is required to collect in order to verify the identity of the importer; (2) identify reasonable procedures that a broker is required to follow in order to verify the authenticity of the information collected from the importer; and (3) require the broker to maintain records of the information collected by the broker used to substantiate the importer's identity. Section 116 also empowers the Secretary to assess a monetary penalty for each violation for a broker that fails to collect the information, as well as revoke or suspend the license or permit of the broker.

www.cbp.gov/trade/programs-administration/customs-brokers/validating-power-attorney.

III. Discussion of Proposed Amendments

CBP proposes to amend the CBP regulations to standardize the process by which customs brokers verify the identity of their clients, specifically importers and nonresident importers. These proposed regulations illuminate, for the international trade community and the public in general, the important role customs brokers have in verifying prospective clients and in ensuring the quality and integrity of the information they keep. When brokers verify the *bona fides* of clients, CBP is better assured that importers are conducting legitimate trade transactions. By formalizing the verification process and requiring that a reverification process be carried out by brokers every year, CBP believes that a broker's knowledge of its importer client would be improved. This improved broker knowledge could allow for commercial fraud prevention and revenue protection and help prevent the use of shell or shelf companies by importers who attempt to evade the customs laws of the United States. Preventing the use of shell or shelf companies by importers would help reduce instances of a misclassification of merchandise to avoid duties, protect against intellectual property rights (IPR) violations, reduce antidumping/countervailing duty (AD/CVD) infractions, and reduce the importation of unsafe merchandise.

As the importer's and nonresident importer's agent, the customs broker is uniquely situated to collect the information necessary to authenticate their identity. CBP has determined that it is most efficient for the broker to collect and verify this information at the time the POA is obtained because the broker must both verify the client's identity and obtain a valid POA before transacting customs business on behalf of the client.

CBP is proposing to add a new section, 111.43, entitled *Importer identity verification,* to title 19 of the CFR to establish the identity collection criteria and to create a required verification process of importer and nonresident importer clients. These proposed regulations set forth the minimum requirements a customs broker must meet to verify the importer's identity prior to transacting customs business on behalf of the importer or nonresident importer client. As discussed above, most customs brokers already meet or exceed these minimum requirements. Customs brokers may continue to exceed the requirements in proposed section 111.43, regarding the collection of information and documents, or conducting research about a client.

Proposed paragraph (a) describes the general scope of the requirements for customs brokers to collect, verify, and maintain the information necessary to authenticate the identity of their clients.

Proposed paragraph (b) provides definitions for this section. In accordance with section 116(a)(i)(4) of TFTEA, the term ''importer'' is defined as one of the parties that qualifies to be an importer of record under 19 U.S.C. 1484(a)(2)(B) and ''nonresident importer'' is defined as an importer of record that is not a citizen of the United States or an alien lawfully admitted for permanent residence in the United States; or a partnership, corporation, or other commercial entity that is not organized under the laws of a jurisdiction within the customs territory of the United States (as such term is defined in General Note 2 of the Harmonized Tariff Schedule of the United States) or in the Virgin Islands of the United States.[5] The definition of the term ''client'' is the importer or nonresident importer of record who is seeking or employing the services of a customs broker to transact customs business on behalf of the importer or nonresident importer of record. The definition of the term ''grantor'' is the individual executing the power of attorney on behalf of the client.

A. Minimum Information That the Customs Broker Is Required To Collect From the Client

Proposed paragraph (c) of section 111.43 identifies the information that the customs broker is required to collect from the client at the time the POA is obtained by the broker. The broker collects this information to verify the client's identity.

At the time the POA is obtained by the broker, the broker must collect, at a minimum, the following information from the client, if applicable:

(1) The client's name;

(2) For a client who is an individual, the client's date of birth;

[5] We note that the definition for ''nonresident importer'' provided by Congress in section 116 of TFTEA differs from the definition of ''nonresident'' in 19 CFR 141.31 governing POAs. CBP does not discuss these differences in this notice of proposed rulemaking (NPRM) because the differing definitions of ''resident'' and ''nonresident'' in 19 CFR part 141 do not influence whether a broker is required to obtain a POA from a client on behalf of which it transacts customs business.

(3) For a client that is a partnership, corporation, or association, the grantor's date of birth;

(4) For a client that is a partnership, corporation, or association, the client's trade or fictitious names;

(5) The address of the client's physical location (for a client that is a partnership, corporation, or association, the physical location would be the client's headquarters) and telephone number;

(6) The client's email address and business website;

(7) A copy of the grantor's unexpired government-issued photo identification;

(8) The client's Internal Revenue Service (IRS) number, employer identification number (EIN), or importer of record (IOR) number;

(9) The client's publicly available business identification number (*e.g.,* Data Universal Numbering System (DUNS) number, etc.);

(10) A recent credit report;

(11) A copy of the client's business registration and license with state authorities; and

(12) The grantor's authorization to execute power of attorney on behalf of client.

The broker must collect all the information that is applicable to that particular client. Some information might not be applicable to a client depending on whether the client is an individual, partnership, corporation, or association. For example, a small business might not have a business website; or a client who is an individual would not have a business registration and license with state authorities or a publicly available business identification number. Additionally, if certain foreign jurisdictions do not provide credit reports, the broker is not required to collect a recent credit report from that client.

Under current practice, most brokers already collect all of the above applicable information from the client in the ordinary course of business. Most brokers currently require this information to ensure that the client is not concealing his or her identity, misusing another business owner's identity, or using a shell or shelf corporation to further a business fraud scheme. By requiring all of the applicable information above from all of the broker's clients, the proposed rule would also eliminate the ability of prospective clients to ''broker shop.''

B. Procedures That a Customs Broker Is Required To Perform To Verify the Information Collected

CBP is proposing procedures for a customs broker to use to verify the authenticity of the information collected from its clients. Proposed paragraph (d) of section 111.43 requires customs brokers to verify all the information collected from the client, under proposed paragraph (c), to ensure accurate identification of the client.

As explained in Section A. above, the broker must collect all the information set forth in proposed paragraph (c) that is applicable to that client. The broker would be required to verify each of the data points (*i.e.* client's name, address, etc.) that the broker collects from that particular client. The means of verification that the customs broker uses for each data point, however, are at the broker's discretion. There are various methods of verification that would satisfy CBP's requirement that the broker verify each data point that the broker collects. The means of verification that CBP recommends for each data point are set forth below and include in-person verification, review of the proper evidence of the grantor's authorization to execute the POA, and/or research performed using various federal agency, state government, and publicly available data sources. The broker must use as many of the recommended verification means as necessary to be reasonably certain of the client's identity.

In addition to verifying each data point collected, the broker would be required to check if the client is a sanctioned or restricted person or entity, or if the client is suspended or debarred from doing business with the U.S. Government.

Under the proposed rule, for any prospective client, the customs broker would be required to perform this verification before transacting customs business on the client's behalf. For existing clients with a POA issued by a partnership, brokers would have two years to verify this information and three years for all other existing clients.

1. The Client's Name, Address, Telephone Number, Email Address, Business Website, Trade or Fictitious Names

A customs broker could verify the client's name, address, telephone number, email, website, and trade or fictitious names, if applicable, through various means. A customs broker could use the Automated Broker Interface (ABI) to access ACE to verify a client's information. This means of verification is only available for a broker to access an existing client's information for transactions where the broker represented the client.

The broker could alternatively check the client's unexpired government-issued photo identification, the state licensing database or use open-source mapping. Customs brokers may also conduct research using reputable business information databases, individual state databases, and credit reporting entities or any other public or private database which provides accurate, timely, and relevant information about the client.

To verify the client's address, the broker could use various navigation and mapping functions available on public websites to verify the location. Warning signs could include an incomplete or inaccurate address, or providing only a post office box address. To verify the telephone number, the broker could verify whether the number is a landline as opposed to a cell phone and could use return call verification to ensure that the number is accurate. To verify the email address, the broker could ensure that there is a return email message.

If applicable, the broker could visit the client's place of business in-person to verify its existence and the client's identity. During this in-person visit, the broker would be looking for any possible indication that the client's identity is not what he or she provided; that the business is defunct or nonexistent; or that the company is a shell or shelf company. To verify a business website, the broker could check the depth of the website, the business universal resource locator (URL), and the viability of any links provided.

2. The Client's or Grantor's Date of Birth

There are various ways that a customs broker could verify the client's or grantor's date of birth. The broker could perform an in-person review of the client's or grantor's unexpired government-issued photo identification to verify the date of birth. Alternatively, a broker could use individual state databases or open-source software.

3. The Grantor's Unexpired Government-Issued Photo Identification

The customs broker can perform an in-person review of the grantor's unexpired government-issued photo identification such as a passport or driver's license. During this in-person verification, the broker would be looking for any possible indications that the grantor's identity is not what he or she provided, or that there is fraud. Alternatively, the broker may conduct research using reputable databases to establish the veracity of the government-issued photo identification.

4. The Client's IRS Number, EIN, or IOR Number

A customs broker could use federal government databases or the client's tax forms to verify the client's IRS, EIN, or IOR number. The broker could also use the ABI to access ACE to verify an existing client's IRS number, EIN, or IOR number. This means of verification is only available for a broker to access an existing client's information for transactions where the broker represented the client. Alternatively, the broker could conduct research using reputable public or private databases and websites, such as *www.freeerisa.com,* which is a private website that provides free access to all Employee Retirement Income Security Act (ERISA) form 5500s filed with the Department of Labor over the past two years.

5. The Client's Publicly Available Business Identification Number

If the client provides a non-government issued business identifier, the broker can use the associated database to verify the relevant aspects of that client's identification. For example, if the client provides its DUNS number, the broker could use the Dun and Bradstreet website at *www.DNB.com* to verify the client's DUNS number, company name, address, and telephone number.

6. A Recent Credit Report

To check the client's credit report, the broker would check with a nationally recognized credit reporting entity. When checking the client's credit report, warning signs could include declarations of bankruptcy, and any delayed payment history. If the client informs the broker that a credit report cannot be provided because its jurisdiction does not provide credit reports, the broker must verify this by checking the address of the client's physical location.

7. The Client's Business Registration and License With State Authorities

A broker could use individual state databases to verify the business registration and license.

8. The Grantor's Authorization To Execute Power of Attorney on Behalf of Client

A broker is required to confirm that the grantor has the authority to execute the POA. When a representative appears on behalf of the client, the representative would be required to provide evidence of his or her authorization to sign the POA. This evidence should be notarized whenever possible; however, the person whose signature is required is dependent on the type of business. To determine the type of evidence required, the broker would review the business's public filings, for example, the articles of incorporation, to determine who holds the key positions. For a corporation, the evidence would be a corporate officer providing certification on the entity's letterhead. For a limited liability company (LLC), the evidence would be the managing partner or member providing certification on the entity's letterhead. For a partnership, authorization would be the general and/or managing partner providing certification on the entity's letterhead. For a sole proprietorship or individual, evidence of authorization would consist of a certification, notarized by the sole proprietor or individual, stating that the representative was authorized to sign on behalf of the individual or the sole proprietor.

9. Check if the Client is a Sanctioned or Restricted Person or Entity by the U.S. Government or if the Client is Suspended or Debarred From Doing Business With the U.S. Government

The broker would be required to check to determine if the client is a sanctioned or restricted person or entity, or if the client is suspended or debarred from doing business with the U.S. Government. The broker could check this information through any of the following websites: *www.sam.gov,* a U.S. government website that may be used to search public records for company registrations; *https://www.treasury.gov/resource-center/sanctions/Pages/default.aspx,* which is a U.S. Department of Treasury website identifying Office of Foreign Assets Control (OFAC) sanctioned companies and individuals; or *https://build.export.gov/main/ecr/eg_main_023148,* which is a consolidated screening list identifying entities that have been sanctioned by U.S. Department of Commerce, International Trade Administration.

C. Requirement To Implement Policies, Procedures and Internal Controls

Proposed paragraph (e) of section 111.43 requires customs brokers to implement policies, procedures, and internal controls to verify a client's identity before transacting customs business on behalf of that client. While most customs brokers already have such policies, procedures, and internal controls in place to collect and verify this information, this requirement is to ensure that all brokers implement these policies, procedures, and internal controls so that brokers are required to collect the required information from the client, and to ensure that the broker has established policies and procedures to verify and reverify the information.

D. Recordkeeping Requirements

Section 116 of TFTEA requires that the regulations also set minimum standards for customs brokers to maintain records of the information used to substantiate the client's identity. Accordingly, proposed paragraph (f) requires all customs brokers to make, retain, and update records containing the information the brokers collected to verify the client's identity.

1. Current Recordkeeping Requirements

Customs brokers must make, retain, and update certain records of their transactions with their clients and must comply with all recordkeeping requirements. For customs brokers, the relevant recordkeeping provisions are in part 111 and part 163 and each broker must comply with the provisions of those parts when maintaining records that reflect on his or her transactions as a broker. 19 CFR 111.21 and 163.2(d). Part 163 governs the maintenance, production, inspection, and examination of records, in general. Part 111 sets forth the specific recordkeeping requirements applicable to customs brokers, and the additional records that each customs broker must make and maintain, and make available for CBP examination.

Pursuant to part 111, customs brokers are required to keep current records of account reflecting all their transactions as a broker, and keep and maintain copies of all correspondence and other records relating to their customs business. 19 CFR 111.21. A broker is not required to file a POA with CBP but must retain the POA as part of his or her records and make it available to representatives of the Department of Homeland Security (DHS).[6] *See* 19 CFR 141.46. Customs brokers must maintain all these records for the required retention periods, in a manner that allows CBP to readily examine them, and pursuant to an allowable method of storage. *See* 19 CFR 111.25 and 163.5. These records, except for POAs, must be retained for at least five years after the date of entry. *See* 19 CFR 111.23 and 163.4. POAs must be retained until

[6] Subpart C of 19 CFR part 111 provides that the POA and other records must be made available to representatives of the Department of the Treasury; however, pursuant to the Homeland Security Act of 2002 and Treasury Order No. 100–16 (Appendix to 19 CFR part 0), this was delegated to representatives of the Secretary of DHS as opposed to representatives of the Department of the Treasury. *See* Pub. L. 107–296, 116 Stat. 2142.

revoked, and revoked POAs and letters of revocation must be retained for five years after the date of revocation or for five years after the date the client ceases to be an ''active client'' as defined in section 111.29(b)(2)(ii), whichever period is later. *See* 19 CFR 111.23 and 163.4.

The proposed regulations add additional records to 19 CFR part 111 that the customs broker must make, retain, update, and have readily available for CBP examination.

2. Retention of Identification and Verification Records

Proposed paragraphs (f)(1) and (2) of section 111.43 set forth the minimum identification and verification records that customs brokers must retain. At a minimum, customs brokers must retain the information required by proposed paragraph (c), including any identification records, which consists of the information presented to the broker used to identify the client as well as any certifications the client makes. Customs brokers must also retain verification records of the means and documents relied on to verify the client's identity as required by proposed paragraph (d) and each record must indicate which information required pursuant to proposed paragraph (c) was verified by those means and documents. At a minimum, for the verification records, customs brokers must retain descriptions of any documents relied upon, any non-documentary methods, any results of measures undertaken, and any resolution of discrepancies as well as who performed the verification and the date the verification was performed. Brokers must indicate in the verification records which information required pursuant to proposed paragraph (c) was not collected from the client because it was inapplicable to that particular client.

3. Records Must Be Readily Available for CBP Examination

The identification and verification records collected by the broker must be retained in accordance with 19 CFR 111.23 and be made available upon request by CBP for examination. The period of retention for the identification and verification records shall be the same as for POAs. *See* 19 CFR 111.23 and 163.4.

4. Updating the POA, Identification and Verification Records

Proposed paragraph (f)(4) requires customs brokers to implement procedures to ensure the accuracy, timeliness, completeness, and relevancy of any POA and any information about the client. These procedures must include a requirement that customs brokers update their records annually with any changes to the client, POA, or the information in the records, and reverify the client's identity.

The customs broker would update this information with new information or records received through either the client or through the broker's independent research. Customs brokers must update their information on an annual basis about any client and its business to ensure that the information they have is timely, accurate, complete, and relevant, and they must reverify the client's identity annually using the procedures set forth in proposed section 111.43(d). Depending on the client, maintaining the information could include setting up news alerts about the client, confirming with a client the accuracy of information, or setting up automatic searches in specific databases. This ensures the quality and integrity of the information in the POA, and in the identification and verification records.

E. Penalties for Failure To Meet the Requirements

Section 116 of TFTEA amended section 641 of the Tariff Act of 1930 (19 U.S.C. 1641) to authorize the Secretary, at his or her discretion, to hold any customs broker liable if the broker fails to collect the required information for a monetary penalty not to exceed $10,000 for each violation and to revoke or suspend a license or permit of the customs broker pursuant to the procedures set forth in section 641(d). Further, it holds that the penalty shall be assessed in the same manner and under the same procedures as the monetary penalties provided for in section 641(d)(2)(A). *See* 19 U.S.C. 1641(d)(2)(A). The provisions relating to assessment of a monetary penalty under sections 641(b)(6) and (d)(2)(A), Tariff Act of 1930, as amended (19 U.S.C. 1641(b)(6) and (d)(2)(A)), are set forth in 19 CFR 111, subpart E.

Proposed paragraph (g) sets forth the conditions under which CBP may assess a monetary penalty and the maximum amount that a penalty may be assessed for. CBP may, at its discretion, assess a monetary penalty for a broker's failure to collect, verify, secure, retain, update, or make available for inspection the information in this section in an amount not to exceed $10,000 per client. CBP could also choose to revoke or suspend the customs broker's license or permit in accordance with 19 U.S.C. 1641(d)(2)(B).

F. Timing of Verifications

Proposed paragraph (h) of section 111.43 provides the different timing requirements for verifications based on whether it is a prospective or existing client. This is to allow customs brokers that are not already collecting, verifying, and maintaining the information, additional time to start complying with the requirements for existing clients.

For prospective clients, customs brokers would be required to comply with proposed 19 CFR 111.43 as of the effective date of the final rule. A customs broker would not be permitted to begin transacting customs business on behalf of that client until the broker collected the required information and verified the client's identity. The broker would also be required to reverify the client's identity on an annual basis.

For existing clients with a POA issued by a partnership, customs brokers would have two years from the effective date of the final rule to verify the client's identity, and to update the necessary identification and verification records. This is because, as discussed above, unlike all other POAs, a POA issued by a partnership is limited to a period not to exceed two years from the date of execution. *See* 19 CFR 141.34. Brokers would have to reverify the client's identity on an annual basis after the initial verification.

For all other existing clients, customs brokers would have three years from the effective date of the final rule to verify the client's identity, and to update the necessary identification and verification records. The three-year period is to allow brokers adequate time to verify existing client's identities pursuant to the new regulatory requirements taking into account the number of existing POAs and the number of hours per existing POA that the verification process will take (*see* Section IV. Executive Orders 13563, 12866, and 13771 for more detailed information). Brokers would have to reverify the client's identity on an annual basis after the initial verification.

IV. Executive Orders 13563, 12866, and 13771

Executive Orders 13563 (''Improving Regulation and Regulatory Review'') and 12866 (''Regulatory Planning and Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563

emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs'') directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

This rule is not designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget. As this rule is not a significant regulatory action, it is exempt from the requirements of Executive Order 13771. *See* OMB's Memorandum titled ''Guidance Implementing Executive Order 13771, Titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017). The regulatory amendments in this rule are the result of the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA) (Pub. L. 114–125). This rule's annualized net regulatory cost is $11.7 million using a 7 percent discount rate and 2017 U.S. dollars. CBP has prepared the following analysis to help inform stakeholders of the impacts of this proposed rule.

1. Need and Purpose of Rule

CBP is one of several agencies that are responsible for issuing regulations governing the importation of goods into the United States. As this process is complex and involves compliance with numerous requirements ranging from agricultural safety to intellectual property rights, to the payment of appropriate duties and fees, CBP licenses customs brokers to assist importers with the importation process. As brokers are knowledgeable about the legal requirements and often have a great deal of visibility into their clients' businesses, they are key partners to CBP in preventing fraud and ensuring that the correct amount of revenue is collected. However, brokers' knowledge of their importer clients can vary as there is no current requirement that standardizes the collection and verification of broker's information about their clients. Most brokers verify their clients' information prior to conducting business with them, even absent a requirement to do so, but some do not and there is no universal standard for this verification. CBP has for many years provided guidance on this matter, but it is non-binding, and not all brokers follow it. We note that CBP's guidance closely follows industry best practice standards that many brokers have been following for years and CBP's guidance standardizes and publicizes the best practices. CBP does not have evidence indicating the guidance changed industry's behavior. As such, brokers who properly verify their importers impose a higher burden on themselves and their clients than brokers who do not properly verify their clients. Also, importers who intend to commit fraud or are otherwise reluctant to share their information likely gravitate toward brokers who do not thoroughly verify their clients' information. This puts brokers who properly verify importers' identities at a competitive disadvantage and makes it easier for fraudulent importers to remain undetected.

Section 116, *Customs Broker Identification of Importers,* of TFTEA requires CBP to prescribe regulations governing the customs broker identification of importers. This proposed rule would satisfy this requirement by setting minimum standards for importers to provide the information and for customs brokers to collect this information and verify the identity of their importer or nonresident importer clients. The definition of the term ''client'' is the importer or nonresident importer of record who is seeking or employing the services of a customs broker to transact customs business on behalf of the importer or nonresident importer of record. The definition of the term ''grantor'' is the individual executing the power of attorney on behalf of the client. This regulation would reduce fraud by helping to eliminate the use of shell or shelf companies, protect U.S. Government revenue, and ensure level competitiveness among brokers.

2. Background

Each year, approximately 350,000 importers actively transact customs business with CBP through one of approximately 2,093 permitted customs brokers.[7] By regulation, each importer is required to have a Power of Attorney (POA) with the broker before the broker may transact customs business on behalf of the client. In addition to assisting the importer with its filings, the broker has an important function in preventing fraud. As an importer's agent and CBP-licensed entity, the broker is uniquely situated to verify specific data on its importer and nonresident importer clients. The most timely and efficient way for a broker to request identity-verifying information is to do so at the point of the POA development. A valid POA is the written appointment of the broker as the true and lawful agent of the principal (*i.e.,* client) allowed to transact ''customs business'' in the name of that principal. The broker's own professional business interest and continuing obligation to demonstrate reasonable care involves determining that a POA is valid. Currently, the information required for a valid POA is limited to:

(1) A statement from the principal authorizing the broker to act as the principal's agent and for the customs broker to file entry/entry summary in the principal's name for a shipment;

(2) The name of the individual or authorized representative of the sole proprietorship, partnership, or corporation executing the POA; and

(3) The name and address of the individual or business on whose behalf the POA is being executed.

As noted previously, the vast majority of customs brokers verify their clients' identity and industry groups have established best practices for doing so over the years. While there is no current requirement for brokers to verify their client's information prior to transacting customs business on their behalf and only a limited amount of information is required for a valid POA, the majority of brokers currently require importers to provide them with certain additional information when a POA is obtained from an importer, which is used by the broker to verify the importer's existence and identity. This includes, but is not limited to, the registration of the importer's business with a state government and the Articles of Incorporation under which that business is formed. As this validation is important to prevent fraud and to protect a broker's business interests, CBP provides non-binding guidance on how brokers can validate importers when they obtain a POA. For example, CBP recommends that a broker should, whenever possible, do the following:[8]

(1) Complete POAs in-person and review personal identification (driver's license, passport, etc.);

(2) Check applicable websites to verify the business registration with State authorities;

[7] Source: Email correspondence with CBP's Broker Management Branch, Office of Trade [hereinafter referred to as CBP's Broker Management Branch], on August 15, 2017.

[8] Source: U.S. Customs and Border Protection, ''Validating the Power of Attorney.'' Last published May 25, 2018. Available at *https://www.cbp.gov/trade/programs-administration/customs-brokers/validating-power-attorney.* Accessed May 31, 2018.

(3) Confirm business's trade or fictitious names that may appear on the POA;

(4) Verify that the importer's name, importer number, and Employer Identification Number (EIN) (also known as the Federal Tax Identification Number) on the POA match what is in CBP's Automated Commercial Environment (ACE); and

(5) Check whether an importer is named as a sanctioned or restricted person or entity by the U.S. Government.

This proposed rule standardizes the process by which brokers verify the identities of their importer clients by requiring that the broker collect specified identity-verifying information from the client at the time the POA is obtained and mandating procedures for the broker to verify the importer client's identity. Since CBP has determined that it is most efficient for brokers to collect this information and verify at the time the POA is obtained, this analysis uses the number of POAs created and existing to determine when the importer client's identity must be verified pursuant to this proposed rule's requirements.

According to CBP's Broker Management Branch and conversations with members of the trade community, including one of the major broker associations and some individual brokers, for the vast majority—about 95 percent—of POAs obtained by brokers, the broker has sufficiently verified the importer client's identity, a process that takes about 2 hours per POA.[9] The 2 hour time burden can be divided into four major categories which include time for recordkeeping. Brokers who sufficiently verify their clients' identity spend approximately 40 minutes to check state or local business status via appropriate channels, 20 minutes to check their clients' business profile via organizations such as Dun and Bradstreet,[10] 40 minutes to access and review credit reports, and 20 minutes for internet research on the client's company. CBP requests comment on these estimates.

CBP estimates that approximately 100,000 new POAs are created annually when an importer either enters into a relationship with a broker for the first time or the particulars of the POA change and a new one is needed.[11] Therefore, CBP estimates that brokers currently spend approximately 190,000 hours per year validating 95 percent of the importer clients' identities at the time the POA is obtained. It also takes time for importers to provide their information to their brokers for a POA and the additional information required to verify the client's identity. Based on conversations with the trade community, CBP expects that it would take each importer approximately 1 hour to provide the broker with this verifying information. Accordingly, CBP estimates that importers currently spend approximately 95,000 hours per year gathering the necessary information to complete a POA and the additional information required to verify the client's identity.

3. Impacts of Rule

CBP proposes to formalize the process by which customs brokers verify importers and nonresident importer clients. This proposed rule would require the broker to collect specified information from the importer client and for the broker to verify the information from importers before it begins working under a new POA allowing the broker to transact customs business on behalf of the client.[12] In addition, within three years of the effective date of this proposed rule being finalized,[13] brokers would also need to verify this information from existing clients.[14] Additionally, brokers must continue to make and retain identification and verification records. This requirement would be enforceable according to the recordkeeping requirements of current broker regulations in 19 CFR part 111 and part 163. Finally, brokers will now be required to reverify the client's identity and update their records annually with any changes to the client, POA, or information in the records.

The information that the customs broker would now be required to collect, at minimum, from the importer client under this proposed rule is as follows, if applicable:

- The client's name;
- For a client who is an individual, the client's date of birth;
- For a client that is a partnership, corporation, or association, the grantor's date of birth;
- For a client that is a partnership, corporation, or association, the client's trade or fictitious names;
- The address of the client's physical location (for a client that is a partnership, corporation, or association, the physical location would be the client's headquarters) and telephone number;
- The client's email address and business website;
- A copy of the grantor's unexpired government-issued photo identification;
- The client's Internal Revenue Service (IRS) number, Employer Identification Number (EIN), or Importer of Record (IOR) number;
- The client's publicly available business identification number (*e.g.,* DUNS number, etc.);
- A recent credit report;
- A copy of the client's business registration and license with state authorities; and
- The grantor's authorization to execute power of attorney on behalf of client.

Importer clients can obtain a DUNS number without cost and already report their DUNS number on CBP Form 5106. Brokers can verify the DUNS number online for free. The time it takes to do this is included in the estimated time to verify an importer client's information.

The broker must collect all the information that is applicable to that particular client. Some information might not be applicable to a client depending on whether the client is an individual, partnership, corporation or association. For example, a small business might not have a business website; and a client who is an individual would not have a business registration and license with state authorities or a publicly available business identification number. Additionally, certain foreign jurisdictions do not provide credit reports; accordingly, if the address of

[9] Source: Email correspondence with CBP's Broker Management Branch on August 15, 2017, and numerous conversations with the trade in August 2017. The exact percentage of customs brokers that do not properly verify importers and nonresident importer clients is unknowable, as no broker will readily admit that it is not adequately verifying importer and nonresident importer information.

[10] Source: Dun and Bradstreet. Get a Dun & Bradstreet DUNS number. *https://www.dnb.com/duns-number/get-a-duns.html.* Accessed March 28, 2019.

[11] Source: Email correspondence with CBP's Broker Management Branch on August 16, 2017, and March 27, 2018. The actual number of new POAs varies each year. In 2015, there were 84,520 new POAs, in 2016 there were 101,945, and in 2017 there were 101,110.

[12] Many brokers currently collect more information than what this proposed rule requires and they may continue to do so. This proposed rule simply establishes a minimum threshold of information that the client must provide and that the broker must verify.

[13] For any existing client with a POA issued by a partnership, the broker also must verify the client's identity. Existing clients with partnership POAs will need to have their identities verified within two years from the effective date of this proposed rule being finalized and reverified every year thereafter. However, according to subject matter experts from CBP's Broker Management Branch, partnership POAs represent less than 1% of active POAs, though we lack data on the precise number of partnership POAs. To the extent partnership POAs are affected, it will increase broker costs by a small amount because they may require verification sooner than estimated.

[14] Source: Email correspondence with CBP's Broker Management Branch on May 17, 2017.

the client's physical location is located in one of those jurisdictions, the broker is not required to collect a recent credit report from that client.

Once customs brokers collect this data from importers and nonresident importers, brokers would need to check to determine whether the importer client is named as a sanctioned or restricted person or entity by the U.S. Government, or if the client is suspended or debarred from doing business with the U.S. Government, and would need to verify all the information collected from the importer client using various federal agency, state government, and publicly available data sources. The means of verification are at the customs broker's discretion. The broker must use as many of the recommended verification means as necessary to be reasonably certain as to the client's identity. Some of the tools that are recommended for verifying this information include:

- A check of the appropriate websites to determine whether the client is named as a sanctioned or restricted person or entity by the U.S. Government, or if the client is suspended or debarred from doing business with the U.S. Government;
- An in-person review of the grantor's unexpired government-issued identification;
- An in-person client meeting;
- An in-person visit of the client's place of business;
- A review of the client's Articles of Incorporation; and
- A query of publicly available information, business information and credit reporting entities, Federal, state, and local databases or websites and any other relevant trade or business sources.

As previously stated, conscientious brokers already require information from the importer or nonresident importer client in order to verify the client's identity. According to CBP's Broker Management Branch and conversations with the trade community, for approximately 5 percent of POAs, the brokers do not require most or any of this additional information and the importer clients' identities are not currently verified or are only minimally verified.[15] As a result of this rule, all brokers will be required to verify all of the specified information collected from the client to verify the client's existence and identity for all POAs granted by importers and nonresident importer clients and this information will need to be reverified annually. CBP analyzes the costs and benefits of these new requirements over a 5-year period of analysis spanning from 2019 to 2023.

4. Costs

Costs to Brokers

Brokers currently have approximately 350,000 POAs with importer clients, for which brokers would now need to verify the client's identity under this rule within three years of the effective date of this proposed rule being finalized. CBP assumes that brokers would verify the importer client's identity for one-third of these existing POAs each year beginning in 2019—or about 116,666 each year from 2019 to 2021—to satisfy this rule's new verification requirement (*see* Table 1).[16] These existing verifications would each take approximately 2 hours and can be divided into four distinct time-burden categories that were identified earlier.[17] [18] There is a time cost of $59.52 each, according to CBP's assumed hourly time value for customs brokers of $29.76.[19] [20] Based on the historical number of POAs created each year, CBP estimates that 100,000 new POAs would be created each year between 2019 and 2023 (*see* Table 1). CBP estimates that in the absence of this rule, brokers would have verified 95 percent of the importer clients' identities for new POAs—or 95,000 POAs—while the remaining 5 percent—or 5,000—new POAs would have the clients' identities go unverified based on historical estimates. According to CBP's Broker Management Branch, this rule's verification requirements would not increase the time burden for the 95 percent of instances where brokers verify the importer client's identity for each new POA. The specific information brokers currently require may be different than the information required under this rule, but we estimate that it takes approximately two hours to verify either set of data. As such, this rule will have no additional time burden to do the initial validation of the importer client's identity for the POA. The remaining 5 percent of brokers who do not currently verify the client's identity would incur a two-hour time burden for the verification of the importer client's identity for a POA under this rule,[21] at an added time cost of $59.52 per new POA according to CBP's assumed hourly time value for customs brokers.[22]

[15] Source: Email correspondence with CBP's Broker Management Branch on August 15, 2017. The exact percentage of customs brokers that do not properly verify importers and nonresident importer clients is unknowable because no broker will readily admit that it is not adequately verifying importer and nonresident importer information.

[16] Source: Email correspondence with CBP's Broker Management Branch on August 15, 2017.

[17] The two hours includes the time to implement policies, procedures and internal controls for identity verification, and to keep records containing the information used to verify the importer.

[18] Source: Email correspondence with CBP's Broker Management Branch on August 15, 2017.

[19] 2-hour time burden for broker to verify information of the client's identity for an existing POA × $29.76 hourly time value for customs brokers = $59.52 time cost.

[20] CBP bases the $29.76 hourly time value for customs brokers on the Bureau of Labor Statistics' (BLS) 2017 median hourly wage rate for Cargo and Freight Agents ($20.11), which CBP assumes best represents the wage for brokers, by the ratio of BLS' average 2017 total compensation to wages and salaries for Office and Administrative Support occupations (1.4801), the assumed occupational group for brokers, to account for non-salary employee benefits, and rounded. Source of median wage rate: U.S. Bureau of Labor Statistics. Occupational Employment Statistics, ''May 2017 National Occupational Employment and Wage Estimates, United States—Median Hourly Wage by Occupation Code: 43–5011.'' Updated March 30, 2018. Available at *https://www.bls.gov/oes/2017/may/oes_nat.htm#43-0000* . Accessed March 26, 2019. The total compensation to wages and salaries ratio is equal to the calculated average of the 2017 quarterly estimates (shown under Mar., June, Sep., Dec.) of the total compensation cost per hour worked for Office and Administrative Support occupations divided by the calculated average of the 2017 quarterly estimates (shown under Mar., June, Sep., Dec.) of wages and salaries cost per hour worked for the same occupation category. Source of total compensation to wages and salaries ratio data: U.S. Bureau of Labor Statistics. Employer Costs for Employee Compensation. Employer Costs for Employee Compensation Historical Listing March 2004–December 2018, ''Table 3. Civilian workers, by occupational group: Employer costs per hours worked for employee compensation and costs as a percentage of total compensation, 2004–2018 by Respondent Type: Office and administrative support occupations.'' Available at *https://www.bls.gov/web/ecec/ececqrtn.pdf.* Accessed March 26, 2019.

[21] Source: Email correspondence with CBP's Broker Management Branch in March 2018. The 100,000 figure is a rounded average of the number of POAs that were filed in 2015 (84,520), 2016 (101,945), and 2017 (101,110).

[22] 2-hour added time burden for broker to verify information of the importer's identity for a new POA × $29.76 hourly time value for customs brokers = $59.52 time cost.

TABLE 1—PROJECTED NUMBER OF POAS REQUIRING BROKER VERIFICATION WITH RULE

Year	Existing POAs requiring identity-verification	New POAs requiring identity-verification	Total POAs requiring identity-verification
2019	116,667	5,000	121,667
2020	116,667	5,000	121,667
2021	116,666	5,000	121,667
2022	0	5,000	5,000
2023	0	5,000	5,000
Total	350,000	25,000	375,000

To estimate the total time cost for brokers to verify existing importer clients' identities, CBP multiplies the projected number of existing POAs requiring identity-verification during the period of analysis shown in Table 1 by the $59.52 time cost to complete each identity-verification of an existing client by measuring the existing POAs. Accordingly, CBP finds that brokers would incur undiscounted costs totaling $20.8 million to verify existing clients' identities from 2019 to 2023 following this rule's implementation (*see* Table 2). Brokers who do not already conduct client identity verifications would sustain a total time cost of $1.5 million for verification of the importer client's identity based on their $59.52 added time burden and their projected number of client identities verified measured by the number of projected POAs over the period of analysis (*see* Table 1 and Table 2). Altogether, the total undiscounted cost of this rule to brokers would measure $22.3 million from 2019 to 2023.

TABLE 2—TOTAL COST FOR BROKERS TO VERIFY CLIENT'S IDENTITY FOR EXISTING AND NEW POAS WITH RULE

[Undiscounted 2017 U.S. dollars]

Year	Time cost to verify existing POAs	Time cost to verify new POAs	Total time cost for brokers to verify existing and new POAs
2019	$6,944,020	$297,600	$7,241,620
2020	6,944,020	297,600	7,241,620
2021	6,944,020	297,600	7,241,620
2022	0	297,600	297,600
2023	0	297,600	297,600
Total	20,832,000	1,488,000	22,320,000

Additionally, as a result of this rule, customs brokers will need to update their records and reverify on an annual basis that the POA information, and the identification and verification records for their importer clients is accurate. According to CBP's Broker Management Branch, there are approximately 350,000 active importers of record (IORs) in any given year and that is not expected to change significantly—on average any new IORs are offset by IORs that become inactive.[23] Brokers will now have to verify all 350,000 existing client's identities as measured by the existing POAs within three years of the effective date of this proposed rule being finalized and reverify the client's identity annually thereafter. As discussed earlier, we expect brokers to do the initial verification evenly over the course of the first three years (*see* Table 1). The reverifications, then, will lag the initial verifications by a year. As the new importers are offset by importers who become inactive, brokers will need to reverify 350,000 existing clients' identities each year, after the initial 3-year verification window. Table 3 shows the number of verifications we estimate for each year. These verifications would each take approximately 45 minutes (.75 hours) to complete,[24] at a time cost of $22.32 each, according to CBP's assumed hourly time value for customs brokers of $29.76.[25] Table 3 shows the estimated costs of this reverification. The total undiscounted cost to verify and update recordkeeping requirements for existing and prospective clients as measured by existing and new POAs is $23,436,022 over the period of the analysis.

TABLE 3—TOTAL COST FOR BROKERS TO VERIFY AND UPDATE RECORDKEEPING REQUIREMENTS FOR EXISTING AND NEW CLIENTS WITH RULE

[Undiscounted 2017 U.S. dollars]

Year	Total POAs requiring annual reverification	Total time cost to reverify POAs
2019	0	$0
2020	116,667	2,604,007
2021	233,334	5,208,015
2022	350,000	7,812,000
2023	350,000	7,812,000
Total	1,050,000	23,436,022

Costs to Importers

In addition to its costs to brokers, this rule would impose costs on the broker's existing and prospective importer clients now required to provide additional identity-verifying data to brokers for their existing and new POAs. Based on conversations with the trade

[23] Source: Email correspondence with CBP's Broker Management Branch on April 12, 2018.

[24] Source: Email correspondence with CBP's Broker Management Branch on March 20, 2018.

[25] 0.75-hour time burden for broker to verify information of the importer client's identity for an existing POA × $29.76 hourly time value for customs brokers = $22.32 time cost.

community, CBP assumes that each existing POA corresponds to a unique importer of record.[26] As a result, CBP estimates that 350,000 existing importer clients would provide identity-verifying data to brokers for 350,000 existing POAs within three years of the effective date of this proposed rule being finalized (*see* Table 1). CBP expects that it would take each importer approximately one hour to provide the broker with this identity-verifying information, at a time cost of $29.76 according to CBP's assumed hourly time value for importers of $29.76.[27] [28] Considering this time cost and the projected number of existing POAs where the importer's identity must be verified during the period of analysis (*see* Table 1), CBP finds that importers would incur a total cost of $10.4 million to provide identity-verifying information to their brokers for existing POAs (*see* Table 4). For new POAs where the importer's identity must be verified, CBP estimates that importers already provide most of the additional identity-verifying information required in this rule to brokers for 95 percent—or 95,000—of new POAs each year. As stated above, while the specific information brokers require currently may vary, it is generally very similar to what this rule requires that the brokers collect. Hence, CBP assumes these importers would not incur an added burden to provide identity-verifying information to their brokers with this rule beyond what they already bear. For the remaining 5 percent—or 5,000—of POAs where the importer's identity is not currently verified, this rule would require brokers to collect such information from their clients. Like with existing POAs, CBP believes that it would take each importer approximately one hour to provide the broker with this identity-verifying information, at a time cost of $29.76 according to CBP's assumed hourly time value for importers of $29.76.[29] By applying this time cost to the 5,000 new POAs where the importer's identity would not be verified absent this rule, CBP estimates that some importers would sustain undiscounted costs totaling $0.7 million over the period of analysis from this rule's identity-verifying data submission requirement (*see* Table 4). In all, this rule would impose undiscounted costs of $11.2 million on importers between 2019 and 2023, as illustrated in Table 4.

TABLE 4—TOTAL COST FOR IMPORTERS TO PROVIDE IDENTITY-VERIFYING DATA FOR EXISTING AND NEW POAS WITH RULE

[Undiscounted 2017 U.S. dollars]

Year	Time cost for existing importers to provide verifying data for existing POAs	Time cost for new importers to provide data for verification	Total time cost for importers to provide data for verification of existing and new POAs
2019	$3,472,010	$148,800	$3,620,810
2020	3,472,010	148,800	3,620,810
2021	3,471,980	148,800	3,620,810
2022	0	148,800	148,800
2023	0	148,800	148,800
Total	10,416,000	744,000	11,160,000

Brokers are required to obtain recent credit reports from their client importers for use in the verification process. We next estimate the cost of running credit reports to the importer. It is common practice among businesses to periodically run their own credit report, so we expect most importers to simply provide the broker with a previously run credit report. For the purposes of this analysis, we again assume that 95% of importers are already providing their credit report to the broker or that they routinely run their own credit report for their own purposes. There is not a financial cost to these importers.[30] The remaining 5 percent or approximately 5,000 importers will incur a costs by purchasing credit reports with credit scores from each of the credit bureaus (Equifax, Experian, and Transunion). The three reports costs approximately $40.[31] Table 5 shows the costs to importers working with brokers not currently accessing free credit reports from their clients.

[26] Some importers have several importer of record numbers, but each requires its own POA.

[27] 1-hour time burden for importer to provide broker with the required information to verify the importer's identity for an existing POA × $29.76 hourly time value for importers = $29.76 time cost.

[28] CBP bases the $29.76 hourly time value for importers on the Bureau of Labor Statistics' (BLS) 2017 median hourly wage rate for Cargo and Freight Agents ($20.11), which CBP assumes best represents the wage for importers, by the ratio of BLS' average 2017 total compensation to wages and salaries for Office and Administrative Support occupations (1.4801), the assumed occupational group for importers, to account for non-salary employee benefits, and rounded. Source of median wage rate: U.S. Bureau of Labor Statistics. Occupational Employment Statistics, ''May 2017 National Occupational Employment and Wage Estimates, United States—Median Hourly Wage by Occupation Code: 43–5011.'' Updated March 30, 2018. Available at *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed March 26, 2019. The total compensation to wages and salaries ratio is equal to the calculated average of the 2017 quarterly estimates (shown under Mar., June, Sep., Dec.) of the total compensation cost per hour worked for Office and Administrative Support occupations divided by the calculated average of the 2017 quarterly estimates (shown under Mar., June, Sep., Dec.) of wages and salaries cost per hour worked for the same occupation category. Source of total compensation to wages and salaries ratio data: U.S. Bureau of Labor Statistics. Employer Costs for Employee Compensation. Employer Costs for Employee Compensation Historical Listing March 2004–December 2018, ''Table 3. Civilian workers, by occupational group: employer costs per hours worked for employee compensation and costs as a percentage of total compensation, 2004–2017 by Respondent Type: Office and administrative support occupations.'' Available at *https://www.bls.gov/web/ecec/ececqrtn.pdf.* Accessed March 26, 2019.

[29] 1-hour time burden for importer to provide broker with information to verify the importer's identity for a new POA × $29.76 hourly time value for importers = $29.76 time cost.

[30] Source: Communication with CBP's Broker Management Branch on March 23, 2019, and numerous conversations with the trade in August 2017. During the March 23, 2019 discussion with the Broker Management Branch, the branch noted that there can be a cost to brokers for collecting credit reports that range between $35 to $50 depending on the source.

[31] Source: Experian. Consumer Products. *https://www.experian.com/consumer-products/experian-equifax-transunion-credit-report-and-score.html.* Accessed March 27, 2019.

TABLE 5—COST OF CREDIT REPORT FOR IMPORTERS

[Undiscounted 2017 U.S. dollars]

Year	New POAs requiring identity-verification	Credit report costs
2019	5,000	$200,000
2020	5,000	200,000
2021	5,000	200,000
2022	5,000	200,000
2023	5,000	200,000
Total	25,000	1,000,000

Total Costs

Table 6 summarizes the costs of this rule to brokers and importers. Altogether, this rule would impose a total undiscounted cost of $57.9 million on the trade community from 2019 to 2023.

TABLE 6—TOTAL COST OF RULE TO BROKERS AND IMPORTERS

[Undiscounted 2017 U.S. dollars]

Year	Total cost of importer ID rule
2019	$11,062,430
2020	13,666,437
2021	16,270,355
2022	8,458,400
2023	8,458,400
Total	57,916,022

When discounted, as shown in Table 7, this cost would measure $51.4 million in present value and $11.7 million on an annualized basis (using a 7 percent discount rate and 2017 U.S. dollars).

TABLE 7—TOTAL MONETIZED PRESENT VALUE AND ANNUALIZED COSTS OF RULE, 2019–2023

[2017 U.S. dollars]

	3% Discount rate	7% Discount rate
Present Value Cost	$54,922,999	$51,403,406
Annualized Cost	11,643,386	11,716,647

Note: The estimates in this table are contingent upon CBP's projections as well as the discount rates applied.

5. Benefits

Most brokers are already verifying the identity of their prospective clients when they begin their business relationship, but there are some who do not. Based on conversations with the broker community, CBP estimates that five percent of importers' identities are not currently verified or are only minimally verified. Those who do not wish to be thoroughly verified sometimes ''broker shop'' for a broker that does not require the same amount of verifying information. While some importers simply do not want to share more information with their brokers than is required, others intend to commit fraud and import illicit and/or counterfeit goods into the United States. These fraudulent importers seek out brokers who do not ask for verifying information in order to use a shell or shelf company to import fraudulent goods into the United States. When the customs broker or CBP discovers the illegal activities and attempts to penalize the shell or shelf company, it disappears. By formalizing the verification process for importers and requiring that it be carried out every year, this proposed rule would help prevent the use of shell or shelf companies by importers who attempt to commit fraud against the United States.

The fraud this proposed rule is intended to prevent can take a number of forms. It can range from misclassifying merchandise to avoid duties to intellectual property rights (IPR) violations, to antidumping/countervailing duty (AD/CVD) infractions, to the importation of unsafe merchandise. CBP believes that this proposed rule would improve brokers' knowledge of the importers. This improved broker knowledge could allow for commercial fraud prevention and revenue protection. According to CBP's Broker Management Branch, from approximately 2007 to 2017, there was about $3.3 billion in uncollected duties related to AD/CVD violations by shell companies. Fifteen percent of these business entities are out of business. Their business model is to open, import merchandise subject to AD/CVD for a short period of time, and then shut down operations and disappear to avoid paying the required duties.[32] As CBP cannot find the party responsible for importing, the duties can remain unpaid forever. Similarly, these shell companies frequently engage in the trade of counterfeit and pirated goods. The Organization for Economic Cooperation and Development estimates that counterfeit and pirated products accounted for as much as $461 billion dollars in world trade in 2013.[33] This proposed rule will help prevent companies from engaging in these types of fraud because they will need to share real, verified information with their broker, which will make it much more difficult for those liable to disappear.

When shell or shelf companies importing goods into the United States do disappear before paying outstanding customs bills for duties, taxes and fees, CBP must collect the outstanding debt from sureties who issue bonds for the imported merchandise. The amount of duties, taxes, and fees that CBP may collect from sureties is limited by the value of the bond. In some instances, the bond value is insufficient to cover all outstanding duties, taxes, and fees owed by the importer. Consequently, there is a loss of revenue for CBP. At the same time, sureties incur additional costs to cover the duties, taxes, and fees collected against the bonds. This proposed rule will allow brokers to more effectively vet importers and reduce the number of bad actors. This will decrease revenue loss for the government and reduce costs incurred by sureties.

Reducing fraud by shell or shelf companies is a benefit to all parts of the economy. The United States Government would benefit by collecting the appropriate revenue for imported merchandise. To the extent that it avoids fruitless enforcement actions against shell or shelf companies that disappear, it would also save on

[32] Source: Email correspondent with CBP's Broker Management Branch on April 20, 2018.

[33] Source: Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact. Accessed April 25, 2018. *http://www.oecd.org/industry/global-trade-in-fake-goods-worth-nearly-half-a-trillion-dollars-a-year.htm.*

enforcement costs. Brokers would benefit as they would have better knowledge of their importers and would be better able to avoid engaging in business with fraudulent companies. Brokers would also benefit through the leveling of the playing field in obtaining new clients or retaining current clients. Currently, brokers who properly verify their importer client's identity when the POA is obtained incur costs verifying the importer's identity and can lose customers to brokers who do not ask importers for information to verify their identity. This proposed rule would eliminate the opportunity to ''broker shop'' for a broker that does not require as much identifying information from the importers. The larger trade community would benefit from this proposed rule as it would reduce identity theft, the number of counterfeit or IPR-violative imports, and it would help enforce AD/CVD laws. The American public would benefit through any reduction in unsafe merchandise that results from this proposed rule. Finally, this proposed rule fulfills the congressional mandate in TFTEA that CBP issue regulations governing the broker identification of importers.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires agencies to assess the impact of regulations on small entities. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

This proposed rule will affect all customs brokers and IORs. The vast majority of customs brokers and importers are small businesses, so this rule would have an impact on a substantial number of small entities. However, these impacts will not be significant. As stated above, as a result of this rule, brokers would need to collect identity-verifying information from both their existing importer clients and prospective importer clients within three years of the effective date of this proposed rule being finalized.[34] CBP estimates that the monetized value of time spent by importers to provide this data costs $29.76 per POA. Additionally about five percent of importers not currently working with brokers requesting credit reports with scores might incur a $40 fee, as noted above. CBP does not consider the time cost of $29.76 and possibly a $40 fee to be a significant cost to importers. It is possible that some importers may have more than one IOR number and therefore more than one POA where their identity would need to be verified, but that is less likely for small businesses. We note that even in an extreme case where a small business has 10 POAs for each of its IOR numbers, the time cost would be only $297.60 (or even less if there are efficiencies in submitting similar information multiple times) with a possible $40 credit report fee, which CBP also does not consider a significant impact.

Brokers would incur costs associated with verifying their importer client's identity whether they are prospective or existing clients. Above, as seen in Tables 2 and 3 we estimate that in the most costly year (2021), 2,093 permitted brokers bear total costs of $12,449,635 for an average of $5,948.22 per permitted broker. However, it is unlikely that the burden is spread evenly among brokers; those with more clients would need to verify more importer clients' identities, so their costs would be higher. To estimate the burden per broker and to assess whether the burden is significant, we will go through the following steps:

- Estimate the number of small brokers in various revenue categories.
- Per each category of brokers, estimate the additional number of POAs for which brokers will need to verify the importer client's identity.
- Estimate the cost per permitted broker of these verifications.
- Estimate the ratio of costs to annual revenue to assess whether the costs are significant.

To estimate the number of small brokers in different size categories, we use data from the U.S. Census Bureau. The U.S. Census Bureau categorizes customs brokers under the North American Industry Classification System (NAICS) code 488510, which also includes other businesses such as freight forwarders.[35] The Small Business Administration (SBA) considers a business entity classified under the 488510 NAICS code as small if it has less than $15 million in annual receipts.[36] As shown in Table 8, 95 percent of businesses classified under this NAICS code are small businesses. For the purposes of this analysis, we will assume that all brokers are small businesses. To the extent some are not, the impact on small businesses will be smaller than estimated in this analysis. We estimate the number of firms in each revenue category by allocating the 2,093 permitted brokers proportionally to the number of total firms in the NAICS code.

TABLE 8—BUSINESS ENTITY DATA FOR NAICS CODE 488510

Annual revenue ($) (midpoint)	Number of firms	Small	Estimated number of permitted brokers
<100,000 (50,000)	2,195	Yes	323
100,000–499,999 (300,000)	4,935	Yes	727
500,000–999,999 (750,000)	2,330	Yes	343
1,000,000–2,499,999 (1,750,000)	2,429	Yes	358
2,500,000–4,999,999 (3,750,000)	1,208	Yes	178
5,000,000–7,499,999 (6,250,000)	540	Yes	80
7,500,000–9,999,999 (8,750,000)	284	Yes	42
10,000,000–14,999,999 (12,500,000)	282	Yes	42

[34] For any existing client with a POA issued by a partnership, the broker also must verify the client's identity. Existing clients with partnership POAs will need to have their identities verified within two years from the effective date of this proposed rule being finalized and reverified every year thereafter. However, according to subject matter experts from CBP's Broker Management Branch, partnership POAs represent less than 1% of active POAs, though we lack data on the precise number of partnership POAs. To the extent partnership POAs are affected, it will increase broker costs by a small amount.

[35] Source: U.S. Census. *http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=488510&search=2012%20NAICS%20Search.* Accessed August 8, 2018.

[36] Source: U.S. Small Business Administration. Table of Small Business Size Standards Matched to North American Industry Classification System Codes. *https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf.* Accessed March 21, 2019.

TABLE 8—BUSINESS ENTITY DATA FOR NAICS CODE 488510—Continued

Annual revenue ($) (midpoint)	Number of firms	Small	Estimated number of permitted brokers
>15,000,000	815	No	0
Total	15,018	*(14,203/15,018)	2,093

Source: U.S. Census Bureau. 2012 SUSB Annual Data Tables by Establishment Industry. *https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html.*
*95 percent are small.

Now that we have estimated the number of permitted brokers in each size category, we estimate how much of each type of IOR verification will be done by brokers in each category. We use total annual revenue as a proxy for the number of clients (IORs) each broker has. While cases may exist where a broker generates a lot of revenue from just a few IORs or conversely that a broker generates little revenue from many IORs, on average we expect that the number of clients is well correlated with the broker's revenue. To estimate total revenue for each size category, we use the category's revenue midpoint. We determine the different types of client identities that need to be verified as existing importer clients; clients that need their POAs, information and records to be annually reverified and updated; and prospective clients, and we allocate these to the different types of POAs (existing POAs requiring identity-verification, POAs needing annual verification, and new POAs needing identity-verification) proportionally to the total revenue for each size category. Table 9 shows the number of brokers in each revenue category, their total revenue, and the number of each type of POA for which the brokers would need to verify the importer client's identity under this proposed rule. Note that we present estimates for 2021, which is the most costly year for brokers.

TABLE 9—POAS BY SIZE CATEGORY IN 2021

Annual revenue ($) (midpoint)	Estimated number of brokers	Total revenue (000')	Existing POAs	POAs requiring annual reverification	New POAs requiring verification
<100,000 (50,000)	323	$16,150	593	1,186	25
100,000–499,999 (300,000)	727	218,100	8,007	16,013	343
500,000–999,999 (750,000)	343	257,250	9,444	18,888	405
1,000,000–2,499,999 (1,750,000)	358	626,500	22,999	45,999	986
2,500,000–4,999,999 (3,750,000)	178	667,500	24,504	49,009	1,050
5,000,000–7,499,999 (6,250,000)	80	500,000	18,355	36,711	787
7,500,000–9,999,999 (8,750,000)	42	367,500	13,491	26,982	578
10,000,000–14,999,999 (12,500,000)	42	525,000	19,273	38,546	826
Total	2,093	3,178,000	116,667	233,334	5,000

We next estimate the costs per broker. In the analysis above, we estimated that the cost per verification for existing clients' identities for each POA and the initial verification of the prospective client's identity for new POAs was each $59.52. Additionally, as shown in the analysis above, the cost for each reverification of the client's identity was $22.32. We multiply these costs to the number of POAs from Table 9 to reach the total costs for each broker category, shown in Table 10 below.

TABLE 10—BROKER COSTS BY SIZE CATEGORY IN 2021

Annual revenue ($) (midpoint)	Cost for existing POAs	Cost for annual revalidation	Cost for new POAs requiring verification	Total cost
<100,000 (50,000)	$35,288	$26,466	$1,512	$63,267
100,000–499,999 (300,000)	476,555	357,416	20,424	854,394
500,000–999,999 (750,000)	562,099	421,574	24,090	1,007,762
1,000,000–2,499,999 (1,750,000)	1,368,920	1,026,690	58,668	2,454,278
2,500,000–4,999,999 (3,750,000)	1,458,506	1,093,880	62,507	2,614,893
5,000,000–7,499,999 (6,250,000)	1,092,514	819,386	46,822	1,958,722
7,500,000–9,999,999 (8,750,000)	802,998	602,248	34,414	1,439,660
10,000,000–14,999,999 (12,500,000)	1,147,140	860,355	49,163	2,056,658
Total	6,944,020	5,208,015	297,600	12,449,635

We next calculate the cost per broker and assess whether it is a significant impact. To calculate the cost per broker for each size category, we simply divide the total cost for the category from Table 10 by the number of brokers in it. Then we compare the cost per broker by the revenue per broker (again using the midpoint for each range) to assess whether the costs significant. The results are presented in Table 11. As shown, the costs are about 0.4 percent of revenue. CBP does not consider this to be significant.

TABLE 11—COSTS PER BROKER IN 2021

Annual revenue ($) (midpoint)	Estimated number of brokers	Total cost	Cost per broker	Cost to revenue ratio
<100,000 (50,000)	323	$63,267	$195.87	0.004
100,000–499,999 (300,000)	727	854,394	1,175.23	0.004
500,000–999,999 (750,000)	343	1,007,762	2,938.08	0.004
1,000,000–2,499,999 (1,750,000)	358	2,454,278	6,855.53	0.004
2,500,000–4,999,999 (3,750,000)	178	2,614,893	14,690.41	0.004
5,000,000–7,499,999 (6,250,000)	80	1,958,722	24,484.02	0.004
7,500,000–9,999,999 (8,750,000)	42	1,439,660	34,277.63	0.004
10,000,000–14,999,999 (12,500,000)	42	2,056,658	48,968.04	0.004
Total	2,093	12,449,635	5,948.22	

In summary, this proposed rule would affect a substantial number of importers and brokers. However, the costs do not rise to the level of economic significance. Therefore, CBP certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. CBP welcomes comments on this conclusion and any additional data.

VI. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB. The collections of information and recordkeeping requirements related to this NPRM will be submitted for approval by OMB under a revision and extension of collection number 1651–0034 (CBP Regulations Pertaining to Customs Brokers). The likely respondents are importers and customs brokers.

Customs Brokers Verification Burden

Number of Respondents: 121,667.
Number of Responses per Respondent: 1.
Total Number of Responses: 121,667.
Time per Response: 2 hours.
Total Annual Burden Hours: 243,334.

The estimated total annual burden associated with the collection of information in this NPRM is 243,334 hours.

VII. Signing Authority

This document is being issued in accordance with 19 CFR 0.1(b)(1), which provides that the Secretary of the Treasury delegated to the Secretary of Homeland Security the authority to prescribe and approve regulations relating to customs revenue functions on behalf of the Secretary of the Treasury for when the subject matter is not listed as provided by Treasury Department Order No. 100–16. Accordingly, this proposed rule to amend such regulations may be signed by the Secretary of Homeland Security (or his or her delegate).

List of Subjects in 19 CFR Part 111

Administrative practice and procedure, Brokers, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth above, CBP proposes to amend 19 CFR part 111 as set forth below:

PART 111—CUSTOMS BROKERS

■ 1. The general authority citation for part 111 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624, 1641.

* * * * *

■ 2. Add § 111.43 to read as follows:

§ 111.43 Importer identity verification.

(a) *Scope.* This section sets forth the minimum requirements for importer and nonresident importer clients to provide information and for customs brokers to collect, verify, and maintain information about the identities of their resident and nonresident importer clients. The customs broker must collect certain information from the importer client when the importer client provides the customs broker with a power of attorney and the customs broker must verify all of the information collected before the broker may transact customs business on behalf of that client.

(b) *Definitions.* (1) *Importer and nonresident importer.* For purposes of this section, ''importer'' is defined as one of the parties qualifying as an importer of record under 19 U.S.C. 1484(a)(2)(B). ''Nonresident importer'' is defined as an importer of record that is not a citizen of the United States or an alien lawfully admitted for permanent residence in the United States; or a partnership, corporation, or other commercial entity that is not organized under the laws of a jurisdiction within the customs territory of the United States (as such term is defined in General Note 2 of the Harmonized Tariff Schedule of the United States) or in the Virgin Islands of the United States.

(2) *Client.* For purposes of this section, the ''client'' is defined as the importer or nonresident importer of record who is seeking or employing the services of a customs broker to transact customs business on behalf of the importer or nonresident importer of record.

(3) *Grantor.* For purposes of this section, the ''grantor'' is defined as the individual executing the power of attorney on behalf of the client.

(c) *Minimum information that the customs broker must collect from the client.* The customs broker must collect, at minimum, the following information, if applicable, from the client to allow the customs broker to verify the client's identity when the customs broker, as required by § 141.46 of this chapter, obtains a power of attorney:

(1) The client's name;

(2) For a client who is an individual, the client's date of birth;

(3) For a client that is a partnership, corporation, or association, the grantor's date of birth;

(4) For a client that is a partnership, corporation, or association, the client's trade or fictitious names;

(5) The address of the client's physical location (for a client that is a partnership, corporation, or association, the physical location would be the client's headquarters) and telephone number;

(6) The client's email address and business website;

(7) A copy of the grantor's unexpired government-issued photo identification;

(8) The client's Internal Revenue Service (IRS) number, employer identification number (EIN), or importer of record (IOR) number;

(9) The client's publicly available business identification number;

(10) A recent credit report;

(11) A copy of the client's business registration and license with state authorities; and

(12) The grantor's authorization to execute power of attorney on behalf of client.

(d) *Verification of information by customs broker.* Before transacting customs business on behalf of a client, the customs broker must authenticate the client's identity by verifying all the information collected from the client pursuant to paragraph (c) of this section. The customs broker must verify all the information collected from the client or the inapplicability of the information to that client. The customs broker also must check to determine whether the client is named as a sanctioned or restricted person or entity by the U.S. Government, or if the client is suspended or debarred from doing business with the U.S. Government. The means of verification are at the customs broker's discretion; however, the broker must use as many of the recommended verification means as necessary to be reasonably certain as to the client's identity. These means include:

(1) A check of the appropriate websites to determine whether the client is named as a sanctioned or restricted person or entity by the U.S. Government, or if the client is suspended or debarred from doing business with the U.S. Government;

(2) An in-person review of the grantor's government-issued photo identification;

(3) An in-person client meeting;

(4) An in-person visit of the client's place of business;

(5) A review of the client's Articles of Incorporation;

(6) A query of publicly available information, business information and credit reporting entities, Federal, state, and local databases or websites and any other relevant trade or business sources.

(e) *Establishment of policies, procedures and internal controls.* All customs brokers must implement policies, procedures, and internal controls to identify and verify a client's identity before transacting customs business on behalf of that client. The policies, procedures, and internal controls must also fulfill the recordkeeping requirements in paragraph (f) of this section, particularly the requirement for updating information and records, and reverifying the client's identity.

(f) *Recordkeeping.* All customs brokers must make, retain, and update records containing the required information used to identify and to verify the client's identity.

(1) *Identification records.* At a minimum, customs brokers must retain any information collected pursuant to paragraph (c) of this section, including any identifying information presented to the customs broker, as well as any certifications the client has made.

(2) *Verification records.* At a minimum, customs brokers must retain descriptions of any documents relied upon, any non-documentary methods relied upon, any results of measures undertaken, and any resolution of discrepancies used to verify the client's identity as required by paragraph (d) of this section. The verification records must indicate which information collected pursuant to paragraph (c) was verified, who performed the verification, and the date the verification was performed.

(3) *Compliance with other recordkeeping provisions.* All customs brokers must comply with the recordkeeping provisions of this part, part 141 of this chapter, and part 163 of this chapter. The identification and verification records must be retained and made available upon request for CBP examination in accordance with parts 111, 141, and 163 of this chapter. The required retention period for the identification and verification records is the same period as is required for a power of attorney in §§ 111.23 and 163.4 of this chapter.

(4) *Updating information.* All customs brokers must implement procedures to update the records required in this section and to reverify the information collected from the client pursuant to the procedures set forth in paragraph (d) annually to ensure that the information is accurate, timely, and complete.

(g) *Penalties for noncompliance.* Failure to collect, verify, secure, retain, update, or make available for inspection the information required in this section is grounds for a monetary penalty to be assessed against the customs broker not to exceed $10,000 per client in accordance with 19 U.S.C. 1641(d)(2)(A), or revocation or suspension of the customs broker's license or permit in accordance with 19 U.S.C. 1641(d)(2)(B).

(h) *Timing of verifications.* (1) *Prospective clients.* For all prospective clients, customs brokers must verify the information required in this section before the customs broker may begin to transact customs business on behalf of that client. The customs broker must comply with all the requirements in this section for that client including updating all records and information.

(2) *Existing clients.* For existing clients with a power of attorney issued by a partnership, customs brokers must, within two years of the final rule being effective, update and verify the information required in this section. For all other existing clients, customs brokers must, within three years of the final rule being effective, update and verify the information required in this section. By these dates, the customs broker must have complied with all the requirements in this section, including the updating of all records and information, and must continue to comply.

(3) *Reverification.* Reverification must occur annually after the initial verification required by this section.

Dated: August 6, 2019.

Kevin K. McAleenan,

Acting Secretary.

[FR Doc. 2019–17179 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–130700–14]

RIN 1545–BM41

Classification of Cloud Transactions and Transactions Involving Digital Content

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations regarding the classification of cloud transactions for purposes of the international provisions of the Internal Revenue Code. These proposed regulations also modify the rules for classifying transactions involving computer programs, including by applying the rules to transfers of digital content.

DATES: Comments and requests for a public hearing must be received by November 12, 2019.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–130700–14), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–130700–14), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC. Alternatively, taxpayers may submit comments electronically via the Federal eRulemaking Portal at *www.regulations.gov* (REG–130700–14).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations Robert Z. Kelley, (202) 317–6939; concerning submissions of comments and requests for a public hearing, Regina L. Johnson, (202) 317–6901 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Background

These regulations (the proposed regulations) clarify the treatment under certain provisions of the Internal Revenue Code (Code) of income from transactions involving on-demand network access to computing and other similar resources. The proposed regulations also extend the classification rules in existing § 1.861–18 to transfers of digital content other than computer programs and clarify the source of income for certain transactions governed by existing § 1.861–18.

Existing § 1.861–18 provides rules for classifying transactions involving computer programs. For this purpose, § 1.861–18(a)(3) defines a computer program as ''a set of statements or instructions to be used directly or indirectly in a computer in order to bring about a certain result'' and includes ''any media, user manuals, documentation, data base or similar item if the media, user manuals, documentation, data base or similar item is incidental to the operation of the computer program.'' Under § 1.861–18(b)(1), a transaction to which the section applies is categorized as (i) a transfer of a copyright right in a computer program; (ii) a transfer of a copy of a computer program (a ''copyrighted article''); (iii) the provision of services for the development or modification of a computer program; or (iv) the provision of know-how relating to computer programming techniques. Section 1.861–18(c) provides that a transfer of a computer program is classified as the transfer of a copyright right if there is a non-de minimis grant of any of the following four rights: (i) The right to make copies of the computer program for purposes of distribution to the public by sale or other transfer of ownership, or by rental, lease, or lending; (ii) the right to prepare derivative computer programs based upon the copyrighted computer program; (iii) the right to make a public performance of the computer program; or (iv) the right to publicly display the computer program. Section 1.861–18(f) further categorizes a transfer of a copyright right as either the sale or license of the copyright right and a transfer of a copyrighted article as either the sale or lease of the copyrighted article.

Section 1.861–18 generally does not provide a comprehensive basis for categorizing many common transactions involving what is commonly referred to as ''cloud computing,'' which typically is characterized by on-demand network access to computing resources, such as networks, servers, storage, and software. *See, e.g.,* National Institute of Standards and Technology, Special Publication 500–322 (February 2018) (''NIST Report''). Cloud computing transactions typically are described for non-tax purposes as following one or more of the following three models: Software as a Service (''SaaS''); Platform as a Service (''PaaS''); and Infrastructure as a Service (''IaaS''). SaaS allows customers to access applications on a provider's cloud infrastructure through an interface such as a web browser. NIST Report, p. 9–10. PaaS allows customers to deploy applications created by the customer onto a provider's cloud infrastructure using programming languages, libraries, services, and tools supported by the provider. NIST Report, pp. 10–11. IaaS allows customers to access processing, storage, networks, and other infrastructure resources on a provider's cloud infrastructure. NIST Report, p. 11. A cloud computing transaction typically does not involve any transfer of a computer program classified under § 1.861–18 as a transfer of a copyright right or copyrighted article or any provision of development services or know-how relating to computer programs or programming. Although certain cloud computing transactions may provide similar functionality with respect to computer programs as transactions subject to § 1.861–18 (for example, the transfer of a computer program via download may provide similar functionality as the same program accessed via a web browser), § 1.861–18 does not address the provision of online access to use the computer program. Accordingly, § 1.861–18 would not apply to classify such a transaction.

In addition to the cloud computing models described above, other transactions exist that are not solely related to computing but still involve on-demand network access to technological resources (these transactions and cloud computing transactions are collectively referred to herein as ''cloud transactions''). These transactions have increased in frequency over time and share similarities with the three cloud computing models described above. Examples include streaming music and video, transactions involving mobile device applications (''apps''), and access to data through remotely hosted software. These transactions may not involve, in whole or in part, a transfer under § 1.861–18 of a copyright right or copyrighted article, or a provision of development services or know-how relating to computer programs or programming.

In general, a cloud transaction involves access to property or use of property, instead of the sale, exchange, or license of property, and therefore typically would be classified as either a lease of property or a provision of services. Section 7701(e) and case law provide factors that are relevant for classifying a transaction as either a lease of property or a provision of services. In particular, section 7701(e)(1) provides that a contract that purports to be a service contract will be treated instead as a lease of property if the contract is properly treated as a lease taking into account all relevant factors, including whether (1) the service recipient is in physical possession of the property, (2) the service recipient controls the property, (3) the service recipient has a significant economic or possessory interest in the property, (4) the service provider does not bear any risk of substantially diminished receipts or substantially increased expenditures if there is nonperformance under the contract, (5) the service provider does not use the property concurrently to provide significant services to entities unrelated to the service recipient, and (6) the total contract price does not substantially exceed the rental value of the property for the contract period. Section 7701(e)(2) provides that the factors in section 7701(e)(1) apply to determine whether any arrangement, not just contracts which purport to be service contracts, is properly treated as a lease. Consistent with the inclusive statutory language, the legislative history indicates that this list of factors

is meant to be non-exclusive and constitutes a balancing test, such that the presence or absence of a single factor may not be dispositive in every case. S. Prt. No. 169 (Vol. I), 98th Cong., 2d Sess., at 138 (1984); Joint Committee on Taxation Staff, *General Explanation of the Revenue Provisions of the Deficit Reduction Act of 1984,* 98th Cong., at 60 (Comm. Print 1984).

In addition, courts have also considered other factors in determining whether transactions are leases of property or the provision of services, including whether the service provider had the right to replace the relevant property with comparable property, whether the property was a component of an integrated operation in which the service provider had other responsibilities, whether the service provider operated the equipment, and whether the service provider's fee was based on a measure of work performed rather than the mere passage of time. *See, e.g., Musco Sports Lighting, Inc.* v. *Comm'r,* T.C. Memo 1990–331, *aff'd,* 943 F.2d 906 (8th Cir. 1991); *Xerox Corp* v. *U.S.,* 656 F.2d 659 (Ct. Cl. 1981); and *Smith* v. *Comm'r,* T.C. Memo 1989–318.

Explanation of Provisions

I. Proposed § 1.861–19

Proposed § 1.861–19 provides rules for classifying a cloud transaction as either a provision of services or a lease of property. Proposed § 1.861–19(a) specifies that the rules apply for purposes of sections 59A, 245A, 250, 267A, 367, 404A, 482, 679, and 1059A; subchapter N of chapter 1; chapters 3 and 4; and sections 842 and 845 (to the extent involving a foreign person), as well as with respect to transfers to foreign trusts not covered by section 679.

In order to make other sections consistent with proposed § 1.861–19, *Example 5* in § 1.937–3(e) is proposed to be removed from the rules for determining whether income is derived from sources within a U.S. possession or territory.

A. Definition of ''Cloud Transaction''

Proposed § 1.861–19(b) defines a cloud transaction as a transaction through which a person obtains non-de minimis on-demand network access to computer hardware, digital content (as defined in proposed § 1.861–18(a)(3)), or other similar resources. This definition is not limited to computer hardware and software, or to the IaaS, PaaS, and SaaS models described above, because it is intended also to apply to other transactions that share characteristics of on-demand network access to technological resources, including access to streaming digital content and access to information in certain databases. Although this definition is broad, it does not encompass every transaction executed or completed through the internet. For example, proposed § 1.861–19 clarifies that the mere download or other electronic transfer of digital content for storage and use on a person's computer hardware or other electronic device does not constitute on-demand network access to the digital content and so would not be considered a cloud transaction for purposes of proposed § 1.861–19.

B. Classification of Cloud Transactions

1. Single Classification

Proposed § 1.861–19(c) provides that a cloud transaction is classified solely as either a lease of property or the provision of services. Certain cloud transactions may have characteristics of both a lease of property and the provision of services. Such transactions are generally classified in their entirety as either a lease or a service, and not bifurcated into a lease transaction and a separate service transaction. For example, section 7701(e)(1) classifies a purported service contract as either a lease or a service contract and does not contemplate mixed classifications of a single, integrated transaction. In *Tidewater* v. *U.S.,* 565 F.3d 299 (5th Cir. 2009), *action on dec.,* 2010–01 (June 1, 2010) (*Tidewater*), the Fifth Circuit applied the factors in section 7701(e)(1) to determine a single character for a time charter with respect to an ocean-going vessel, rather than following the taxpayer's allocation of consideration from the transaction into separate service and lease components.

In some cases, the facts and circumstances may support the conclusion that an arrangement involves multiple cloud transactions to which proposed § 1.861–19 applies. In such cases, proposed § 1.861–19 requires a separate classification of each cloud transaction except any transaction that is de minimis.

2. Determination Based on All Relevant Factors

Proposed § 1.861–19(c)(1) provides that all relevant factors must be taken into account in determining whether a cloud transaction is classified as a lease of property (specifically, computer hardware, digital content (as defined in proposed § 1.861–18(a)(3)), or other similar resources) or the provision of services. The relevance of any factor varies depending on the factual situation, and any particular factor may not be relevant in a given instance.

Proposed § 1.861–19(c)(2) contains a non-exhaustive list of factors for determining whether a cloud transaction is classified as the provision of services or a lease of property. In general, application of the relevant factors to a cloud transaction will result in the transaction being treated as the provision of services rather than a lease of property. In addition to the statutory factors described in section 7701(e)(1), the proposed regulations set forth several factors applied by courts that the Treasury Department and the IRS have determined are relevant in demonstrating that a cloud transaction is classified as the provision of services: Whether the provider has the right to determine the specific property used in the cloud transaction and replace such property with comparable property; whether the property is a component of an integrated operation in which the provider has other responsibilities, including ensuring the property is maintained and updated; and whether the provider's fee is primarily based on a measure of work performed or the level of the customer's use rather than the mere passage of time. The proposed regulations include several examples applying the factors in proposed § 1.861–19(c)(2) to different types of cloud transactions.

Certain factors that are relevant under proposed § 1.861–19(c) may be the same as or similar to those used to determine whether transactions other than cloud transactions are classified as leases or services under other authorities. However, cloud transactions, which involve on-demand network access to property such as computer hardware and digital content, may have significant differences from other lease and service transactions that involve direct physical access to property. Accordingly, the interpretation of factors and their application to cloud transactions require an analysis that is sensitive to the inherent differences between transactions involving physical access to property and transactions involving on-demand network access.

C. Classification of Cloud Transactions Related to Other Transactions

Certain arrangements may involve multiple transactions, where one or more transactions would be classified as a cloud transaction under proposed § 1.861–19(b) and one or more transactions do not qualify as a cloud transaction and would be classified under other sections of the Code and regulations, or under general tax law principles. For example, an arrangement

might involve both a cloud transaction and a transaction that would be classified under the rules of § 1.861–18 as a lease of a copyrighted article. Proposed § 1.861–19(c)(3) provides that, in such cases, the classification rules apply only to classify the cloud transaction, and any non-cloud transaction will be classified separately under such other section of the Code or regulations, or under general tax law principles. However, for purposes of administrability, proposed § 1.861–19(c)(3) provides that no transaction will be classified separately if it is de minimis. This rule is illustrated by examples contained in proposed § 1.861–19(d).

II. Modifications of § 1.861–18

A. Scope of Application

The preamble to the final regulations under § 1.861–18 governing the classification of transactions involving computer programs (T.D. 8785, 63 FR 52971 (October 2, 1998)) indicated that § 1.861–18 would apply only to such transactions because the need for guidance with respect to transactions involving computer programs was most pressing. The preamble noted, however, that the Treasury Department and the IRS may consider as part of a separate guidance project whether to apply the principles of those regulations to other transactions. Since § 1.861–18 was adopted as a final regulation in 1998, content in digital format and subject to copyright law, including music, video, and books, has become a common basis for commercial transactions. Consumption of such digital content has grown in part because of new computer hardware, including laptops, tablets, e-readers, and smartphones, that allows users to more easily obtain and use digital content.

The Treasury Department and the IRS have determined that the rules and principles underlying existing § 1.861–18 have provided useful guidance with respect to computer programs and that these rules and principles should apply to certain other digital content. Accordingly, proposed § 1.861–18 broadens the scope of existing § 1.861–18 to apply to all transfers of ''digital content,'' defined in proposed § 1.861–18(a)(3) as any content in digital format and that is either protected by copyright law or is no longer protected by copyright law solely due to the passage of time, whether or not the content is transferred in a physical medium. Digital content includes, for example, books, movies, and music in digital format in addition to computer programs.

Certain terms have been changed in proposed § 1.861–18, including references to computer programs being replaced with references to digital content. The application of proposed § 1.861–18 to digital content other than computer programs is illustrated by proposed § 1.861–18(h)(19) through (21) (Examples 19 through 21).

B. Rights To Advertise Copyrighted Articles

Comments received on the proposed regulations (REG–251520–96; 61 FR 58152; November 13, 1996) (the ''1996 proposed regulations'') that were finalized in 1998 as existing § 1.861–18 recommended that the transfer of a right to publicly perform or display a computer program should not be considered the transfer of a copyright right if the right is limited to the advertisement of a copyrighted article and the public performance or display of the entire copyrighted article is not permitted. The recommendation of these comments was not incorporated into existing § 1.861–18, but the Treasury Department and the IRS acknowledged in the preamble to existing § 1.861–18 that it may be appropriate to revisit the issue in the future and observed that the transfer of such rights to advertise a copyrighted article in many cases would be de minimis under existing § 1.861–18(c)(1)(ii).

In light of experience in administering existing § 1.861–18, the Treasury Department and the IRS have determined that the transfer of the right to publicly perform or display digital content for the purpose of advertising the sale of the digital content should not constitute the transfer of a copyright right for purposes of those portions of the Code enumerated in § 1.861–18(a)(1). For example, rights provided to a video game retailer allowing the retailer to display screenshots of a video game on television commercials promoting sales of the game generally would not, on their own, constitute a transfer of copyright rights that is significant in context. Accordingly, proposed § 1.861–18 modifies existing § 1.861–18(c)(2)(iii) and (iv) to provide that a transfer of the mere right to public performance or display of digital content for purposes of advertising the digital content does not by itself constitute a transfer of a copyright right.

C. Source of Income for Sales of Copyrighted Articles in Electronic Medium

Comments received on the 1996 proposed regulations addressed the sourcing of income from the sale of computer programs through electronic downloads and noted uncertainty regarding the application of the title passage rule of § 1.861–7(c) to these sales of copyrighted articles. Although the preamble indicated that the parties in many cases can agree where title passes for inventory property, the final regulations under § 1.861–18 included only a general reference to the relevant source rules and did not specifically address the application of the title passage rule for sales of copyrighted articles. Based on experience in administering existing § 1.861–18 since 1998, the Treasury Department and the IRS have become more aware of the uncertainty associated with determining the source of sales of copyrighted articles by application of § 1.861–7(c), in particular in the context of electronically downloaded software. In many sales of copyrighted articles, the location where rights, title, and interest are transferred is not specified. In some cases, due to intellectual property law concerns, there may be no passage of legal title when the copyrighted article is sold. Moreover, the Treasury Department and the IRS have determined that contractual specification of a location—other than the customer's location—as the location of transfer could be easily manipulated and would bear little connection to economic reality in the case of a transfer by electronic medium of digital content, given that a sale and transfer of digital content by electronic medium generally would not be considered commercially complete until the customer has successfully downloaded the copy.

In light of these considerations, proposed § 1.861–18(f)(2)(ii) provides that when copyrighted articles are sold and transferred through an electronic medium, the sale is deemed to occur at the location of download or installation onto the end-user's device used to access the digital content for purposes of § 1.861–7(c). It is expected that vendors generally will be able to identify the location of such download or installation. Comments are requested as to the availability, reliability and cost of this information. In the absence of information about the location of download or installation onto the end-user's device used to access the digital content, the sale is deemed to have occurred at the location of the customer based on the taxpayer's recorded sales data for business or financial reporting purposes. Consistent with existing § 1.861–18, proposed § 1.861–18(f)(2)(ii) provides that income from sales or exchanges of copyrighted articles is sourced under sections 861(a)(6),

862(a)(6), 863, or 865(a), (b), (c), or (e), as appropriate. The Treasury Department and the IRS do not expect proposed § 1.861–18(f)(2)(ii) to impact the application of income tax treaties to which the United States is a party given that the taxation of gains under those treaties is generally determined by reference to the residence country of the seller and not the source of income from the sale. Income from leases of copyrighted articles is sourced under section 861(a)(4) or 862(a)(4), as appropriate.

In order to make other sections consistent with proposed § 1.861–18(f)(2)(ii), a cross-reference has been added in the rules for sales of inventory property in § 1.861–7(c), and Example 4 in § 1.937–3(e) has been removed from the rules for determining whether income is derived from sources within a U.S. possession or territory.

III. Change in Method of Accounting

The application of these new rules for purposes of the affected Code sections may require certain taxpayers to change their methods of accounting under section 446(e) for affected transactions. Any change in method of accounting that a taxpayer makes in order to comply with these regulations would be a change initiated by the taxpayer. Accordingly, the change in method of accounting must be implemented under the rules of § 1.446–1(e) and the applicable administrative procedures that govern voluntary changes in method of accounting under section 446(e).

IV. Request for Comments

Comments are requested on all aspects of these proposed regulations, including the following topics:

(1) Whether the definition of digital content should be defined more broadly than content protected by copyright law and content that is no longer protected by copyright law solely due to the passage of time;

(2) whether any special considerations should be taken into account in applying the rules in existing § 1.861–18 to transfers of digital content other than computer programs;

(3) whether any other aspects of existing § 1.861–18 need to be modified if that section is amended as proposed;

(4) whether the classification of cloud transactions as either a service or a lease is correct, or whether cloud transactions are more properly classified in another category (for example, a license or a sale);

(5) realistic examples of cloud transactions that would be treated as leases under proposed § 1.861–19;

(6) the existence of arrangements involving both a transaction that would qualify as a cloud transaction and another non-de minimis transaction that would be classified under another provision of the Code or Regulations, or under general tax law principles;

(7) potential bases for allocating consideration in arrangements involving both a transaction that would qualify as a cloud transaction and another non-de minimis transaction that would be classified under another provision of the Code or Regulations, or under general tax law principles;

(8) administrable rules for sourcing income from cloud transactions in a manner consistent with sections 861 through 865; and

(9) application of proposed § 1.861–19 to an arrangement that involves non-de minimis rights both to access digital content on-demand over a network and to download such digital content onto a user's electronic device for offline use.

Proposed Effective Date

The regulations are proposed to apply to taxable years beginning on or after the date of publication of the Treasury decision adopting these regulations as final regulations in the **Federal Register**. No inference should be drawn from the proposed effective date concerning the treatment of transactions involving digital content or cloud transactions entered into before the regulations are applicable. For transactions involving transfers of computer programs occurring pursuant to contracts entered into before publication of the final regulations, the rules in former § 1.861–18, T.D. 8785 and T.D. 9870, will apply. For proposed dates of applicability, see §§ 1.861–18(i) and 1.861–19(e).

Special Analyses

Regulatory Planning and Review

Executive Orders 13563 and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

These proposed rules have been designated by the Office of Management and Budget's Office of Information and Regulatory Affairs as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (MOA) (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. The Treasury Department and the IRS project that these rules are not economically significant because current industry practice is generally consistent with the principles underlying the proposed regulations. Comments are requested as to whether this characterization of industry practice is inaccurate.

A. Background

When assessing tax on income arising from international transactions, the ''source'' of income is important in determining a taxpayer's tax liability. U.S. sourcing rules, generally contained in code sections 861 to 865, determine whether income earned is considered domestic or foreign source. For U.S. resident taxpayers, the U.S. generally taxes both domestic and foreign source income and, for the latter, provides credits for foreign taxes up to the level of U.S. tax. Taxpayers with significant foreign tax credits (FTCs) typically prefer that income be considered foreign rather than U.S. source in order to maximize their use of FTCs and minimize their U.S. taxes.

Proper assessment of the source of a particular item of income depends on the nature and type (or character) of that income (for example, interest, dividend, compensation for services, royalties paid under a license, gains recorded in a sale). Source rules differ for different types of income, so it is first necessary for income tax purposes to classify the character of an item of income. In the case of transactions involving digital content and cloud transactions, the types of income most relevant are sales, licenses, and services, but there are currently no regulations specifically applicable to the classification of transactions involving digital content other than computer programs or the classification of transactions involving remote access to digital content through the cloud. These proposed regulations provide that guidance.

The character of income also affects the U.S. taxation of income earned by U.S. taxpayers through their foreign subsidiary corporations. Certain U.S. shareholders of controlled foreign corporations (as defined in section 957) must include their share of a controlled foreign corporation's subpart F income in the U.S. shareholder's gross income on a current basis. Section 951(a)(1)(A). The characterization of income can impact whether it is considered subpart F income (as defined in section 952).

B. Need for Proposed Regulations

Transactions involving digital content and cloud computing have become common due to the growth of electronic commerce. Such transactions must be classified in terms of character in order to apply various provisions of the Code, such as sourcing rules and subpart F. Existing Reg. § 1.861–18, finalized in 1998, provides rules for classifying transactions involving computer programs as, for example, a license of a computer program, a rental of a computer program, or a sale of a computer program. These existing regulations, however, do not explicitly cover transactions involving other digital content, such as digital music and video, or to cloud computing transactions, and thus taxpayers must determine how these transactions should be classified for tax purposes without clear guidance. The proposed regulations are needed to reduce this uncertainty. The proposed regulations also reduce the opportunities for taxpayers to take positions on source and character that inappropriately minimize their taxes.

C. Overview of Proposed Regulations

The proposed regulations provide updated guidance with respect to the classification of transactions involving digital content (proposed § 1.861–18) and new guidance with respect to cloud transactions (proposed § 1.861–19).

Existing rules, particularly final regulations under § 1.861–18, which were adopted in 1998, govern the classification of transactions involving computer programs. The Treasury Department and the IRS have determined that the rules and principles underlying existing § 1.861–18 provide useful guidance for transactions involving digital content. Proposed § 1.861–18 broadens the scope of its application to include digital content, which is defined in proposed § 1.861–18(a)(3) as any content in digital format that is either protected by copyright law or is no longer protected solely due to the passage of time (*e.g.,* books, movies, and music in digital format, in addition to computer programs).

Cloud computing transactions, which are typically characterized by on-demand network access to computing resources, would not generally be subject to classification under existing § 1.861–18 since such transactions typically do not include the transfer of a computer program, nor would such transactions be subject to proposed § 1.861–18 since such transactions typically do not include the transfer of a copyright right or copyrighted article, or provision of development services related to computer programming. Consequently, proposed § 1.861–19 provides rules for classifying a cloud transaction as either a provision of service or a lease of property.

D. Economic Analysis

1. Baseline

The Treasury Department and the IRS have assessed the benefits and costs of the proposed regulation compared to a no-action baseline that reflects anticipated Federal income tax-related behavior in the absence of these proposed regulations.

2. Summary of Economic Effects

The proposed regulations provide certainty and clarity with respect to the characterization of income from digital transactions and cloud computing. In the absence of such guidance, the chances that different U.S. taxpayers would interpret the Code differentially, either from each other or from the intents and purposes of the underlying statutes, would be exacerbated. This divergence in interpretation could cause U.S. businesses to make economic decisions based on different interpretations of, for example, whether income from making digital music available to a user would be characterized as derived from a service or a lease transaction for purposes of applying sourcing rules and thus whether such income is considered domestic or foreign. If economic decisions are not guided by uniform incentives across otherwise similar investors and across otherwise similar investments, the resulting pattern of economic activity is generally inefficient. Thus, the Treasury Department and the IRS expect that the definitions and guidance provided in the proposed regulation will help support an efficient allocation of economic activity among taxpayers, relative to the baseline.

The characterization of income from digital transactions and cloud computing, for example, may impact taxpayer incentives under section 59A (the tax on certain base erosion payments) and section 250 (foreign derived intangible income and global intangible low-taxed income). For example, under section 59A, the characterization of a cloud transaction as a service, as opposed to a lease, may implicate the services cost method exception under section 59A(d)(5). Such characterization may also impact the documentation requirements or eligibility for treatment as foreign-derived intangible income under section 250(b). However, because current industry practice is generally consistent with the principles underlying the proposed regulations, the Treasury Department and the IRS expect these regulations to have only a small effect on economic activity or compliance costs relative to the baseline.

The Treasury Department and IRS solicit comments on the economic effects of the proposed regulations.

3. Economic Effects of Specific Provisions

a. Transactions Involving Copyright-Protected Digital Content

Existing § 1.861–18 provides rules for classifying transfers of computer programs as, for example, a license of a computer program, a lease of a computer program, or a sale of a computer program. Proposed § 1.861–18 broadens the scope of existing § 1.861–18 to apply to all transfers of digital content. In addition, as discussed in Part II.B of the Explanation of Provisions section, proposed § 1.861–18 clarifies that a transfer of the mere right to public performance or display of digital content for advertising purposes does not by itself constitute a transfer of a copyright right. Further, as explained in Part II.C of the Explanation of Provisions section, proposed § 1.861–18 provides clarity around the title passage rule of § 1.861–7(c) by providing that when copyrighted articles are sold, the sale is deemed to occur at the location of the download or installation onto the end-user's device, or in the absence of that information then at the location of the customer. Proposed 1.861–7(c) provides that a sale of personal property is consummated at the place where the rights, title, and interest of the seller in the property are transferred to the buyer, or, when bare legal title is retained by the seller, where beneficial ownership passes.

In considering how the place of sale should be determined for digital content, the Treasury Department and the IRS considered, as an alternative, not issuing specific rules and instead retaining the existing rules without further clarification for copyrighted articles. The Treasury Department and the IRS elected to provided further clarity about the sourcing of income from the sale of copyrighted articles because (1) in the context of electronically downloaded software, the location in which rights, title, and interest are transferred is often difficult to determine or not specified, and (2) the location of transfer could be easily manipulated (for example, the server location from which a copyrighted

article is downloaded). Consequently, for administrative and clarification purposes, proposed § 1.861–18(f)(2)(ii) provides that when a copyrighted article is sold through an electronic medium, the sale is deemed to occur at the location of download or installation onto the end-user's device. The Treasury Department and the IRS are proposing this location definition because that is where the sale is completed, since until the download is complete, the content is not entirely transferred.

The Treasury Department and the IRS solicit comments on these proposed regulations and particularly solicit comments that provide data, other evidence, or models that would enhance the rigor with which the final regulations governing digital content might be developed.

b. Cloud Transactions

Proposed § 1.861–19 provides rules for classifying a cloud transaction as either a lease of property (*i.e.,* computer hardware, digital content, or other similar resources) or a provision of services. These rules contain a non-exhaustive list of factors which include statutory factors described in section 7701(e)(1) and factors applied by courts, as explained in Part I.B.2. of the Explanation of Provisions section.

As an alternative, the Treasury Department and the IRS considered not providing further specific guidance regarding how cloud computing transactions should be classified (for sourcing and other purposes). The Treasury Department and the IRS have developed the proposed regulations (proposed § 1.861–18 and proposed § 1.861–19) because they will provide clarity to taxpayers and the IRS when determining the character of income arising from transactions involving digital content and cloud computing. This increased clarity, relative to the baseline, will reduce the potential for tax planning strategies that exploit uncertainty resulting from the lack of explicit guidance for characterizing common transactions involving digital content and cloud computing. Consistent reporting across taxpayers also increases the IRS's ability to consistently enforce the tax rules, thus increasing equity and decreasing opportunities for tax evasion.

The Treasury Department and the IRS solicit comments on these proposed regulations and particularly solicit comments that provide data, other evidence, or models that would enhance the rigor with which the final regulations governing cloud transactions might be developed.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act requires consideration of the regulatory impact on small businesses. It is hereby certified that these proposed regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. chapter 6).

As discussed elsewhere in the Special Analyses, transactions involving digital content and cloud computing have become common due to the growth of electronic commerce. Such transactions must be classified in terms of character in order to apply various provisions of the Code, such as sourcing rules and subpart F. Existing Reg. § 1.861–18, finalized in 1998, provides rules for classifying transactions involving computer programs as, for example, a license of a computer program, a rental of a computer program, or a sale of a computer program. These existing regulations, however, do not explicitly cover transactions involving other digital content, such as digital music and video, or to cloud computing transactions and thus taxpayers must determine how these transactions should be classified for tax purposes without clear guidance. The proposed regulations provide certainty and clarity to these affected taxpayers.

Although data are not readily available to estimate the number of small entities that would be affected by this proposed rule, the Treasury Department and the IRS project that any economic impact of the regulations would be minimal for businesses regardless of size. These proposed regulations generally provide clarification of definitions regarding how transactions are classified, they are not expected to have an impact on burden for large or small businesses. The Treasury Department and the IRS project that any economic impact would be small because current industry practice is generally consistent with the principles underlying the proposed regulations.

Notwithstanding this certification that the proposed rule will not have a significant economic impact on a substantial number of small entities, the Treasury Department and the IRS invite comments on the impact this proposed rule would have on small entities.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** section. All comments will be available at *www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Robert Z. Kelley of the Office of the Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, reporting, and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.861–7 is amended by revising paragraph (c) to read as follows:

§ 1.861–7 Sale of personal property.

* * * * *

(c) *Country in which sold.* For purposes of part I (section 861 and following), subchapter N, chapter 1 of the Code, and the regulations thereunder, a sale of personal property is consummated at the time when, and the place where, the rights, title, and interest of the seller in the property are transferred to the buyer. Where bare legal title is retained by the seller, the sale shall be deemed to have occurred at the time and place of passage to the buyer of beneficial ownership and the risk of loss. For determining the place of sale of copyrighted articles transferred in electronic medium, see § 1.861–18(f)(2)(ii). However, in any case in which the sales transaction is arranged in a particular manner for the primary purpose of tax avoidance, the foregoing rules will not be applied. In such cases, all factors of the transaction, such as negotiations, the execution of the agreement, the location of the property, and the place of payment, will be considered, and the sale will be treated as having been consummated at

the place where the substance of the sale occurred.

* * * * *

■ **Par. 3.** Section 1.861–18 is amended as follows:

■ a. For each paragraph listed in the following table, removing the language in the ''Remove'' column and adding in its place the language in the ''Add'' column.

Paragraph	Remove	Add
(a)(1)	computer programs	digital content.
(b)(1) introductory text	a computer program	digital content.
(b)(1)(i)	computer program	digital content.
(b)(1)(ii)	computer program	digital content.
(b)(1)(iii)	computer program	digital content.
(b)(1)(iv)	computer programming techniques	development of digital content.
(b)(2), first sentence	Any transaction	Any arrangement.
(b)(2), first sentence	computer programs	digital content.
(b)(2), second sentence	overall transaction	overall arrangement.
(c)(1)(i), first sentence	a computer program	digital content.
(c)(1)(i), third sentence	a computer program	digital content.
(c)(1)(i), third sentence	that program	that digital content.
(c)(1)(ii)	a computer program	digital content.
(c)(1)(ii)	the computer program	the digital content.
(c)(2)(i)	computer program	digital content.
(c)(2)(ii)	computer programs	digital content.
(c)(2)(ii)	copyrighted computer program	digital content.
(c)(3), first sentence	a computer program	digital content.
(c)(3), second sentence	program	digital content.
(d)	a newly developed or modified computer program.	newly developed or modified digital content.
(d)	computer program	digital content.
(e) introductory text	a computer program	digital content.
(e)(1)	computer programming techniques	the development of digital content.
(f)(3), subject heading	computer programs	digital content.
(f)(3), first sentence	computer programs	digital content.
(f)(3), second sentence	a computer program on disk	digital content on a disk.
(f)(3), third sentence	program	digital content.
(g)(2)	a computer program	digital content.
(g)(3)(i), first sentence	a computer program	digital content.
(g)(3)(i), first sentence	the program	the digital content.
(g)(3)(i), first sentence	software	digital content.
(g)(3)(ii), first sentence	a computer program	digital content.
(g)(3)(ii), first sentence	the program	the digital content.
(g)(3)(ii), second sentence	a computer program	digital content.
(g)(3)(ii), second sentence	the program	the digital content.

■ b. Amend paragraph (a)(1) by:

■ i. Adding before ''367'' sections ''59A, 245A, 250, 267A,'';

■ ii. Removing ''551,''; and

■ iii. Removing ''chapter 3, chapter 5'' and adding in its place ''chapters 3 and 4,''.

■ c. Revising paragraphs (a)(3), (c)(2)(iii) and (iv), and (f)(2).

■ d. Redesignating Examples 1 through 18 of paragraph (h) as paragraphs (h)(1) through (18), respectively.

■ e. Adding paragraphs (h)(19) through (21).

■ f. Revising paragraphs (i) and (j).

■ g. Removing paragraph (k).

The revisions and additions read as follows:

§ 1.861–18 Classification of transactions involving digital content.

* * * * *

(a) * * *

(3) *Digital content.* For purposes of this section, digital content means a computer program or any other content in digital format that is either protected by copyright law or no longer protected by copyright law solely due to the passage of time, whether or not the content is transferred in a physical medium. For example, digital content includes books in digital format, movies in digital format, and music in digital format. For purposes of this section, a computer program is a set of statements or instructions to be used directly or indirectly in a computer in order to bring about a certain result and includes any media, user manuals, documentation, data base, or similar item if the media, user manuals, documentation, data base, or other similar item is incidental to the operation of the computer program.

* * * * *

(c) * * *

(2) * * *

(iii) The right to make a public performance of digital content, other than a right to publicly perform digital content for the purpose of advertising the sale of the digital content performed; or

(iv) The right to publicly display digital content, other than a right to publicly display digital content for the purpose of advertising the sale of the digital content displayed.

* * * * *

(f) * * *

(2) *Transfers of copyrighted articles*—(i) *Classification.* The determination of whether a transfer of a copyrighted article is a sale or exchange is made on the basis of whether, taking into account all facts and circumstances, the benefits and burdens of ownership have been transferred. A transaction that does not constitute a sale or exchange because insufficient benefits and burdens of ownership of the copyrighted article have been transferred, such that a person other than the transferee is properly treated as the owner of the copyrighted article, will be classified as a lease generating rental income.

(ii) *Source.* Income from transactions that are classified as sales or exchanges of copyrighted articles will be sourced under section 861(a)(6), 862(a)(6), 863,

or 865(a), (b), (c), or (e), as appropriate. When a copyrighted article is sold and transferred through an electronic medium, the sale is deemed to have occurred at the location of download or installation onto the end-user's device used to access the digital content for purposes of § 1.861–7(c), subject to the tax avoidance provisions in § 1.861–7(c). However, in the absence of information about the location of download or installation onto the end-user's device used to access the digital content, the sale will be deemed to have occurred at the location of the customer, which is determined based on the taxpayer's recorded sales data for business or financial reporting purposes. Income derived from leasing a copyrighted article will be sourced under section 861(a)(4) or 862(a)(4), as appropriate.

* * * * *

(h) * * *

(19) *Example 19*—(i) *Facts.* Corp A operates a website that offers electronic books for download onto end-users' computers or other electronic devices. The books offered by Corp A are protected by copyright law. Under the agreements between content owners and Corp A, Corp A receives from the content owners a digital master copy of each book, which Corp A downloads onto its server, in addition to the non-exclusive right to distribute for sale to the public an unlimited number of copies in return for paying each content owner a specified amount for each copy sold. Corp A may not transfer any of the distribution rights it receives from the content owners. The term of each agreement Corp A has with a content owner is shorter than the remaining life of the copyright. Corp A charges each end-user a fixed fee for each book purchased. When purchasing a book on Corp A's website, the end-user must acknowledge the terms of a license agreement with the content owner that states that the end-user may view the electronic book but may not reproduce or distribute copies of it. In addition, the agreement provides that the end-user may download the book onto a limited number of its devices. Once the end-user downloads the book from Corp A's server onto a device, the end-user may access and view the book from that device, which does not need to be connected to the internet in order for the end-user to view the book. The end-user owes no additional payment to Corp A for the ability to view the book in the future.

(ii) *Analysis.* (A) Notwithstanding the license agreement between each end-user and content owner granting the end-user rights to use the book, the relevant transactions are the transfer of a master copy of the book and rights to sell copies from the content owner to Corp A, and the transfers of copies of books by Corp A to end-users. Although the content owner is identified as a party to the license agreement memorializing the end-user's rights with respect to the book, each end-user obtains those rights directly from Corp A, not from the content owner. Because the end-user receives only a copy of each book and does not receive any of the copyright rights described in paragraph (c)(2) of this section, the transaction between Corp A and the end-user is classified as the transfer of a copyrighted article under paragraph (c)(1)(ii) of this section. See paragraphs (h)(1) and (2) of this section (*Example 1* and *Example 2*). Under the benefits and burdens test of paragraph (f)(2) of this section, the transaction is classified as a sale and not a lease, because the end-user receives the right to view the book in perpetuity on its device.

(B) The transaction between each content owner and Corp A is a transfer of copyright rights. In obtaining a master copy of the book along with the right to sell an unlimited number of copies to customers, Corp A receives a copyright right described in paragraph (c)(2)(i) of this section. For purposes of paragraph (b)(2) of this section, the digital master copy is de minimis. Under paragraph (f)(1) of this section, there has not been a transfer of all substantial rights in the copyright rights to the content because each content owner retains the right to further license or sell the copyrights, subject to Corp A's interest; Corp A has acquired no right itself to transfer the copyright rights to any of the content; and the grant of distribution rights is for less than the remaining life of the copyright to each book. Therefore, the transaction between each content owner and Corp A is classified as a license, and not a sale, of copyright rights.

(20) *Example 20*—(i) *Facts.* Corp A offers end-users memberships that provide them with unlimited access to Corp A's catalog of copyrighted music in exchange for a monthly fee. In order to access the music, an end-user must download each song onto a computer or other electronic device. The end-user may download songs onto a limited number of its devices. Under the membership agreement terms, an end-user may listen to the songs but may not reproduce or distribute copies of them. Once the end-user stops paying Corp A the monthly membership fee, an electronic lock is activated so that the end-user can no longer access the music.

(ii) *Analysis.* The end-users receive none of the copyright rights described in paragraph (c)(2) of this section and instead receive only copies of the digital content. Therefore, under paragraph (c)(1)(ii) of this section, each download is classified as the transfer of a copyrighted article. Although an end-user will retain a copy of the content at the end of the payment term, the end-user cannot access the content after the electronic lock is activated. Taking into account the special characteristics of digital content as provided in paragraph (f)(3) of this section, the activation of the electronic lock is the equivalent of having to return the copy. Therefore, under paragraph (f)(2) of this section, each transaction is classified as a lease of a copyrighted article because the right to access the music is limited.

(21) *Example 21*—(i) *Facts.* Corp A offers a catalog of movies and TV shows, all of which are subject to copyright protection. Corp A gives end-users several options for viewing the content, each of which has a separate price. A ''streaming'' option allows an end-user to view the video, which is hosted on Corp A's servers, while connected to the internet for as many times as the end-user wants during a limited period. A ''rent'' option allows an end-user to download the video to its computer or other electronic device (which does not need to be connected to the internet for viewing) and watch the video as many times as the end-user wants for a limited period, after which an electronic lock is activated and the end-user may no longer view the content. A ''purchase'' option allows an end-user to download the video and view it as many times as the end-user chooses with no end date. Under all three options, the end-user may view the video but may not reproduce or distribute copies of it. Under the ''rent'' and ''purchase'' options, the end-user may download the video onto a limited number of its devices.

(ii) *Analysis.* (A) With respect to the ''rent'' and ''purchase'' options, the end-user receives none of the copyright rights described in paragraph (c)(2) of this section but, rather, receives only copies of the digital content. Therefore, transactions under those two options are transfers of copyrighted articles. Transactions for which the end-user chooses the ''purchase'' option are classified as sales of copyrighted articles under the benefits and burdens test of paragraph (f)(2) of this section because the end-user receives the right to view the videos in perpetuity. Transactions under the ''rent'' option are classified as leases of copyrighted articles under paragraph (f)(2) of this section because the end-user's right to view the videos is for a limited period.

(B) For transactions under the ''streaming'' option, there is no transfer of any copyright rights described in paragraph (c)(2) of this section. There is also no transfer of a copyrighted article, because the content is not downloaded by an end-user, but rather is accessed through an on-demand network. The transaction also does not constitute the provision of services for the development of digital content or the provision of know-how under paragraph (b)(1) of this section. Therefore, paragraph (b)(1) of this section does not apply to such transaction. Instead, the transaction is a cloud transaction that is classified under § 1.861–19. See § 1.861–19(d)(9).

(i) *Effective date.* This section applies to transactions involving the transfer of digital content, or the provision of services or of know-how in connection with digital content, pursuant to contracts entered into in taxable years beginning on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. For transactions involving computer programs occurring pursuant to contracts entered into in taxable years beginning before the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**, see § 1.861–18(i) as contained in T.D. 8785 and T.D. 9870.

(j) *Change in method of accounting required by this section.* In order to

comply with this section, a taxpayer engaging in a transaction involving digital content pursuant to a contract entered into in taxable years beginning on or after the date described in paragraph (i) of this section may be required to change its method of accounting. If so required, the taxpayer must secure the consent of the Commissioner in accordance with the requirements of § 1.446–1(e) and the applicable administrative procedures for obtaining the Commissioner's consent under section 446(e) for voluntary changes in methods of accounting.

■ **Par. 4.** Section 1.861–19 is added to read as follows:

§ 1.861–19 Classification of cloud transactions.

(a) *In general.* This section provides rules for classifying a cloud transaction (as defined in paragraph (b) of this section) either as a provision of services or as a lease of property. The rules of this section apply for purposes of Internal Revenue Code sections 59A, 245A, 250, 267A, 367, 404A, 482, 679, and 1059A; subchapter N of chapter 1; chapters 3 and 4; and sections 842 and 845 (to the extent involving a foreign person), and apply with respect to transfers to foreign trusts not covered by section 679.

(b) *Cloud transaction defined.* A cloud transaction is a transaction through which a person obtains on-demand network access to computer hardware, digital content (as defined in § 1.861–18(a)(3)), or other similar resources, other than on-demand network access that is de minimis taking into account the overall arrangement and the surrounding facts and circumstances. A cloud transaction does not include network access to download digital content for storage and use on a person's computer or other electronic device.

(c) *Classification of transactions*—(1) *In general.* A cloud transaction is classified solely as either a lease of computer hardware, digital content (as defined in § 1.861–18(a)(3)), or other similar resources, or the provision of services, taking into account all relevant factors, including the factors set forth in paragraph (c)(2) of this section. The relevance of any factor varies depending on the factual situation, and one or more of the factors set forth in paragraph (c)(2) of this section may not be relevant in a given instance. For purposes of this paragraph (c), computer hardware, digital content, or other similar resources are referred to as ''the property,'' and the party to the transaction making such property available to customers for use is referred to as ''the provider.''

(2) *Factors demonstrating classification as the provision of services.* Factors demonstrating that a cloud transaction is classified as the provision of services rather than a lease of property include the following factors—

(i) The customer is not in physical possession of the property;

(ii) The customer does not control the property, beyond the customer's network access and use of the property;

(iii) The provider has the right to determine the specific property used in the cloud transaction and replace such property with comparable property;

(iv) The property is a component of an integrated operation in which the provider has other responsibilities, including ensuring the property is maintained and updated;

(v) The customer does not have a significant economic or possessory interest in the property;

(vi) The provider bears any risk of substantially diminished receipts or substantially increased expenditures if there is nonperformance under the contract;

(vii) The provider uses the property concurrently to provide significant services to entities unrelated to the customer;

(viii) The provider's fee is primarily based on a measure of work performed or the level of the customer's use rather than the mere passage of time; and

(ix) The total contract price substantially exceeds the rental value of the property for the contract period.

(3) *Application to arrangements comprised of multiple transactions.* An arrangement comprised of multiple transactions generally requires separate classification for each transaction. If at least one of the transactions is a cloud transaction, but not all of the transactions are cloud transactions, this section applies only to classify the cloud transactions. However, any transaction that is de minimis, taking into account the overall arrangement and the surrounding facts and circumstances, will not be treated as a separate transaction, but as part of another transaction.

(d) *Examples.* The provisions of this section may be illustrated by the examples in this paragraph (d). For purposes of this paragraph, unless otherwise indicated, Corp A is a domestic corporation; Corp B is a foreign corporation; end-users are individuals; and no rights described in § 1.861–18(c)(2) (copyright rights) are transferred as part of the transactions described.

(1) *Example 1: Computing capacity*—(i) *Facts.* Corp A operates data centers on its premises in various locations. Corp A provides Corp B computing capacity on Corp A's servers in exchange for a monthly fee based on the amount of computing power made available to Corp B. Corp B provides its own software to run on Corp A's servers. Depending on utilization levels, the servers accessed by Corp B may also be used simultaneously by other customers. The computing capacity provided to Corp B can be sourced from a variety of servers in one or more of Corp A's data centers, and Corp A determines how its computing resources are allocated among customers. Corp A agrees to keep the servers operational, including by performing physical maintenance and repair, and may replace any server with another server of comparable functionality. Corp A agrees to provide Corp B with a payment credit for server downtime. Corp B has no ability to physically alter any server.

(ii) *Analysis.* (A) The computing capacity transaction between Corp A and Corp B is a cloud transaction described in paragraph (b) of this section because Corp B obtains a non-de minimis right to on-demand network access to computer hardware of Corp A.

(B) Corp B has neither physical possession of nor control of the servers, beyond Corp B's right to access and use the servers. Corp A may replace any server with a functionally comparable server. The servers are a component of an integrated operation in which Corp A has other responsibilities, including maintaining the servers. The transaction does not provide Corp B with a significant economic or possessory interest in the servers. The agreement provides that Corp A will provide Corp B with a payment credit for server downtime, such that Corp A bears risk of substantially diminished receipts in the event of contract nonperformance. The servers may, depending on utilization levels, be used by Corp A to provide significant computing capacity to entities unrelated to Corp B. Corp A is compensated according to the level of Corp B's use (that is, the amount of computing power made available) and not solely based on the passage of time. Taking into account all of the relevant factors, the transaction between Corp A and Corp B is classified as the provision of services under paragraph (c) of this section.

(2) *Example 2: Computing capacity on dedicated servers*—(i) *Facts.* The facts are the same as in paragraph (d)(1)(i) of this section (the facts in *Example 1*), except that, in order to offer more security to Corp B, Corp A provides Corp B computing capacity exclusively through designated servers, which are owned by Corp A and located at Corp A's facilities. Corp A agrees not to use a designated server for any other customer for the duration of its arrangement with Corp B. Corp A's compensation reflects a substantial return for maintaining the servers in addition to the rental value of the servers.

(ii) *Analysis.* (A) As in paragraph (d)(1) of this section, the transaction between Corp A and Corp B is a cloud transaction described in paragraph (b) of this section because Corp B obtains a non-de minimis right to on-

demand network access to computer hardware resources of Corp A.

(B) The fact that Corp A provides computing capacity to Corp B through designated servers indicates that such servers are not used concurrently by other Corp A customers. However, Corp A retains physical possession of the servers. In addition, Corp A's sole responsibility for maintaining the servers, and its sole right to replace or physically alter the servers, indicate that Corp A controls the servers. Although Corp B obtains the exclusive right to use certain servers, Corp B does not have a significant economic or possessory interest in the servers because, among other things, Corp A retains the right to replace the servers, Corp A bears the risk of damage to the servers, and Corp B does not share in cost savings associated with the servers because the fee paid by Corp B to Corp A does not vary based on Corp A's costs. The compensation to Corp A substantially exceeds the rental value of the servers. The other relevant factors are analyzed in the same manner as paragraph (d)(1) of this section. Taking into account all of these factors, the transaction between Corp A and Corp B is classified as a provision of services under paragraph (c) of this section.

(3) *Example 3: Access to software development platform and website hosting*—(i) *Facts.* Corp A provides Corp B a software platform that Corp B uses to develop and deploy websites with a range of features, including blogs, message boards, and other collaborative knowledge bases. The software development platform consists of an operating system, web server software, scripting languages, libraries, tools, and back-end relational database software and allows Corp B to use in its websites certain visual elements subject to copyrights held by Corp A. The software development platform is hosted on servers owned by Corp A and located at Corp A's facilities. Corp B's finished websites are also hosted on Corp A's servers. The software development platform and servers are also used concurrently to provide similar functionality to Corp A customers unrelated to Corp B. Corp B accesses the software development platform via a standard web browser. Corp B has no ability to alter the software code. A small amount of scripting code is downloaded onto Corp B's computers to facilitate secure logins and access to the software development platform. All other functions of the software development platform execute on Corp A's servers, and no portion of the core software code is ever downloaded by Corp B or Corp B's customers. Corp A is solely responsible for maintaining the servers and software development platform, including ensuring continued functionality and compatibility with Corp B's browser, providing updates and fixes to the software for the duration of the contract with Corp B, and replacing or upgrading the servers or software at any time with a functionally similar version. Corp B pays Corp A a monthly fee for the platform and website hosting that takes into account the storage requirements of Corp B's websites and the amount of website traffic supported, but there is no stand-alone fee for use of the software development platform. Corp B agrees to pay for Corp A's website hosting services for a minimum period, after which Corp B may continue to pay for Corp A's website hosting services or transfer its developed websites to a different hosting provider. Corp A agrees to provide Corp B with a payment credit for server downtime.

(ii) *Analysis.* (A) Corp A's provision to Corp B of access to the software platform is a cloud transaction described in paragraph (b) of this section because Corp B obtains a non-de minimis right to on-demand network access to computer hardware and software resources of Corp A. Corp A's hosting of Corp B's finished websites is part of the provision of access to the software platform and hardware.

(B) Corp B does not have physical possession of the software platform or servers. Although Corp B uses Corp A's platform to develop and deploy websites, Corp B does not maintain the software platform or the servers on which it is hosted, and Corp B cannot alter the software platform. Accordingly, Corp B does not control the software platform or the servers. Corp A maintains the right to replace or upgrade the software platform and servers with functionally similar versions. The servers and software platform are components of an integrated operation in which Corp A has various responsibilities, including maintaining the servers and updating the software. Corp B does not have a significant economic or possessory interest in Corp A's software platform or servers. Corp B may lose revenue with respect to the websites that it deploys on Corp A's servers when the servers are down; nonetheless, Corp A bears the risk of substantially diminished receipts in the event of contract nonperformance because Corp A will provide Corp B with a payment credit for server downtime. Corp A provides access to the servers and platform to Corp B and other customers concurrently. Corp A is compensated based on Corp B's level of use (that is, the amount of computing resources provided) and not solely by the passage of time. Taking into account all of the factors, the transaction between Corp A and Corp B is classified as a provision of services under paragraph (c) of this section.

(C) Although the download of a small amount of scripting code to facilitate logins and access to the software platform would otherwise constitute a transfer of a computer program, instead of a cloud transaction under paragraph (b) of this section, the download is de minimis in the context of the overall arrangement, and therefore, under paragraph (c)(3) of this section, there is no separate classification of the download. Similarly, the fact that Corp B receives rights to publicly display certain copyrighted visual elements resulting from Corp A's software development platform on Corp B's own websites, which would otherwise constitute a transfer of copyright rights under § 1.861–18, instead of a cloud transaction under paragraph (b) of this section, does not require separate classification because the right to use such elements is also de minimis. Thus, under paragraph (c) of this section, the entire arrangement is classified as a service.

(4) *Example 4: Access to software*—(i) *Facts.* The facts are the same as in paragraph (d)(3)(i) of this section (the facts in *Example 3*), except that, instead of providing website development software, Corp A provides Corp B access to customer relationship management software under several options such as ''entry-level,'' ''mid-level,'' and ''advanced-level,'' via a standard web browser, which Corp A hosts on its servers for a monthly subscription fee. Corp B has no ability to alter the software code, and Corp A agrees to make available new versions of the software as they are developed for the duration of Corp B's contract, and to ensure servers' uptime in accordance with the service level agreement.

(ii) *Analysis.* (A) As in paragraph (d)(3) of this section, the transaction between Corp A and Corp B is a cloud transaction described in paragraph (b) of this section because Corp B obtains a non-de minimis right to on-demand network access to computer hardware and software resources of Corp A.

(B) The relevant factors are analyzed in the same manner as in paragraph (d)(3) of this section, except that compensation due to Corp A is determined based on the option chosen and the passage of time rather than a measure of computing resources utilized. Although as a general matter compensation based on the passage of time is more indicative of a lease than a service transaction, that factor is outweighed by the other factors, which support classification as a service transaction. Taking into account all of the factors, the transaction between Corp A and Corp B is classified as a provision of services under paragraph (c) of this section.

(5) *Example 5: Downloaded software subject to § 1.861–18*—(i) *Facts.* Corp A provides software for download to Corp B that enables Corp B to create a scalable, shared pool of computing resources over Corp B's own network for use by Corp B's employees. Corp B downloads the software, which runs solely on Corp B's servers. Corp A provides Corp B with free updates for download as they become available. Corp B pays Corp A an annual fee, and, upon termination of the arrangement, an electronic lock is activated that prevents Corp B from further using the software.

(ii) *Analysis.* Under paragraph (b) of this section, the download of software for use with Corp B's computer hardware does not constitute on-demand network access by Corp B to Corp A's software. Accordingly, the transaction between Corp A and Corp B is not a cloud transaction described in paragraph (b) of this section. Because the transaction involves the transfer of digital content as defined in § 1.861–18(a)(3), it is classified under § 1.861–18.

(6) *Example 6: Access to online software via an application*—(i) *Facts.* Corp A provides Corp B word processing, spreadsheet, and presentation software and allows employees of Corp B to access the software over the internet through a web browser or an application (''app''). In order to access the software from a mobile device, Corp B's employees usually download Corp A's app onto their devices. To access the full functionality of the app, the device must be connected to the internet. Only a limited number of features on the app are available without an internet connection. Corp B has

no ability to alter the software code. The software is hosted on servers owned by Corp A and located at Corp A's facilities and is used concurrently by other Corp A customers. Corp A is solely responsible for maintaining and repairing the servers and software, and ensuring continued functionality and compatibility with Corp B's employees' devices and providing updates and fixes to the software (including the app) for the duration of the contract with Corp B. Corp B pays a monthly fee based on the number of employees with access to the software. Upon termination of the arrangement, Corp A activates an electronic lock preventing Corp B's employees from further utilizing the app, and Corp B's employees are no longer able to access the software via a web browser.

(ii) *Analysis.* (A) Corp A's provision to Corp B of a non-de minimis right to on-demand network access to Corp A's computer hardware and software resources for the purpose of fully utilizing Corp A's software is a cloud transaction described in paragraph (b) of this section.

(B) Corp B has neither physical possession of nor control over Corp A's word processing, spreadsheet, and presentation software or computer hardware. Additionally, the servers and software are part of an integrated operation in which Corp A maintains the servers and updates the software. Corp A makes available its word processing, spreadsheet, and presentation software and servers to Corp B and other customers concurrently. Corp A's compensation, though based in part on the passage of time, is also determined by reference to Corp B's level of use (that is, the number of Corp B employees with access to the software). Taking into account all of the factors, the transaction between Corp A and Corp B is classified as the provision of services under paragraph (c) of this section.

(C) The provision of the app to Corp B's employees by download onto their devices would be a transfer of a computer program rather than a cloud transaction subject to paragraph (b) of this section. However, under paragraph (c)(3) of this section, it is necessary to consider whether that transfer is de minimis in the context of the overall arrangement and in light of the surrounding facts and circumstances. Here, the significance of the download of the app by Corp B's employees is limited by the fact that the device running the app must be connected to Corp A's servers via the internet to enable most of the app's core functions. The software that enables such functionality remains on Corp A's servers and is accessed through an on-demand network by Corp B's employees. Therefore, the download of the app is de minimis, and under paragraph (c)(3) of this section, the entire arrangement is classified as a service.

(7) *Example 7: Access to offline software with limited online functions*—(i) *Facts.* Corp A provides Corp B word processing, spreadsheet, and presentation software that is functionally similar to the software in paragraph (d)(6) of this section (*Example 6*). The software is made available for access over the internet but only to download the software onto a computer or onto a mobile device in the form of an app. The downloaded software contains all the core functions of the software. Employees of Corp B can use the software on their computers or mobile devices regardless of whether their computer or mobile device is online. When online, the software provides a few ancillary functions that are not available offline, such as access to document templates and data collection for diagnosing problems with the software. Whether working online or offline, Corp B employees can store their files only on their own computer or mobile device, and not on Corp A's data storage servers. Because the software provides near full functionality without access to Corp A's servers, it requires more computing resources on employees' computers and devices than the app in paragraph (d)(6) of this section. Corp B's employees can also download updates to the software as part of the monthly fee arrangement. Upon termination of the arrangement, an electronic lock is activated so that the software can no longer be accessed.

(ii) *Analysis.* The provision of the software constitutes a lease of a copyrighted article under § 1.861–18. See § 1.861–18(h)(4). The access to the online ancillary functions otherwise would constitute a cloud transaction under paragraph (b) of this section, but the access to these functions is de minimis in the context of the overall arrangement, considering that the core functions are available offline through the downloaded software. Because there is no cloud transaction described in paragraph (b) of this section, this section does not apply.

(8) *Example 8: Data storage, separate from access to offline software*—(i) *Facts.* The facts are the same as in paragraph (d)(7)(i) of this section (the facts in *Example 7*), except that Corp A also provides data storage to Corp B on Corp A's server systems in exchange for a monthly fee based on the amount of data storage used by Corp B. Under the data storage terms, Corp B employees may store files created by Corp B employees using Corp A's software or other software. Although Corp A's word processing software is compatible with Corp A's data storage systems, the core functionality of Corp A's software is not dependent on Corp B's purchase of the storage plan. Depending on utilization levels, the server systems providing data storage to Corp B may also be used simultaneously for other customers. The data storage provided to Corp B can be sourced from a variety of server systems in one or more of Corp A's data centers, and Corp A determines how its computing resources are allocated among customers. Corp A agrees to keep the server systems operational, including by performing physical maintenance and repair, and may replace any server system with another one of comparable functionality. Corp A agrees to provide Corp B with a payment credit for server downtime. Corp B has no ability to physically alter the server systems.

(ii) *Analysis.* (A) Corp A's provision of software and data storage capacity constitute separate transactions, and neither is de minimis. Therefore, under paragraph (c)(3) of this section, the transactions are classified separately.

(B) As in paragraph (d)(7), Corp B's download of fully functional software, along with on-demand network access to certain limited online features, does not constitute a cloud transaction, but rather constitutes a lease of a copyrighted article under § 1.861–18.

(C) Corp A's provision of data storage constitutes a cloud transaction because Corp B obtains a non-de minimis right to on-demand network access to computer hardware of Corp A.

(D) Corp B has neither physical possession of nor control of the server systems, beyond Corp B's right to access and use the servers. Corp A may replace any server with a functionally comparable server. The server systems are a component of an integrated operation in which Corp A has other responsibilities, including maintaining the server systems. The transaction does not provide Corp B with a significant economic or possessory interest in the servers. The servers may, depending on utilization levels, be used by Corp A to provide significant services to entities unrelated to Corp B. Corp A is compensated according to the level of Corp B's use (that is, the amount of data storage used by Corp B) and not solely based on the passage of time. Because Corp A will provide Corp B with a payment credit for server downtime, Corp A bears risk of substantially diminished receipts in the event of contract nonperformance. Taking into account all of these factors, the transaction for data storage is classified as a provision of services under paragraph (c) of this section.

(9) *Example 9: Streaming digital content using third-party servers*—(i) *Facts.* Corp A streams digital content in the form of videos and music to end-users from servers located in data centers owned and operated by Data Center Operator. Data Center Operator's content delivery network facility services multiple customers. Each end-user uses a computer or other electronic device to access unlimited streaming video and music in exchange for payment of a flat monthly fee to Corp A. The end-user may select from among the available content the particular video or song to be streamed. Corp A continually updates its content catalog, replacing content with higher quality versions and adding new content at no additional charge to the end-user. Content that is streamed to the end-user is not stored locally on the end-user's computer or other electronic device and therefore can be played only while the end-user's computer or other electronic device is connected to the internet. Corp A pays Data Center Operator a fee based on the amount of data storage used and computing power made available in connection with Corp A's content streaming. The storage and computing power provided to Corp A can be sourced from a variety of servers in one or more of Data Center Operator's facilities, and Data Center Operator determines how computing resources are allocated among its customers. Data Center Operator covenants to keep the servers operational, including performing physical maintenance and repair. Corp A has no right or ability to physically alter the servers.

(ii) *Analysis.* (A) The relevant factors for classifying the transaction between Corp A and Data Center Operator are analyzed in the same manner as the computing capacity and data storage transactions in paragraphs (d)(1) and (8) of this section (*Example 1* and *Example 8*), respectively, such that the transaction between Corp A and Data Center Operator is classified as a provision of services by Data Center Operator to Corp A under paragraph (c) of this section.

(B) A transaction between Corp A and an end-user is a cloud transaction described in paragraph (b) of this section because the end-user obtains a non-de minimis right to on-demand network access to digital content of Corp A.

(C) An end-user has neither physical possession of nor control of the digital content. Additionally, Corp A has the right to determine the digital content used in the cloud transaction and retains the right to modify its selection of digital content. Digital content accessed by end-users is a component of an integrated operation in which Corp A's other responsibilities include maintaining and updating its content catalog. Corp A's end-users do not obtain a significant economic or possessory interest in any of the digital content in Corp A's catalog. The digital content provided by Corp A may be accessed concurrently by multiple unrelated end-users. Although, as a general matter, compensation based on the passage of time is more indicative of a lease than a service transaction, that factor is outweighed by the other factors, which support a services classification. Taking into account all of the factors, a transaction between an end-user and Corp A is classified as a provision of services under paragraph (c) of this section.

(10) *Example 10: Downloaded digital content subject to § 1.861–18*—(i) *Facts.* Corp A offers digital content in the form of videos and music solely for download onto end-users' computers or other electronic devices for a fee. Once downloaded, the end-user accesses the videos and songs from the end-user's computer or other electronic device, which does not need to be connected to the internet in order to play the content. The end-user owes no additional payment to Corp A for the ability to play the content in the future.

(ii) *Analysis.* Under paragraph (b) of this section, the download of digital content onto an end-user's computer for storage and use on that computer does not constitute on-demand network access by the end-user to the digital content of Corp A. Accordingly, the transaction between the end-user and Corp A is not a cloud transaction described in paragraph (b) of this section, and this section does not apply to the transaction. Because the transaction involves the transfer of digital content as defined in § 1.861–18(a)(3), it will be classified under § 1.861–18. See § 1.861–18(h)(21).

(11) *Example 11: Access to online database*—(i) *Facts.* Corp A offers an online database of industry-specific materials. End-users access the materials through Corp A's website, which aggregates and organizes information topically and hosts a proprietary search engine. Corp A hosts the website and database on its own servers and provides multiple end-users access to the website and database concurrently. Corp A is solely responsible for maintaining and replacing the servers, website, and database (including adding or updating materials in the database). End-users have no ability to alter the servers, website, or database. Most materials in Corp A's database are publicly available by other means, but Corp A's website offers an efficient way to locate and obtain the information on demand. Certain materials in Corp A's database constitute digital content within the meaning of § 1.861–18(a)(3), and Corp A pays the copyright owners a license fee for using them. Each end-user may download any of the materials to its own computer and keep such materials without further payment. The end-user pays Corp A a fee based on the number of searches or the amount of time spent on the website, and such fee is not dependent on the amount of materials the end-user downloads. The fee that the end-user pays is substantially higher than the stand-alone charge for accessing the same digital content outside of Corp A's system.

(ii) *Analysis.* (A) Corp A's provision to an end-user of access to Corp A's website and online database is a cloud transaction described in paragraph (b) of this section because the end-user obtains a non-de minimis right to on-demand access to Corp A's computer hardware and software resources.

(B) An end-user's downloading of the digital content would be classified as a sale of copyrighted articles under § 1.861–18. Nonetheless, taking into account the entire arrangement, including that the primary benefit to the end-user is access to Corp A's database and its proprietary search engine, and that the stand-alone charge for accessing the digital content would be substantially less than the fee Corp A charges, the downloads are de minimis. Accordingly, under paragraph (c)(3) of this section, there is no separate classification of the downloads.

(C) The end-user has neither physical possession of nor control of the database, software, or the servers that host the database or software. Corp A retains the right to replace its servers and update its software and database. The database, software, and servers are part of an integrated operation in which Corp A is responsible for curating the database, updating the software, and maintaining the servers. Corp A provides each end-user on-demand network access to its software and online database concurrently with other end-users. Certain end-users pay Corp A a fee based on time spent on Corp A's website, which could be construed as compensation based on the passage of time and thus be more indicative of a lease than a service transaction. However, the fee that the end-user pays is substantially higher than the stand-alone charge for accessing the same digital content outside of Corp A's system. Accordingly, on balance, the fee arrangement supports the classification of the transaction as a service transaction. Taking into account all of these factors, the arrangement between end-users and Corp A is treated as the provision of services under paragraph (c) of this section.

(e) *Effective/applicability date.* This section applies to cloud transactions occurring pursuant to contracts entered into in taxable years beginning on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

(f) *Change in method of accounting required by this section.* In order to comply with this section, a taxpayer engaging in a cloud transaction pursuant to a contract entered into on or after the date described in paragraph (e) of this section may be required to change its method of accounting. If so required, the taxpayer must secure the consent of the Commissioner in accordance with the requirements of § 1.446–1(e) and the applicable administrative procedures for obtaining the Commissioner's consent under section 446(e) for voluntary changes in methods of accounting.

§ 1.937–3 [Amended]

■ **Par. 5.** Section 1.937–3 is amended by removing Examples 4 and 5 from paragraph (e).

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2019–17425 Filed 8–9–19; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 155

[Docket No. USCG–2018–0493]

RIN 1625–AC50

Person in Charge of Fuel Transfers

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Coast Guard is proposing to amend the requirements regulating personnel permitted to serve as a person in charge (PIC) of fuel oil transfers on an inspected vessel by adding the option of using a letter of designation (LOD) in lieu of a Merchant Mariner Credential (MMC) with a Tankerman-PIC endorsement. Thousands of towing vessels are currently transitioning from being uninspected vessels to becoming inspected vessels. This proposal would allow a PIC currently using the LOD option on one of those uninspected vessels to continue to use that option to perform the same fuel oil transfers once the vessel receives its initial Certificate

of Inspection. Under this proposal, obtaining a MMC with a Tankerman-PIC endorsement would become optional for PICs of fuel oil transfers on inspected vessels.

DATES: Comments and related material must be received by the Coast Guard on or before October 15, 2019. Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before October 15, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0493 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

Collection of information. Submit comments on the collection of information discussed in section VI. D of this preamble both to the Coast Guard's online docket and to the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget using one of the following two methods:

- *Email: dhsdeskofficer@omb.eop.gov.*
- *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Cathleen Mauro, Office of Merchant Mariner Credentialing (CG–MMC–1), Coast Guard; telephone 202–372–1449, email *Cathleen.B.Mauro@uscg.mil.*

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I. Public Participation and Request for Comments

The Coast Guard views public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions. Documents this proposal mentions as being available in the docket, and all public comments, will be available in our online docket at *https://www.regulations.gov,* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or if a final rule is published.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *https://www.regulations.gov/privacyNotice.*

We do not plan to hold a public meeting but you may submit a request for one using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking we will issue a **Federal Register** notice to announce the date, time, and location of such a meeting.

II. Abbreviations

CFR Code of Federal Regulations
COI Certificate of Inspection
CPI–U Consumer Price Index for all Urban Consumers
DHS Department of Homeland Security
DOI Declaration of inspection
FR Federal Register
GSA General Services Administration
LOD Letter of designation
MERPAC Merchant Marine Personnel Advisory Committee
MISLE Marine Information for Safety and Law Enforcement
MMC Merchant Mariner Credential
MPH Miles per hour
NPRM Notice of proposed rulemaking
OMB Office of Management and Budget
PIC Person in charge
PWSA Ports and Waterways Safety Act
§ Section
TSAC Towing Safety Advisory Committee
U.S.C. United States Code

III. Basis and Purpose

The Coast Guard's authority under Subtitle II and Chapter 700 of Title 46 United States Code, specifically 46 U.S.C 3306 and 70034,[1] allows us to establish and amend regulations for a person in charge (PIC) of fuel oil transfers. This proposed rule is authorized by Subtitle II provisions to regulate lightering (46 U.S.C. 3715) and personnel qualifications for all inspected vessels, including nontank vessels (46 U.S.C. 3703), and by 46 U.S.C. chapter 700 provisions regarding waterfront safety, including protection of navigable waters and the resources therein (46 U.S.C. 70011).

This proposed rule would allow an alternative method of meeting requirements for personnel allowed to serve as the PIC of a fuel oil transfer on an inspected vessel. In 1998, the Coast Guard established the option of using a letter of designation (LOD) for uninspected vessels in 33 CFR 155.710(e)(2).[2] The LOD designates the holder as a PIC of the transfer of fuel oil and states that the holder has received sufficient formal instruction from the operator or agent of the vessel to ensure his or her ability to safely and adequately carry out the duties and responsibilities of the PIC.[3] The same year we created the LOD option, we stated that the formal instruction required by this option should ensure that personnel acting as PICs of fuel oil transfers have the ability to safely and adequately carry out their duties and

[1] Authority in 46 U.S.C. 70034 was formerly reflected in 33 U.S.C. 1231. On December 4, 2018, the Frank LoBiondo Coast Guard Authorization Act of 2018, Public Law 115–282, was enacted. Its section 401 titled ''Codification of Ports and Waterways Safety Act,'' restated the Ports and Waterways Safety Act (PWSA) authorities in an enacted title of the U.S. Code. Specifically, it added chapter 700, Ports and Waterways Safety, to Title 46. Also, its section 402 repealed the PWSA (Pub. L. 92–340), as amended, which had been reflected in 33 U.S.C. 1221–1231, 1232–1232b.

[2] See Qualifications for Tankermen and for Persons in Charge of Transfers of Dangerous Liquids and Liquefied Gases final rule (63 FR 35822, July 1, 1998).

[3] 33 CFR 155.715.

responsibilities while minimizing the risks of pollution from fuel oil spills.[4]

Thousands of towing vessels are currently transitioning from being uninspected vessels to becoming inspected vessels.[5] While this proposed rule is not limited to towing vessels, it would allow a PIC currently using the LOD option on one of those uninspected towing vessels to continue to use that option to perform the same fuel oil transfers once the vessel becomes an inspected vessel. Both Executive Orders 12866 (Regulatory Planning and Review) and 13777 (Enforcing the Regulatory Reform Agenda) direct us to eliminate unnecessary regulatory burdens.[6] We believe that the LOD option provides a level of safety and protection for fuel oil transfers equivalent to the Tankerman-PIC option, while eliminating the burden of obtaining and maintaining a Merchant Mariner Credential (MMC). As a result, the Coast Guard is proposing to add this LOD alternative so that individuals on inspected vessels would have an option that is currently only available to individuals on uninspected vessels.

This option would be available only for transfers of fuel oil. The PIC requirements in 33 CFR 155.710(a), (b) and (f) for vessels transferring cargo would remain unchanged.

IV. Background

The need to issue this proposed rule to eliminate an unnecessary burden became more evident after we published the ''Inspection of Towing Vessels'' final rule. As towing vessels transition from an uninspected to inspected status, fuel transfer operations on thousands of towing vessels will now require PICs to have MMCs instead of LODs even though fueling operations remain unchanged.[7] The change in the PIC requirement was triggered by the transition to inspected vessels.

The requirements for a Tankerman PIC endorsement described in 46 CFR 13.210 include the completion of Coast Guard approved training in firefighting and in Tankship Dangerous Liquids or Liquefied Gas as appropriate. Training is approved under the requirements in 46 CFR part 10, subpart D. Formal instruction provided by the owner or operator of a vessel does not require review or approval by the Coast Guard prior to delivery.

The Coast Guard compared the requirement to complete approved training in order to obtain an MMC with a Tankerman PIC endorsement for PICs on inspected vessels and the formal instruction provided on uninspected vessels, as a requirement for issuing an LOD on uninspected vessels. The Coast Guard could not discern a meaningful difference in fueling operations on uninspected towing vessels and inspected vessels that require Tankerman-PIC endorsements. As uninspected vessels move to becoming inspected vessels their fuel oil transfer operations do not change, but the change in the requirement to hold an MMC means the individuals conducting the fuel oil transfer must obtain substantially more costly training and demonstrate experience with cargo transfers. While fuel oil transfers are similar in nature to cargo transfers, they cannot be used to demonstrate the service requirements for a Tankerman PIC endorsement described in 46 CFR 13.203(b). As a result, the Coast Guard is proposing to allow the use of LODs on all inspected vessels. The existing § 155.710(e)(1) requirement is overly burdensome on personnel engaged in fuel oil transfers on inspected vessels that require a Declaration of Inspection (DOI),[8] and we have no evidence that it increases the level of safety of life, environmental protection, or protection of property at sea beyond that provided by the LOD option.

A. Requirements in 33 CFR Part 155 for Person in Charge of Fuel Oil Transfers

The regulations in § 155.700 require the designation of a PIC for any transfer of fuel oil to, from, or within a vessel with a capacity of 250 or more barrels, and § 155.710(e) specifically refers to PICs engaged in the transfer of fuel oil requiring a DOI. Personnel designated as a PIC through the LOD option described in 33 CFR 155.715 must receive formal instruction from the operator or agent of the vessel to ensure their ability to safely and adequately carry out the duties and responsibilities of the PIC. The Coast Guard believes this formal instruction, which has been adequate for uninspected vessels, is also adequate for inspected vessels. Section 155.710(e) specifies the qualifications of a PIC for any fuel oil transfer requiring a DOI on inspected and uninspected vessels. On inspected vessels, the PIC of a fuel oil transfer requiring a DOI must hold a valid MMC with either an officer endorsement authorizing service [9] on board the vessel, or a Tankerman-PIC endorsement.

Under § 155.710(e)(2), on uninspected vessels, the PIC of a fuel oil transfer has the option of either meeting PIC requirements for inspected vessels, or being designated as a PIC through an LOD as described in 33 CFR 155.715. The LOD must not only designate the person as a PIC, but it must also state that the person has received sufficient formal instruction from the operator or agent of the vessel to ensure his or her ability to safely and adequately carry out the duties and responsibilities of the PIC described in 33 CFR 156.120 and 156.150.

B. Cargo-Based Origins of Requirements To Obtain MMC Tankerman-PIC Endorsement

In 1995, the Coast Guard established the requirements for Tankerman-PIC endorsements in 46 CFR part 13, which were developed primarily for the transfer of cargo.[10] These requirements were specifically intended to improve the handling of liquid cargoes and reduce the risk and severity of spills from tankships. The provisions were not necessarily designed for transfers of oil solely used to fuel the propulsion or auxiliary machinery of the vessel, but fuel oil transfers are subject to these part 13 requirements. The part 13 training and certification requirements, which include service on tankships and completion of an approved course for Tankship Dangerous Liquids,[11] are extensive and appropriate for complex tankship operations.

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[4] 63 FR 35822, 35825, July 1, 1998.

[5] See 46 CFR 136.202, and discussion in Regulatory Analysis regarding the number of towing vessel making this transition.

[6] See Section 1(b)(11) and Section 1, respectively.

[7] The ''Inspection of Towing Vessels'' final rule established 46 CFR subchapter M, which requires towing vessels described in 46 CFR 136.105 to obtain a Certificate of Inspection. When towing vessels obtain their COI, their status changes from being an uninspected vessel to an inspected vessel, affecting which requirements in § 155.710(e) must be met for someone to serve as the PIC of a fuel oil transfer. (81 FR 40003, June 20, 2016)

[8] Section 156.150(a) requires a DOI before commencing any transfer of fuel oil and applies to vessels with a capacity of 250 barrels or more that engage in the transfer of oil or hazardous material on the navigable waters or contiguous zone of the United States. This requirement does not apply to public vessels. For source of applicability, see § 156.100.

[9] In our references to an officer endorsement required under § 155.710(e), we are referring to an officer endorsement authorizing service as a master, mate, pilot engineer, or operator on the vessel where the office seeks to serve as a PIC for a fuel oil transfer.

[10] A 1995 interim rule set out the handling, transfer, and transport of oil and certain hazardous liquid cargoes in bulk aboard vessels, and at that time the Coast Guard concluded, ''this rule will improve the handling, transfer, and transport of these cargoes and reduce the risk and severity of spillage from tank vessels.'' (60 FR 17134, April 4, 1995). When describing approval of tankerman endorsement courses, we noted that the Coast Guard would evaluate courses—including simulated transfer of cargo—to determine the credit allowed toward meeting the proposed service requirements (60 FR at 17139).

[11] Section 13.201(b)(2) and (4).

C. Different Standards Are Appropriate for Fuel Oil Transfers

Since 1998, when the Coast Guard established the LOD option, it has recognized that not all of the training and service requirements for a Tankerman-PIC endorsement were necessary for fuel oil transfers. The Coast Guard's successful use of LODs for uninspected vessels reflects that service on a tankship, and completing approved training oriented toward tankships, are not necessary for non-tankship inspected vessels when transferring fuel oil. As a result, in March 2017, the Coast Guard issued CG–MMC Policy Letter No. 01–17 titled, ''Guidelines for Issuing Endorsements for Tankerman-PIC Restricted to Fuel Transfers on Towing Vessels.''

Under CG–MMC Policy Letter No. 01–17, personnel on towing vessels have been relieved of some approved training costs, including travel to and from training facilities, and applicable tuition to comply with the full Tankerman-PIC requirements in 46 CFR part 13. In addition, CG–MMC Policy Letter No. 01–17 relieves the requirement for service experience on a tankship. However, under CG–MMC Policy Letter No. 01–17, personnel who do not hold an officer endorsement but who seek to be a PIC on an inspected towing vessel still need to obtain an MMC with a Tankerman-PIC endorsement restricted to fuel transfers on towing vessels to comply with § 155.710(e). This policy eased some of the requirements for obtaining an MMC with a qualifying endorsement for inspected towing vessels, but it did not completely relieve the burden of obtaining the credential or maintaining the endorsement through the renewal process every 5 years and it only addresses inspected towing vessels—not other inspected vessels.

The review of the requirements to obtain an MMC with a Tankerman PIC endorsement leading to the development of CG–MMC Policy Letter No. 01–17 also applies to other categories of inspected vessels transferring fuel oil. The requirements in 46 CFR part 13 were developed primarily for the transfer of cargo, and the approved training and service requirements are not necessary when transferring fuel oil. Although our existing requirements for inspected vessels that receive oil solely to fuel the propulsion or auxiliary machinery of the vessel offer some flexibility by allowing a credentialed officer to act as the PIC, in practice this is of limited value because it is a common practice for towing vessels to engage in operations such as midstreaming—fueling while underway and holding the vessel midstream—where it is not possible for the officers holding an MMC to serve as PIC for the fuel transfer.

D. Federal Advisory Committee Recommendations

The Coast Guard tasked the Towing Safety Advisory Committee (TSAC) [12] and Merchant Marine Personnel Advisory Committee (MERPAC) [13] to review CG–MMC Policy Letter No. 01–17 and the existing PIC requirements for vessel fuel transfers and make recommendations for amendments.

In December 2017, after reviewing CG–MMC Policy Letter No. 01–17 and existing regulations, TSAC recommended that the Coast Guard amend § 155.710(e) so that an LOD can be used by an individual on a towing vessel inspected under subchapter M to satisfy the requirements for the transfer of fuel oil described in 33 CFR 155.710.

MERPAC also reviewed CG–MMC Policy Letter No. 01–17 and the existing regulations. In October 2017, MERPAC issued a report and recommendation that viewed the policy as an appropriate interim solution. However, MERPAC did not endorse requiring MMCs for PICs for the long term. Instead, MERPAC recommended a regulatory change in which all inspected vessels would have the option to satisfy the PIC requirement for fuel transfers through either an LOD, as described in 33 CFR 155.715, or through holding an MMC with an officer or Tankerman-PIC endorsement.

The Coast Guard reviewed the recommendations from both TSAC and MERPAC, and agreed with MERPAC's broader recommendation that all inspected vessels should have the option of using an LOD to satisfy the requirement for designating the PIC of fuel transfers.

Under the LOD option, a PIC's formal instruction is tailored to the vessel identified in the LOD and must meet the requirements in § 155.715. This provides an equivalent level of safety of life, environmental protection, or protection of property at sea as the current requirement for a PIC on an inspected vessel. Therefore, we are proposing to allow the LOD to be used by PICs of fuel oil transfers on any inspected vessel. The TSAC and MERPAC recommendations are available in the docket for this rulemaking.

[12] Issued in June 2016, TSAC Task 16-01, Recommendations Regarding the Implementation of 46 Code of Federal Regulations Subchapter M–Inspection of Towing Vessels, directed TSAC to provide ''comments on the implementation of Subchapter M that the Committee feels are necessary.'' In its third report in response to this task, in December 2017, TSAC issued Report No. 3 that addressed the subject of Persons-In-Charge of Towing Vessel Fuel Transfers. A copy of this report is available in the docket.

[13] Issued in May 2017, MERPAC Task 99, Towing Vessel Restricted Tankerman PIC Endorsement, requested MERPAC to review and comment on CG–MMC Policy Letter 01–17 and the applicable regulations and provide recommendations for amendments, if needed. In October 2017, MERPAC issued its report, which is available in the docket.

V. Discussion of Proposed Rule

The Coast Guard proposes to amend 33 CFR 155.710(e), which sets forth the provisions for the qualifications of the PIC of any fuel oil transfer requiring a DOI. The proposal would not change the existing requirements for the PIC on uninspected vessels, and the requirements for vessels transferring cargo would also remain unchanged. The change would provide inspected vessels two options for meeting requirements to serve as the PIC of a fuel oil transfer. Vessel operators could comply with the current inspected vessel requirement of having a PIC with a valid MMC with either an officer or Tankerman-PIC endorsement, or use the new option for inspected vessels of designating a PIC with an LOD as described in 33 CFR 155.715.

A. Proposed Amendments to § 155.710(e)

We propose to revise the text of current paragraphs (e)(1) and (e)(2) and redesignate them as paragraphs (e)(1)(i) and (e)(1)(ii). We would then redesignate the remaining paragraphs in that section and amend a reference in the redesignated paragraph regarding tank barges to reflect our removal of paragraph (e)(2).

With respect to MMCs, we would also remove obsolete terminology such as merchant mariner ''licenses'' and ''Merchant Mariner Documents.'' The Coast Guard ceased issuing those types of documents in 2009 when we transitioned to the streamlined MMC. Also, we would clarify the first sentence of § 155.710(e) by changing ''shall verify'' to ''must verify.''

B. Proposed Amendments to § 155.715

In § 155.715, we would change the reference to § 155.710(e)(2) so that it refers to § 155.710(e)(1) instead. This change would reflect our amendments to § 155.710(e). Also, to remove a long-standing conflict of referring to the same letter as both ''letter of instruction'' and ''letter of designation,'' we would amend the reference to a letter of instruction by simply referring to it as ''the letter referenced in § 155.710(e)(1).''

This letter has become known by the title we gave it in the § 155.715 heading, ''letter of designation.'' Section 155.715 requires the letter to designate the holder as a PIC of the transfer of fuel oil and to state that the holder has received sufficient formal instruction from the operator or agent of the vessel to ensure his or her ability to safely and adequately carry out the duties and responsibilities of the PIC described in 33 CFR 156.120 and 156.150. Changing our reference to it as ''the letter referenced in § 155.710(e)(1)'' would not change any of those requirements, but it would make it clear that ''letter of designation'' is the correct way to refer to the letter referenced in § 155.710(e) that must satisfy the requirements of § 155.715.

C. Proposed Rule Only Addresses Fuel Oil Transfers, Not LNG Fuel Transfers

This proposed rule would not apply to liquefied natural gas (LNG) fuel transfers. Both §§ 155.710(e) and 155.715 apply solely to the transfer of ''fuel oil.'' *Fuel oil* means any oil used to fuel the propulsion and auxiliary machinery of the ship carrying the fuel.[14]

VI. Regulatory Analyses

A. Regulatory Planning and Review

Executive Orders 13563 (Improving Regulation and Regulatory Review) and 12866 (Regulatory Planning and Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs) directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. DHS considers this rule to be an Executive Order 13771 deregulatory action. See the OMB Memorandum titled ''Guidance Implementing Executive Order 13771, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017). Details on the estimated cost savings of this proposed rule can be found in the rule's economic analysis below.

On June 20, 2016, the Coast Guard published an Inspection of Towing Vessels final rule.[15] The Coast Guard estimated the rule would apply to more than 5,500 towing vessels that had previously been uninspected vessels. That rule established 46 CFR subchapter M, Towing Vessels (parts 136 through 144), which requires vessels subject to it to obtain a certificate of inspection (COI). The phase-in period for obtaining a COI under subchapter M runs from July 20, 2018, to July 20, 2022.[16]

As uninspected vessels subject to the requirements of 33 CFR 155.710(e)(2), these towing vessels had the flexibility of designating a PIC of a fuel oil transfer through an LOD rather than meeting the requirement to have a mariner aboard with a valid MMC with an officer or Tankerman-PIC endorsement.[17] When a towing vessel covered by the 2016 rule (81 FR 40003) obtains a COI, it will become an inspected vessel subject to the requirements of 33 CFR 155.710(e)(1) under which individuals designated as PIC of a fuel oil transfer must hold an MMC with either an officer or Tankerman-PIC endorsement. When exercising the option to designate a PIC through an LOD, the cost of providing formal instruction as described in 33 CFR 155.715 is borne by vessel operating companies; whereas, we are assuming the cost of obtaining the approved training for an MMC with a Tankerman-PIC endorsement is borne by the individual obtaining the credential, making the MMC requirement relatively more expensive for individuals who perform the same function in either case. Further, because a Tankerman-PIC endorsement is available as a minimum qualification, we do not assume that an individual would choose to obtain an officer endorsement as their qualification for PIC because a less burdensome option is available. The option of obtaining an MMC with endorsements other than a Tankerman-PIC, which is the minimum qualification necessary to comply with existing regulations, is the choice of the individual. In cases where an officer endorsement is used to satisfy the PIC requirement, we assume that it is because the individual already holds an MMC with other endorsements. The Coast Guard assumes the MMC was obtained in order to seek employment as an officer on vessels and serves as a PIC as part of their routine duties, rather than obtaining an officer endorsement to serve explicitly as PIC. The Coast Guard seeks input on the validity of this assumption.

In March 2017, the Coast Guard issued CG–MMC Policy Letter No. 01–17 titled ''Guidelines for Issuing Endorsements for Tankerman-PIC Restricted to Fuel Transfers on Towing Vessels.'' This policy minimized the burden of obtaining an MMC with the Tankerman-PIC endorsement necessary to serve as a PIC of a fuel oil transfer on an inspected towing vessel by allowing persons to obtain an MMC with a Tankerman-PIC endorsement restricted to fuel transfers on towing vessels. This policy allows those with an existing LOD to use the LOD to satisfy service requirements. This proposed rule would allow for an alternative method of designating who may serve as the PIC of a fuel oil transfer on an inspected vessel by providing the LOD option to inspected vessels that was previously only available to uninspected vessels. This would ease the economic burden on individuals who would otherwise bear the cost to obtain an MMC with a Tankerman-PIC endorsement.

Section 155.715 of title 33 of the CFR describes the requirements for an LOD, including proof that the holder ''has received sufficient formal instruction from the operator or agent of the vessel to ensure his or her ability to safely and adequately carry out the duties and responsibilities of the PIC.'' This formal instruction is less burdensome than the approved training required to obtain the Tankerman-PIC endorsement, including a Coast Guard-approved firefighting course and a Coast Guard-approved tankship dangerous liquids course.[18] This deregulatory action relieves individuals of the cost of obtaining and renewing an MMC while allowing continued operation of vessels during

[14] As provided in § 155.110, this 33 CFR 151.05 definition of ''fuel oil'' applies to §§ 155.710 and 155.715.

[15] See 81 FR 40003, June 20, 2016.

[16] See 46 CFR 136.202, which calls for 25 percent of the vessels to have COIs by July 22, 2019. It also calls for an additional 25 percent to obtain COIs for each of the remaining 3 years of the phase-in period. The final rule was made effective July 20, 2016, but it delayed implementation of most of its part 140 operations requirements, part 141 lifesaving requirements, part 142 fire protection requirements, part 143 machinery and electrical systems and equipment requirements, and part 144 construction and arrangement requirements until July 20, 2018. See §§ 140.105, 141.105, 142.105, 143.200, and 144.105.

[17] In previous information collections letters of designation, LODs are referred to as letters of instruction (LOIs).

[18] 46 CFR 13.201—Original application for Tankerman-PIC endorsement.

fuel oil transfers. The individuals expected to take advantage of this deregulatory action are the same individuals currently serving as a PIC through the use of an LOD on an uninspected towing vessel. While the inspection status of the vessels in the baseline population changes, we do not expect the fuel oil transfer operations on those vessels to change. Therefore we assume that the baseline risk of fuel oil transfers on towing vessels remains the same.

This deregulatory action would modify the text of 33 CFR 155.710 to specify that inspected vessels would also have the flexibility of designating a PIC of a fuel oil transfer through an LOD rather than meeting the requirement to have a mariner aboard with a valid MMC with an officer or Tankerman-PIC endorsement. This is the only change to § 155.710, as the requirements for an LOD remain the same.

TABLE 1—SUMMARY OF IMPACTS

Category	Summary
Applicability	Extend the LOD option described in 33 CFR 155.710(e)(2) to inspected vessels for fuel oil transfers. This would allow PIC designation to be fulfilled by an LOD rather than an MMC with an officer or Tankerman-PIC endorsement.
Affected Population	The 11,480 individuals on 5,740 vessels that transfer fuel oil and that have a capacity to carry at least 250 barrels or that receive fuel oil from a vessel with a capacity to carry at least 250 barrels.
Cost Savings (2018 $ Discounted at 7%)	10-year period of analysis: $250,384,488, Annualized: $35,649,118.

Affected Population

(1) *Vessel Population.*

Section 155.700 of 33 CFR requires each owner or operator of a vessel with a capacity of 250 barrels or more that engages in the transfer of fuel oil on the navigable waters or contiguous zone of the United States to designate the PIC of each transfer of fuel oil to or from the vessel. The affected population for this deregulatory action is a subset of all inspected vessels subject to the PIC requirements in 33 CFR 155.710(e)(1). The recent change from uninspected to inspected status makes subchapter M vessels uniquely impacted by the MMC requirement. The Coast Guard is not aware of other inspected vessel populations that would likely make use of this rule.

The vessel types identified as the affected population in the subchapter M rule are the same types identified under this rule. Since inspections started in 2018, more vessels have been identified, with a current population of 5,740. There are still difficulties identifying a steady population since inspections are ongoing through year 2022, during which Coast Guard is able to identify previously unencountered vessels and vessels not subject to subchapter M that were previously thought to be.[19]

Not all of the 5,740 affected vessels will become inspected vessels (obtain their COI) at the same time. As of June 2019, there are 766 inspected towing vessels under subchapter M.[20] That number will continue to increase but is subject to change as inspections are completed. Table 2 below lists the number of inspections completed or expected to be completed in each year of the phase-in period.[21] For the purpose of this analysis, the first effective year will be 2020. We will not count cost savings for vessels that already obtained their COI in 2018 and 2019 because we assume they would already need individuals with MMCs to continue operations.

TABLE 2—PROJECTION OF SUBCHAPTER M VESSELS OBTAINING A COI

Year	New COIs	Total subchapter M inspected vessels
2018	253	253
2019	983	1,236
2020	2,031	3,267
2021	1,236	4,503
2022	1,237	5,740

In the case of towing vessels, excluding a vessel from the population based on fuel capacity is unreliable because a vessel with a smaller (under 250 barrels) capacity may obtain fuel oil from a larger (250 or more barrels) vessel causing both to need a PIC to initiate a fuel oil transfer between the vessels. Section 156.120(s) requires a PIC at the transferring and receiving ends, and § 156.115 states that no person may serve as PIC on both ends unless authorized by the captain of the port.

The Coast Guard does not know if a given vessel with a capacity of less than 250 barrels will receive fuel from a vessel with a capacity of 250 or more barrels of fuel oil. Therefore, we assume that vessels with a capacity under 250 barrels may sometimes be required to have a designated PIC when transferring fuel oil with vessels with a larger capacity based on the requirements in § 156.120(s). The number of fuel oil transfers between large- (250 or more barrels) and small- (under 250 barrels) capacity vessels is unknown, but the Coast Guard assumes it to be a significant amount.

(2) *Affected Individuals.*

To estimate the impact of this deregulatory action, we must first establish a baseline of what the world would look like if no deregulatory action was taken. In this case, the baseline assumes that all newly inspected subchapter M vessels would use individuals with MMCs to serve as the PIC for fuel oil transfers. Any cost savings from this rule stem from the utilization of an LOD to qualify as PIC for fuel transfers and thus the avoided costs of obtaining MMCs strictly for the purpose of being qualified as PIC of a fuel oil transfer.

Each vessel from the affected population is assumed to have at least two individuals able to serve as a PIC to ensure that at least one of them is available for duty at any point in a 24-

[19] Several vessel types are currently incorrectly marked as Subchapter M in the Marine Information for Safety and Law Enforcement (MISLE) database, including harbor assist, emergency assist, passenger barges, and non-self-propelled towing vessels. For a list of vessels that are not included in subchapter M applicability, see 46 CFR 136.105.

[20] Monthly numbers of inspections completed from July 2018 through June 2019 provided on June 27, 2019 by the National Towing Vessel Coordinator of the Office of Commercial Vessel Compliance.

[21] Projected inspections provided by the Office of Commercial Vessel Compliance, June 27, 2019. A total of 1,236 inspections are expected to be completed by the end of 2019, with 253 already completed in 2018, and 513 already completed as of June 2019. Another 470 are projected before the end of 2019 for a total of 983 to be completed in 2019. The office expects a surge of inspections in 2020 because all single vessel companies will have to obtain a COI for their vessel by July 2020. In addition the inspections originally scheduled during the government shutdown of early 2019 were rescheduled as soon as possible.

hour period.[22] Because a PIC cannot serve on more than one vessel at a time (unless authorized by the captain of the port), the vessel population can be used as an accurate basis for the number of PICs needed. From the population of 5,740 vessels, each carrying two PICs, we achieve an affected population of individuals equal to 11,480. The population of 5,740 becomes constant in Year 3 of the analysis period or in 2022 and thereafter, once all affected vessels are inspected.

The Coast Guard assumes that as vessels obtain their COI, individuals will get original MMCs to serve as the PIC of fuel oil transfers on those vessels. The Coast Guard uses a turnover rate of 30 percent each year, and assumes that any mariner lost to turnover in a given year is replaced by a mariner with an original MMC in order to maintain a stable population of mariners able to serve the total population of active vessels.[23] Further, it is necessary to track the length of service to determine when mariners would be required to renew their MMC at 5 years of service as the cost of renewal is significantly less than the cost of obtaining an original MMC.[24] We request comment on our assumption of a 30 percent turnover rate.

Two estimates are central to estimating cost savings: First, the number of individuals expected to obtain an original MMC in each year; and second, the number of individuals expected to renew their MMC in each year beginning in Year 4. An original MMC must be renewed every 5 years, such that an MMC originally obtained in 2018 would be renewed in 2023. While we do not count cost savings for original MMCs obtained before 2020, we do count cost savings for avoided renewals of those MMCs since the renewal would occur after the affective year of 2020. The total numbers for these two estimates are listed below in table 3 in the columns labeled ''Total new MMCs'' and ''Renewals.''

TABLE 3—SUMMARY OF AFFECTED POPULATION OF THE PROPOSED RULE

Calendar year	Effective year	Total affected vessels	MMCs needed	New COIs	Original MMCs from new COIs	Original MMCs from turnover	Total new MMCS	Renewals
2018		253	506	253	506	0	506	0
2019		1,236	2,472	983	1,966	152	2,118	0
2020	Year 1	3,267	6,534	2,031	4,062	742	4,804	0
2021	Year 2	4,503	9,006	1,236	2,472	1,960	4,432	0
2022	Year 3	5,740	11,480	1,237	2,474	2,702	5,176	0
2023	Year 4	5,740	11,480	0	0	3,444	3,444	121
2024	Year 5	5,740	11,480	0	0	3,444	3,444	508
2025	Year 6	5,740	11,480	0	0	3,444	3,444	1,153
2026	Year 7	5,740	11,480	0	0	3,444	3,444	1,064
2027	Year 8	5,740	11,480	0	0	3,444	3,444	1,243
2028	Year 9	5,740	11,480	0	0	3,444	3,444	827
2029	Year 10	5,740	11,480	0	0	3,444	3,444	827

Note: This table does not contain totals because the values in the columns are not additive. The columns merely show the affected population annually and should not be used for summation.

The ''Total new MMCs'' column equals the number of individuals who are newly credentialed each year due to vessels obtaining COIs and individuals who are newly credentialed to replace those who left in the previous year. This is the sum of the columns ''Original MMCs from new COIs'' and ''Original MMCs from turnover.'' In Year 1 (2020), there are 4,062 original MMCs from new COIs and 742 original MMCs from turnover in 2019, for a total of 4,804 original MMCs. The 742 original MMCs from turnover account for 30 percent of the total number of 2,472 MMCs needed in 2019. In Year 2 (2021), there are 4,432 total new MMCs—2,472 are due to new COIs and 1,960 are from turnover in the first year. The 1,960 new MMCs due to turnover in the first year account for 30 percent of the 6,534 total MMCs needed for that year.

We calculate renewals by multiplying the total number of original MMCs in a given starting year by the probability that an individual would still be employed as a PIC after five years. Where $((1-0.30)^{(5-1)} = (0.7^4)$ is the probability of remaining, (0.7) given a turnover rate of 0.3, compounded for each year after the first year of having the MMC in the 5 years before renewal. For Year 4, this is equivalent to 121 = $[506 \times (0.7^4)]$. For Year 5, this is equivalent to 508 = $[2,118 \times (0.7^4)]$. For Year 6, this is equivalent to 1,153 = $[4,804 \times (0.7^4)]$. For Year 7, this is equivalent to 1,064 = $[4,432 \times (0.7^4)]$. For Year 8, this is equivalent to 1,243 = $[5,176 \times (0.7^4)]$. For Year 9 and all subsequent years, renewals become 827 = $[3,444 \times (0.7^4)]$.

Cost Savings

Cost savings come from the forgone cost to individuals of obtaining and renewing an MMC. For towing vessels that only recently became inspected vessels, the cost of an MMC for the sole purpose of serving as PIC of a fuel oil transfer is a new burden. Not all of the individuals impacted by the 2016 towing vessel final rule have obtained an MMC yet.[25] The cost savings for this deregulatory analysis assumes that the cost PICs would save for an MMC is comprised of two elements: (1) PICs who obtained an MMC but would no longer need to renew it; and (2) PICs who avoid getting an MMC altogether. The avoided cost includes the evaluation and issuance fees for an MMC, the tuition and travel expenses associated with the required approved training, and the expense of meeting the MMC renewal requirements every 5 years.

Based on the requirement in 33 CFR 155.715 for the operator or agent of a vessel to ensure the holder of an LOD has received formal instruction to ensure their ability to carry out the

[22] Information collection request (ICR), ''Waste Management Plans, Refuse Discharge Logs, and Letters of Instruction for Certain Persons-in-Charge (PIC) and Great Lakes Dry Cargo Residue Recordkeeping'' OMB control number 1625–0072.

[23] We obtained the 30 percent turnover rate from an OMB-approved ICR (OMB Control Number 1625–0072), which we updated as part of a periodic renewal in 2018.

[24] An MMC is valid for a term of 5 years from the date of issuance. Per 46 CFR 10.205(a).

[25] 81 FR 40003.

duties of a PIC, the Coast Guard assumes that companies utilizing an LOD would provide the formal instruction. All those companies already utilizing an LOD while their vessels are uninspected would already have the capacity to provide the formal instruction required for the holder of an LOD on an inspected vessel after this rule; therefore, we estimate companies who employ PICs would not incur additional costs (and subsequently cost savings) as a result of the requirements of this proposed rule. The Coast Guard requests comments from the public on whether or not your company, who provides formal instruction for the purpose of a PIC obtaining an LOD, would incur costs from this proposed rule.

The costs to individuals stem from the requirements to obtain an MMC with a Tankerman-PIC endorsement as described in 46 CFR 13.201. These requirements include completion of Coast Guard-approved courses in both firefighting and tankship Dangerous Liquids. As of May 2019, the average cost of a Basic Fire Fighting course is $731.31 and ranges in length of 2 to 5 days depending on whether it is offered as a separate module or as part of the International Convention on Standards of Training, Certification, and Watchkeeping for Seafarers Basic Training. We assume an average course length of 27 hours, which would require 4 days of training. Similarly, the average cost of a Dangerous Liquids course is $985.62 with almost all offerings being 5 days in duration with an average of 38 hours of training. The length of the training in days assumes an 8-hour day, and that any part of an additional day would be considered a full day's opportunity cost in order to account for travel (that is, a mariner would not be able to leave training at noon and return to work). Because very few of the training facilities offer both courses—and none of the training facilities offer the courses concurrently—mariners would need to schedule each training course separately. See table 4 below for the summary of course costs.

TABLE 4—AVERAGE COURSE COSTS

Course	Tuition	Length (days)	Length (days rounded)	Length (hours)
Basic Fire Fighting	$731.31	3.27	4	27
Dangerous Liquids	985.62	4.80	5	38
Summary	1,716.93	8.07	9	65

In addition, 46 CFR 10.219 prescribes the fees for obtaining an MMC with a Tankerman-PIC endorsement. This includes an evaluation fee of $95 and an issuance fee of $45. Every 5 years there is a cost to renew the credential with the endorsement, which includes a $50 evaluation fee and a $45 issuance fee.[26] For the original issuance and renewal, there is a security screening expense of $125.25.[27]

The Coast Guard assumes varying modes of travel for mariners getting to and from approved training based on the distribution of travel modes derived in the Vessel Security Officer (VSO) Interim Rule.[28] The percentages below in table 5 reflect the same percentages from this rule.[29] In further analysis, we use the average cost per mariner, weighted by the distribution of travel type.[30] We estimate the total travel cost of the for mariners to be about $102,837,070, undiscounted. We estimate the average travel cost for a mariner to be about $8,958, undiscounted.

TABLE 5—DISTRIBUTION OF TRAVEL COSTS FOR INDIVIDUALS

Mode of transport	Distribution (%)	Affected mariner population	Cost (2018 USD)
Commute	26.50	3,042	$27,072,685
Drive/Lodge	16.70	1,917	15,590,931
Fly/Lodge	56.80	6,521	60,173,453
Total	100	11,480	102,837,070
Average Cost per Mariner	.....	.....	8,958

Note: Totals may not sum due to independent rounding.

In table 6, we show the unit costs that comprise the total costs to individuals in table 9. Each method of travel has a different cost, while the costs of training courses and MMC applications are the same for all travel types. The total cost per mariner includes the fixed costs of the two approved training courses and travel costs. As travel costs are highly

[26] From 46 CFR 10.219(a), Table 1—Fees. Using column ''Evaluation then the fee is . . .'' and rows ''Original endorsement for ratings other than qualified ratings'' and ''Renewal endorsement for ratings other than qualified ratings.''

[27] Transportation Security Administration 30-Day notice. [Docket No. TSA–2006–24191] Revision of Agency Information Collection Activity Under OMB Review: Transportation Worker Identification Credential (TWIC®) Program (82 FR 14521, March 21, 2017).

[28] 73 FR 29060, May 20, 2008, ''Implementation of Vessel Security Officer Training and Certification Requirements-International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as Amended'' rule corrected June 17, 2008 (73 FR 34190).

[29] See Table 4.—TOTAL NATIONAL SHARE OR PERCENTAGE OF—Total National Share of Percentage of VSOs THAT WILL COMMUTE, DRIVE/LODGE, AND FLY/LODGE That Will Commute, Drive/Lodge, and Fly/Lodge in 73 FR 29060, 29065.

[30] We use the average cost because the distribution in travel does not change in any given year. If the actual locations of individuals used to develop the baseline was known, then we could base the distribution on actual travel. However, this information is not known and could not be known for every individual in each year.

variable, we obtained the most recent cost figures for travel and lodging, available from either 2017 or 2018, as described in the source reference column.

TABLE 6—UNIT TRAVEL COST ESTIMATES

[Adjusted to 2018 USD]

Item	Unit cost	Source reference
Opportunity cost of applicant time.	$60.66	The total opportunity cost of time is the base wage multiplied by the loaded wage factor to obtain total compensation including non-wage benefits. $39.61 is the mean wage estimate from the 2019 National Occupation Employment and Wage Statistics for Captains, Mates, and Pilots of Water Vessels (53–5021). *https://www.bls.gov/oes/2018/may/oes535021.htm*. The loaded wage factor of (33.11/21.62) is obtained by dividing the total compensation by wages and salaries for full-time transportation workers. These are annual averages of quarterly data series CMU2010000520610D and CMU2020000520610D respectively, obtained from BLS Employer Cost for Employee Compensation. *https://www.bls.gov/data/*.
Driving Mileage (rate per mile).	$0.58	''Privately Owned Vehicle Mileage Reimbursement Rates'' from GSA tables published on January 1, 2019. *https://www.gsa.gov/travel/plan-book/transportation-airfare-rates-pov-rates/privately-owned-vehicle-pov-mileage-reimbursement-rates*.
Non-Commuting Driving Time.	100 mile/27.08 mph commuting speed.	For a mariner who would drive/lodge to the school 100 miles round trip, we divide 100 miles by the average commuting speed of 27.08 miles per hour (mph). We obtained 27.08 mph from the Federal Highway Administration's (FHA) Summary of Travel Trends, 2017. *https://www.fhwa.dot.gov/policyinformation/documents/2017_nhts_summary_travel_trends.pdf.* pg 79.
Round-trip Air-Fare	$346	From the U.S. Department of Transportation (DOT), Bureau of Transportation Statistics (BTS). Average price of a round-trip airfare for 2018 in unadjusted dollars. *https://www.bts.gov/sites/bts.dot.gov/files/Annual%20Fares%201995-2018.xlsx*.
Round-trip Airport Transfer	$61.28	We used the cost of a round-trip airport transfer from a Coast Guard interim rule, ''Validation of Merchant Mariners' Vital Information and Issuance of Coast Guard Merchant Mariner's Licenses and Certificates of Registry'', published on January 13, 2006 (71 FR 2154). Figure found in table 4, page 2160. A later figure could not be found so this figure was adjusted for inflation using the GDP deflator factor of 1.23 times the original cost of $50. The round-trip airport transfer cost is based on research of the average private and public transfer costs, including taxi or car rental costs associated with U.S. airports and regional destinations. It is not a mathematical or rigorous estimate, but an average transfer cost based on information available from associations and trade groups, airports, transit authorities, and governments.
Flying Excursion Time	16 hours	A mariner that would fly/lodge in order to attend a training course or school would incur an opportunity cost of flying. We assume the total air excursion time of 16 hours, equivalent to two days of travel.
Incidentals and Meals (per diem).	$64.57	Obtained from the Composite of General Services Administration (GSA) domestic per diem rates for meals/incidentals (*https://www.gsa.gov/travel/plan-book/per-diem-rates*) in training site and REC cities for January 2018. Taxes ARE included in the M&IE rate per FAQ #12. *https://www.gsa.gov/travel/plan-book/per-diem-rates/frequently-asked-questions-per-diem#12*.
Lodging (per night)	$142.16	Obtained from the Composite of General Services Administration (GSA) domestic per diem rates for lodging (*https://www.gsa.gov/travel/plan-book/per-diem-rates*) training site, and REC cities for January 2018. Taxes are not automatically included, so lodging taxes and state sales taxes were added to the lodging per diem.

Table 7, ''MMC Costs for Mariners,'' shows how the above unit costs for travel and tuition contribute to the total average cost per mariner. The average cost of $8,957.93 is for each mariner expected to obtain an original MMC. Tuition costs and travel costs do not apply for renewal if a mariner served at least 90 days of service during the preceding 5 years.[31] If a mariner cannot fulfill that service requirement, we assume that they turnover and must complete the requirements for an original MMC. The Coast Guard estimates the average travel cost for a mariner that commutes to approved training is about $8,899.05. The average travel cost for a mariner that drives and stays overnight for approved training is about $8,132.31. Finally, we estimate the average travel cost for a mariner that flies and stays overnight for approved training to be about $9,228.15. This cost analysis uses an average because the distribution of travel is constant year to year.

[31] See 46 CFR 13.120 Renewal of tankerman endorsement.

TABLE 7—MMC COSTS FOR MARINERS

Category	Derivation	Amount	Training cost by travel mode		
			Commuting	Drive/Lodge	Fly/Lodge
Tuition	Average price of $731.31 for Basic Firefighting, and $985.62 for Dangerous Liquids.	$1,716.93	$1,716.93	$1,716.93	$1,716.93
MMC Fees	$95 evaluation fee, $45 issuance fee.	140.00	140.00	140.00	140.00
Security Screening Fee	$125.25	125.25	125.25	125.25	125.25
Round-trip Airfare	$346.00	346.00	NA	NA	346.00
Round-trip Airport transfer	$61.28	61.28	NA	NA	61.28
Lodging	$142.16 per lodging night × 9 lodging nights.	1,279.45	NA	1,279.45	1,279.45
Commuting Meals & Incidental Expenses.	$48.43 per diem × 9 training days (equivalent to 75% of full per diem).	435.86	435.86	NA	NA
Non-Commuting Meals & Incidental Expenses.	$64.57 per diem × (7 training days) + $48.43 × (4 first and last days of travel 75% of total).	645.71	NA	645.71	645.71
Commuting Motor Vehicle Costs	100-mile commute × $0.58 per mile × 9 training days.	522.00	522.00	NA	NA
Non-Commuting Motor Vehicle Costs.	100-mile round-trip × $0.58 per mile	58.00	NA	58.00	NA
Training Time (Opportunity Cost)	65 hrs. training × loaded hourly wage.	3,942.95	3,942.95	3,942.95	3,942.95
Commuting Driving Time (Opportunity Cost).	(100-mile round trip ÷ 27 mph commuting speed) × loaded hourly wage × 9 days.	2,016.05	2,016.05	NA	NA
One Non-Commuting Driving Time (Opportunity Cost).	(100-mile round trip ÷ 27 mph commuting speed) × loaded hourly wage.	224.01	NA	224.01	NA
One Flying Time (Opportunity Cost)	16 hours × loaded hourly wage	970.57	NA	NA	970.57
Total Cost per Mariner			8,899.05	8,132.31	9,228.15

Note: Totals may not sum due to independent rounding.

Table 8, ''Cost Savings to Individuals,'' shows how the introduction of newly inspected vessels, and turnover from subsequent years, impact costs over a 10-year period of analysis. It should be noted that the renewal costs only enter in Year 6, when the first cohort of original MMCs from Year 1 would be eligible to renew, given turnover in the first 5 years. The affected population in this analysis are reflected in the columns ''Original MMCs'' and ''Renewals'' in table 10. We showed this population previously in table 3. As shown in table 8, the Coast Guard estimates the total discounted costs savings to mariners of this deregulatory savings analysis over a 10-year period of analysis to be about $249.2 million using a 7-percent discount rate. We estimate the annualized cost savings over 10 years to be about $35.5 million using a 7-percent discount rate.

TABLE 8—COST SAVINGS TO INDIVIDUALS

Calendar year	Effective year	Original MMCs	Total cost of original MMC*	Renewals	Renewal fee + security screening	Total annual cost of new MMCs	Total annual cost of renewals	Grand total annual cost	Grand total annual cost discounted 7%	Grand total annual cost discounted 3%
2018		506								
2019		2,118								
2020	1	4,804	$8,958			$43,030,327		$43,030,327	$40,215,258	$41,777,016
2021	2	4,432	8,958			39,703,350		39,703,350	34,678,444	37,424,216
2022	3	5,176	8,958			46,364,469		46,364,469	37,847,218	42,430,057
2023	4	3,444	8,958	121	220	30,851,121	26,758	30,877,879	23,556,586	27,434,596
2024	5	3,444	8,958	508	220	30,851,121	111,994	30,963,114	22,076,273	26,709,055
2025	6	3,444	8,958	1,153	220	30,851,121	254,024	31,105,145	20,726,672	26,050,069
2026	7	3,444	8,958	1,064	220	30,851,121	234,384	31,085,505	19,358,490	25,275,360
2027	8	3,444	8,958	1,243	220	30,851,121	273,707	31,124,828	18,114,933	24,570,226
2028	9	3,444	8,958	827	220	30,851,121	182,126	31,033,247	16,880,030	23,784,399
2029	10	3,444	8,958	827	220	30,851,121	182,126	31,033,247	15,775,729	23,091,650
Total								346,321,110	249,229,632	298,546,644
Annualized									35,484,693	34,998,774

Note: Totals may not sum due to independent rounding.
*This column includes the cost for courses plus travel costs and fees.

We do not estimate cost savings to owners and operators of vessels because we assume that companies operating towing vessels already have the capability of providing necessary formal instruction to those individuals being issued an LOD since they offered this formal instruction prior to their vessels becoming inspected under the 2016 rule (81 FR 40003). Turnover in owners and operators is expected to be stable for the near future, so we do not expect there

to be new companies that would have to establish new formal instruction capabilities.[32]

Without this deregulatory action, the Coast Guard would need to evaluate the MMC applications that would be submitted if an MMC with a Tankerman PIC endorsement were still required to serve as a PIC for fuel oil transfers. This deregulatory savings analysis accounts for the cost savings to the Coast Guard as MMC applications for Tankerman-PIC endorsements would no longer require evaluation or issuance. Each application takes approximately 55 minutes to process, at a GS–8 loaded mean hourly wage rate of $49, for a cost of $44.92 per application.[33] As shown in table 9, over a 10-year period of analysis, the Coast Guard would save about $1,402,143 in 2018 dollars, discounted at a 7-percent discount rate, from the lower volume of MMC applications. We estimate annualized cost savings to the government to be $199,634 using a 7-percent discount rate.

TABLE—9 COST SAVINGS TO THE COAST GUARD

Effective year	Original MMCs	Cost of reviewing original MMC	Renewals	Cost of reviewing renewed MMC	Grand total annual cost	Grand total annual cost discounted 7%	Grand total annual cost discounted 3%
1	4,804	$44.92		$	$215,762	$201,646	$209,477
2	4,432	44.92			199,080	173,884	187,652
3	5,176	44.92			232,480	189,773	212,752
4	3,444	44.92	121	44.92	160,150	122,178	142,291
5	3,444	44.92	508	44.92	177,532	126,578	153,141
6	3,444	44.92	1,153	44.92	206,497	137,598	172,938
7	3,444	44.92	1,064	44.92	202,492	126,102	164,645
8	3,444	44.92	1,243	44.92	210,511	122,520	166,180
9	3,444	44.92	827	44.92	191,835	104,345	147,025
10	3,444	44.92	827	44.92	191,835	97,519	142,743
Total					1,988,174	1,402,143	1,698,844
Annualized						199,634	199,156

Note: Totals may not sum due to independent rounding.

Costs Incurred To Prepare Letter of Designation

While the use of an LOD saves the individual approved training costs, the actual letter of designation still takes time to prepare. Using the time estimate from the existing collection of information for PICs, we assume the preparation of a letter takes approximately 10 minutes.[34]

The projected number of LODs used is based on the number of vessels becoming inspected and otherwise requiring a credentialed mariner to serve as PIC of a fuel oil transfer. The opportunity cost of the time to prepare an LOD uses the wage of a compliance officer, with a loaded mean hourly wage rate of $53.39, multiplied by the time to prepare the LOD ($53.39 × 10 minutes or 0.167 hours), which is approximately $8.92.[35] The opportunity cost for new individuals using an LOD over the 10-year analysis period is about $247,287 in 2018 dollars, discounted, using a 7-percent discount rate. See table 10 below. We estimate the annualized cost to be about $35,208 using a 7-percent discount rate.

TABLE 10—COSTS OF PREPARING AN LOD

Year	Individuals needing a new LOD	Cost of preparing LOD per mariner	Total annual cost of preparing LOD	Grand total annual cost discounted 7%	Grand total annual cost discounted 3%
1	4,804	$8.92	$42,827	$40,025	$41,579
2	4,432	8.92	39,515	34,514	37,247
3	5,176	8.92	46,145	37,668	42,229
4	3,444	8.92	30,705	23,425	27,281
5	3,444	8.92	30,705	21,892	26,486
6	3,444	8.92	30,705	20,460	25,715
7	3,444	8.92	30,705	19,122	24,966
8	3,444	8.92	30,705	17,871	24,239
9	3,444	8.92	30,705	16,702	23,533
10	3,444	8.92	30,705	15,609	22,847
Total			343,423	247,287	296,124

[32] Analysis from the 2016 towing vessel final rule found entry of 91 vessels and exit of 88 vessels. A subject matter expert confirmed that these numbers are similar and that it matches with firms' ownership.

[33] Information provided by subject matter expert in the Office of Merchant Mariner Credentialing, and corroborated by NMC officials. GS–8 mean hourly wage rate is $49 Outside Government Rate per Commandant Instruction 7310.1T November 2018.

[34] From OMB Control Number 1625–0072 (ICR 201803–1625–007)—0.167 hours equals approximately 10 minutes from Table 12.3 in Appendix A of ICR 201803–1625–007 (OMB Control Number 1625–0072) last updated in 2018.

[35] $34.86 is the mean hourly wage estimate from the 2018 National Occupation Employment and Wage Statistics for Compliance Officers (13–1041) *https://www.bls.gov/oes/2018/may/oes131041.htm*. The loaded wage factor of ($33.11/$21.62) is obtained by dividing the total compensation by wages and salaries for full-time transportation workers. These are annual averages of quarterly data series CMU2010000520610D and CMU2020000520610D respectively, obtained from BLS Employer Cost for Employee Compensation (*https://www.bls.gov/data/*).

TABLE 10—COSTS OF PREPARING AN LOD—Continued

Year	Individuals needing a new LOD	Cost of preparing LOD per mariner	Total annual cost of preparing LOD	Grand total annual cost discounted 7%	Grand total annual cost discounted 3%
Annualized				35,208	34,715

Note: Totals may not sum due to independent rounding.

Costs Incurred by the Coast Guard

The cost incurred by the Coast Guard only includes the time for inspectors in the field to review the documentation designating a PIC of a fuel oil transfer on board, which takes the same amount of time whether an LOD or an MMC is being reviewed since any method used to designate a PIC must be immediately available for inspection. We assume no cost change to the Coast Guard. Since the LOD is not a credential issued by the Coast Guard, and is only verified on board a vessel, there is no additional time cost to reviewing LODs.

Net Cost Savings

Using a perpetual period of analysis, the Coast Guard estimates the total annualized cost savings of the proposed rule to be $24,442,840 in 2016 dollars, using a 7-percent discount rate. The total cost savings is the sum of the cost savings to individuals no longer obtaining MMCs, shown in table 8, and the time cost savings to the Coast Guard, shown in table 9, of no longer reviewing MMCs. Net cost savings are the total cost savings minus the costs incurred, shown in table 11. We estimate the net cost savings of this proposed rule over a 10-year period of analysis to be about $250,384,488 discounted at 7-percent in 2018 dollars.

TABLE 11—SUMMARY OF NET COST SAVINGS OF THE PROPOSED RULE 2018$

	Cost savings	Costs incurred	Net cost savings	Annualized cost savings
Grand Total	$348,309,284	$343,423	$347,965,861	
Discounted 7%	250,631,775	247,287	250,384,488	35,649,118
Discounted 3%	300,245,488	296,124	299,949,365	35,163,216

Alternatives Considered

(1) *MMC with officer or Tankerman-PIC endorsement (No Limited Endorsement).*

Continue to require inspected vessels with a fuel oil capacity of 250 barrels or more—or that obtain fuel oil from a vessel with a fuel oil capacity of 250 barrels or more—to have an individual holding an MMC with either an officer or Tankerman-PIC endorsement designated as the PIC of any fuel oil transfer. Under this alternative, any designated PIC of a fuel oil transfer would be required to hold an MMC with an officer or Tankerman-PIC endorsement, without a limited endorsement for fuel oil transfers.

The Coast Guard rejected this alternative because there are no cost savings associated with it and therefore it would not meet the Coast Guard's goal of reducing regulations under E.O. 13771. Individuals would still bear the cost of obtaining an MMC, and after a vessel receives its COI, individuals previously qualified as PIC through the LOD options would not be able to be designated as a PIC until they obtain their MMC.

(2) *Continue to Issue Limited Endorsement MMCs with Tankerman-PIC Restricted to Fuel Oil Transfers on Towing Vessels.*

No regulatory change would be associated with this alternative. The Coast Guard would continue to utilize the CG–MMC Policy Letter 01–17 to issue MMC endorsements for Tankerman-PIC Restricted to Fuel Transfers on Towing Vessels. Under this continued action alternative, the existing policy letter would continue to provide a means for individuals on towing vessels previously designated as PIC of a fuel oil transfer using an LOD to be issued a limited endorsement Tankerman-PIC restricted to Fuel Transfers.

While limited endorsements save individuals the cost of approved training courses, such that they only pay the cost of applying for an MMC, the Coast Guard must still evaluate the MMC application and issue the credentials. These applications take 45 minutes to evaluate at a loaded GS–8 wage rate of $49 per hour for a labor cost of about $36.75. Over a 10-year period of analysis, we estimate the cost to the Government to review these applications to be about $861,027 in 2018 dollars. In total, the net costs of continuing the letter over a 10-year period of analysis are about $ $8,984,618 in 2018 dollars using a 7-percent discount rate. We estimate annualized cost savings to be about $1,279,208 using a 7-percent discount rate.

The Coast Guard rejected this alternative because it provides neither a full solution nor long-term alternatives for designating the PIC of a fuel oil transfer and it is more costly than the preferred alternative. The policy letter only applies to one industry segment, and individuals who obtain an MMC according to the policy letter would still incur the cost of renewing their credential every 5 years.

(3) *Preferred Alternative—new regulatory action allowing use of LODs for inspected vessels.*

Under this alternative, the regulations would be modified to provide the option for inspected vessels to designate the PIC of a fuel oil transfer utilizing an LOD. Under a new regulatory action, the Coast Guard would provide flexibility to all inspected vessels in how they designate the PIC of a fuel oil transfer. This is the preferred alternative as it relieves individuals who would otherwise not be required to have an MMC to obtain and renew a credential, and provides flexibility to industries equally.

Conclusion

The Coast Guard is interested in the potential impacts from this rule and we request public comment on these potential impacts. If you think that this rule would have a significant economic impact on you, your business, or your organization, please submit a comment to the docket at the address under **ADDRESSES** in the rule. In your comment, explain why, how, and to

what degree you think this rule would have an economic impact on you. We are especially interested in information on interactions of small and large vessels for fuel oil transfers.

B. Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. Below is a threshold analysis of the small entity impacts.

In lieu of current revenue figures which may be distorted by ongoing inspections, for this analysis we use the small entity impact analysis of the 2016 Subchapter M rule, which we assume will be closely representative of revenues after the inspection period is over. The 2016 rule's small entity impact analysis used a sample of 304 vessels from the population of 5,509.[36] Of the 304 vessels, about 59 percent were owned or operated by a small entity. We assume the same number of small entities would be impacted going forward, but will know better once inspections are completed and all fleets resume active status. As this is a deregulatory action, the majority of impact is cost savings to individuals, who do not qualify as small entities. The only impact to small entities is the cost imposed to industry as the time cost of preparing the letter of designation.

The Coast Guard finds the average annual cost to be $75.91 based on the known fleet sizes of all towing vessel entities. Ideally, we would use the same population used in the cost model to account for turnover, but accounting for turnover within each entity is complex. Instead, we make the most conservative assumption, which is that entities would need to prepare LODs for their entire fleet every year and compare to the revenue of the lowest earning fleet. There is no additional initial cost, only this annual cost.

Average annual cost takes the number of vessels in a fleet, times the cost of preparing a letter, $8.92, times 2 to account for each of the two PICs needed per vessel. This average varies by the number of vessels in an entity's fleet, see the distribution below. Note that the number of vessels in a fleet does not correlate with company size; a small business may have a large fleet or a large business may have a small fleet. On average, the cost incurred per entity is $75.91, which is on average 0.0152 percent of revenues.[37]

TABLE 14— AVERAGE COST BY FLEET SIZE CATEGORY

Fleet size category	Description	Number of entities	Average cost	Average of cost as % of total revenue
Small_1	Entity with only one vessel	611	$17.83	0.0011
Small_2–5	Entity with 2 to 5 vessels	472	52.25	0.0037
Medium	Entity with 6 to 25 vessels	179	194.05	0.0292
Large	Entity with >25 vessels	32	873.17	0.0072
Avg	All fleet sizes		75.91	0.0152

In the most conservative case, a medium-sized fleet owned by the entity with the lowest revenue in the sample, which would have the highest possible cost as percentage of total revenue for the affected population, the cost imposed by this rule is still less than one percent of total revenues. In this conservative example, the entity's estimated annual cost would be approximately $321 for a fleet of 18 vessels, 0.76 percent of their $42,000 revenue.[38] On average, the cost incurred is less than a quarter of one percent of revenues.

TABLE 15—DISTRIBUTION OF REVENUE IMPACTS

% Revenue impact	Average annual impact	Small entities with known revenue impact	Portion of small entities with known revenue data
<1	$75.91	183	100
1–3	75.91	0	0
>3	75.91	0	0

Since the most conservative case shows that the impact of this rule would be less than 1 percent of revenues for a small entity, no small entity would have an impact greater than 1 percent of revenues. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment to the docket at the address listed in the **ADDRESSES** section. In your comment, explain why you think it qualifies and how and to what degree this proposed rule would economically affect it.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking.

[36] See 81 FR 40003, June 20, 2016.

[37] While fleet size is known for all 1,295 entities covering the entire affected population of vessels, revenues are known only for a sample of 183 vessels of the original 5,509 vessels, data from the original FRFA of Inspection of Towing Vessels final rule (81 FR 40003). In Table 14, ''Average cost'' is based on the entire population of entities, ''average of cost as a % of total revenue'' is based only on entities for whom revenue is known.

[38] The value of $42,000 comes from the original FRFA of 81 FR 40003, June 20, 2016.

If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

This proposed rule would call for a collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow below. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

The collection of information under this proposed rule falls under the same collection of information already required for letters of designation described in OMB Control Number 1625–0072. This proposed rule does not change the content of responses, nor the estimated burden of each response, but does increase the number of annual respondents and responses from 190 to 3,111.

Title: Waste Management Plans, Refuse Discharge Logs, and Letters of Instruction [39] for Certain Persons-in-Charge (PIC) and Great Lakes Dry Cargo Residue Recordkeeping.

OMB Control Number: 1625–0072.*Summary of the Collection of Information:* The Letter of Instruction's contents should verify the PIC's credentials, stating that the holder has received sufficient formal instruction from the owner, operator, or agent of the vessel, as required by 33 CFR 155.715 and the current CFR 155.710(e)(2) and proposed 155.710(e)(1).

Need for Information: This information is needed to ensure that: (1) Certain U.S. vessels develop and maintain a waste plan; (2) certain U.S. vessels maintain refuse discharge records; (3) certain individuals that act as fuel transfer PIC receive a letter of instruction for prevention of pollution; and (4) certain Great Lakes vessels conduct dry cargo residue recordkeeping.

Use of Information: To ensure that fuel transfer competency standards are met, all PICs on uninspected vessels must carry a Letter of Instruction if they do not hold a Coast Guard issued credential.

Description of Respondents: Compliance officers for entities conducting transfers of fuel oil and needing to designate a PIC of such transfers.

Number of Respondents: Increase of 3,254 respondents from 190 to 3,444.

Burden of Response: 0.167 hours.

Estimate of Total Annual Burden: Increase of 611 hours from 32 hours to 643 hours.

As required by 44 U.S.C. 3507(d), we will submit a copy of this proposed rule to OMB for its review of the collection of information.

We ask for public comment on the proposed collection of information to help us determine, among other things—

- How useful the information is;
- Whether the information can help us perform our functions better;
- How we can improve the quality, usefulness, and clarity of the information;
- Whether the information is readily available elsewhere;
- How accurate our estimate is of the burden of collection;
- How valid our methods are for determining the burden of collection; and
- How we can minimize the burden of collection.

If you submit comments on the collection of information, submit them by the date listed in the **DATES** section of this preamble to both the OMB and to the docket where indicated under **ADDRESSES**.

You need not respond to a collection of information unless it displays a currently valid control number from OMB. Before the Coast Guard could enforce the collection of information requirements in this proposed rule, OMB would need to approve the Coast Guard's request to collect this information.

E. Federalism

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

It is well settled that States may not regulate in categories reserved for regulation by the Coast Guard. It is also well settled that all of the categories covered in 46 U.S.C. 3306, 3703, 7101, and 8101 (design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels)—as well as the reporting of casualties and any other category in which Congress intended the Coast Guard to be the sole source of a vessel's obligations—are within the field foreclosed from regulation by the States. *See* the Supreme Court's decision in *United States* v. *Locke and Intertanko* v. *Locke,* 529 U.S. 89, 120 S.Ct. 1135 (2000).) This proposed rule, as promulgated under 46 U.S.C. 3306 and 3703, concerns personnel qualifications because it would amend requirements for who may serve as the PIC of fuel oil transfers on inspected vessels. Therefore, because the States may not regulate within these categories, this rule is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

While it is well settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, the Coast Guard recognizes the key role that State and local governments may have in making regulatory determinations. Additionally, for rules with federalism implications and preemptive effect, Executive Order 13132 specifically directs agencies to consult with State and local governments during the rulemaking process. If you believe this rule has implications for federalism under Executive Order 13132, please call or

[39] As stated in the Discussion of Proposed rule section, this proposed rule would provide for a consistent name of this letter by referring to it as a ''Letter of Designation,'' and we would accordingly amend the title of this collection of information.

email the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

F. Unfunded Mandates

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

G. Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

H. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, (Civil Justice Reform), to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this proposed rule under Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks). This proposed rule is not an economically significant rule and would not create an environmental risk to health or a risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

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

K. Energy Effects

We have analyzed this proposed rule under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Technical Standards

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. This proposed rule would be categorically excluded under paragraph L56 in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. Paragraph L56 pertains to the training, qualifying, licensing, and disciplining of maritime personnel. This proposed rule involves letters of designation to assign PIC of fuel oil transfers on inspected vessels. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 155

Alaska, Hazardous substances, Oil pollution, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard proposes to amend part 155 as follows:

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

■ 1. The authority citation for part 155 is revised to read as follows:

Authority: 3 U.S.C. 301 through 303; 33 U.S.C. 1321(j), 1903(b), 2735; 46 U.S.C 3306, 3703, 70011, 70034; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1. Section 155.1020 also issued under section 316 of Pub. L. 114–120. Section 155.480 also issued under section 4110(b) of Pub. L. 101–380.

Note: Additional requirements for vessels carrying oil or hazardous materials are contained in 46 CFR parts 30 through 40, 150, 151, and 153.

■ 2. Amend § 155.710(e) as follows:

■ a. In the introductory text, remove the word ''shall'' and add, in its place, the word ''must'';

■ b. Revise paragraph (e)(1);

■ c. Remove paragraph (e)(2);

■ d. Redesignate paragraphs (e)(3) and (e)(4) as paragraphs (e)(2) and (e)(3), respectively; and

■ e. In newly redesignated paragraph (e)(2), remove the text ''or (2)''.

The revision reads as follows:

§ 155.710 Qualifications of person in charge.

* * * * *

(e) * * *

(1) On each inspected vessel required by 46 CFR chapter I to have an officer aboard, and on each uninspected vessel, either:

(i) Holds a valid merchant mariner credential issued under 46 CFR chapter I, subchapter B, with an endorsement as master, mate, pilot, engineer, or operator aboard that vessel, or holds a valid merchant mariner credential endorsed as Tankerman-PIC; or

(ii) Carries a letter satisfying the requirements of § 155.715 and designating him or her as a PIC, unless equivalent evidence is immediately available aboard the vessel or at his or her place of employment.

* * * * *

§ 155.715 [Amended]

■ 3. In § 155.715, remove the text ''letter of instruction required in § 155.710(e)(2)'' and add, in its place, the text ''letter referenced in § 155.710(e)(1)''.

Dated: August 9, 2019.

David C. Barata,

Captain, U.S. Coast Guard, Acting Assistant Commandant for Prevention Policy.

[FR Doc. 2019–17457 Filed 8–13–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2008–0108; FRL–9998–00–Region 1]

Air Plan Approval; Massachusetts; Transport State Implementation Plans for the 1997, 2008, and 2015 Ozone Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Massachusetts that address the interstate transport of air pollution requirements for Infrastructure SIPs for the 1997, 2008, and 2015 ozone national ambient air quality standards (NAAQS) (*i.e.,* Transport SIPs). The intended effect of this action is to propose approval of the Transport SIPs as revisions to the Massachusetts SIP. This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before September 13, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2008–0108 at *https://www.regulations.gov,* or via email to *simcox.alison@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/commenting-epa-dockets.* Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square–Suite 100, Boston, MA. EPA requests that, if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square–Suite 100, (Mail code 05–2), Boston, MA 02109–3912, tel. (617) 918–1684, email *simcox.alison@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. The term ''the Commonwealth'' refers to the State of Massachusetts.

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I. Background

On January 31, 2008, February 9, 2018, and September 27, 2018, the Massachusetts Department of Environmental Protection (DEP) submitted revisions to its State Implementation Plan (SIP) consisting of interstate transport SIPs for the 1997, 2008, and 2015 ozone NAAQS. The interstate transport SIPs we are proposing to approve were submitted to address the infrastructure requirements of section 110(a)(2)(D)(i)(I) of the Clean Air Act (CAA).

Over the past two decades, EPA has revised the primary ozone standard three times. On July 18, 1997, EPA revised the ozone standard from 0.120 parts per million (ppm), based on a one-hour average, to 0.08 ppm, based on a three-year average of the annual fourth-highest daily maximum 8-hour average. *See* 62 FR 38856. On March 12, 2008, EPA revised the level of the primary ozone standard from 0.08 ppm to 0.075 ppm and maintained the form of the standard. *See* 73 FR 16436. Most recently, on October 1, 2015, EPA revised the primary ozone standard by lowering the level to 0.070 ppm while maintaining the form of the standard. *See* 80 FR 65292.

Section 110(a)(1) of the CAA requires states to submit SIPs to address a new or revised NAAQS within three years after promulgation of a standard, or within a shorter period as EPA may prescribe. Section 110(a)(2) lists the elements that new SIPs must address, as applicable, including section 110(a)(2)(D)(i), which pertains to interstate transport of certain emissions.

The interstate transport SIP provisions require each state to submit a SIP that prohibits emissions that have certain adverse effects in another state due to interstate transport of air pollution. Section 110(a)(2)(D)(i) identifies four elements related to the evaluation of impacts of interstate transport of air pollutants; in this rulemaking, we are addressing the first two elements; the remaining two elements will be acted on under separate rulemaking actions. Specifically, the portions that we are proposing to approve pertain to section 110(a)(2)(D)(i)(I): (1) Significant contribution to nonattainment of the ozone NAAQS in any other state (commonly called ''prong 1''); and (2) interference with maintenance of the ozone NAAQS (commonly called ''prong 2'') by any other state. These two provisions (or ''prongs'') are commonly referred to as the ''good neighbor'' provisions of the CAA. The first provision requires that a state's SIP for a new or revised NAAQS contain adequate measures to prohibit any source or other type of emissions activity in the state from emitting pollutants in amounts that ''contribute significantly'' to nonattainment of the NAAQS in another state. The second provision requires that a state's SIP prohibit any source or other type of emissions activity in the state from emitting pollutants in amounts that will ''interfere with maintenance'' of the applicable NAAQS in any other state.

II. EPA's Evaluation of the State's Submittals

A. Background and Evaluation of the Transport SIP for the 1997 Ozone Standard

On April 25, 2005, EPA published a final rule that made a finding that all 50 states had failed to submit, pursuant to Section 110(a)(2)(D)(i) of the CAA, interstate transport SIPs for the 1997 ozone NAAQS. *See* 70 FR 21147. Subsequently, on August 15, 2006, EPA issued a guidance memorandum that provided recommendations to states for making submissions to meet the requirements of section 110(a)(2)(D)(i) for the 1997 8-hour ozone and 1997 fine-particle ($PM_{2.5}$) standards (2006 Guidance).[1]

The CAA does not specifically mandate how to determine significant contribution to nonattainment or interference with maintenance of the NAAQS. Therefore, EPA has interpreted these terms in past regulatory actions, such as the 1998 nitrogen oxides (NO_X) SIP Call, in which EPA took action to address emissions of NO_X that significantly contributed to nonattainment of, or interfered with maintenance of, the then-applicable ozone NAAQS. *See* 63 FR 57356 (October 27, 1998).

The NO_X SIP Call was the mechanism through which EPA evaluated whether NO_X emissions from sources in certain states had prohibited interstate impacts, and if they did, required the states to adopt SIP revisions to eliminate the NO_X emissions through participation in a regional cap-and-trade program or by other means.

After promulgation of the 1997 8-hour ozone and $PM_{2.5}$ NAAQS, EPA recognized that regional transport was a serious concern throughout the eastern United States and, therefore, developed the 2005 Clean Air Interstate Rule (CAIR) to address emissions of sulfur dioxide (SO_2) and NO_X that exacerbate ambient ozone and $PM_{2.5}$ levels in many downwind areas through interstate transport. *See* 70 FR 25162. In CAIR, EPA interpreted the term ''interfere with maintenance'' as part of the evaluation of whether the emissions of sources in certain states had impacts on areas that could put them at risk of violating the NAAQS in a modeled future-year unless actions were taken by upwind states to reduce SO_2 and NO_X emissions. Through CAIR, EPA required states that had such interstate impacts to adopt SIP revisions to eliminate the SO_2 and NO_X emissions, whether through participation in a regional cap-and-trade program or by other means. Massachusetts was included in CAIR as a state that, under the 1997 ozone NAAQS, contributed significantly to ozone-season nonattainment in another state.

EPA's 2006 Guidance addressed CAA section 110(a)(2)(D)(i) requirements for the 1997 8-hour ozone and $PM_{2.5}$ NAAQS. For those states subject to CAIR, EPA indicated that compliance with CAIR would meet the two requirements of section 110(a)(2)(D)(i)(I) for these NAAQS.

In 2008, the U.S. Court of Appeals for the D.C. Circuit found that CAIR and the related CAIR federal implementation plans (FIPs) were unlawful.[2] Among other issues, the court held that EPA had not correctly addressed the second element of section 110(a)(2)(D)(i)(I) in CAIR and noted that ''EPA gave no independent significance to the 'interfere with maintenance' prong of section 110(a)(2)(D)(i)(I) to separately identify upwind sources interfering with downwind maintenance.'' [3] EPA's approach, the court reasoned, would leave areas that are ''barely meeting attainment'' with ''no recourse'' to address upwind emissions sources.[4] The court, therefore, concluded that a plain-language reading of the statute requires EPA to give independent meaning to the ''interfere with maintenance'' requirement of section 110(a)(2)(D)(i)(I) and that the approach used by EPA in CAIR failed to do so.

On August 8, 2011, to address the judicial remand of CAIR, EPA adopted a new rule to address interstate transport of air pollution pursuant to section 110(a)(2)(D)(i): ''Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone, and Correction of SIP Approvals,'' known as the Cross State Air Pollution Rule (CSAPR). *See* 76 FR 48208. As part of CSAPR, EPA reexamined the section 110(a)(2)(D)(i)(I) requirements for the 1997 8-hour ozone and $PM_{2.5}$ NAAQS in other states.[5] In CSAPR, EPA developed an approach to predict which areas that would violate the 1997 8-hour ozone and $PM_{2.5}$ NAAQS in the future, and which areas that would be close to the level of these NAAQS and, therefore, at risk of becoming nonattainment areas. This approach starts by identifying geographic areas for which further evaluation is appropriate and differentiates between areas where the concern is ''significant contribution to nonattainment'' from those where the concern is ''interference with maintenance.''

Under CSAPR, EPA evaluated data from air-quality monitors over three overlapping 3-year periods (*i.e.,* 2003–2005, 2004–2006, and 2005–2007), as well as data from air-quality modeling to predict which areas would violate the 1997 8-hour ozone and $PM_{2.5}$ NAAQS in 2012, and which areas would have difficulty maintaining attainment. If an area's projected monitoring data for 2012 indicated that it would violate the NAAQS based on the average of these three overlapping periods, then this monitor was considered appropriate for comparison for purposes of the ''significant contribution to nonattainment'' element. However, if an area's projected data indicated that it would violate the NAAQS based on a single period, but not over the average of the three periods, then this monitor was considered appropriate for comparison for purposes of the ''interfere with maintenance'' element.

EPA's 2006 Guidance did not specifically recommend this approach to states. However, in light of the court's decision on CAIR, EPA used this approach to evaluate whether Massachusetts had met its ''good neighbor'' obligations with respect to the 1997 ozone standard. In this guidance, EPA stated that ''EPA believes that the contents of the SIP submission required by section 110(a)(2)(D) may vary, depending upon the facts and circumstances related to the specific NAAQS. In particular, the data and analytical tools available at the time the State develops and submits a SIP for a new or revised NAAQS necessarily affects the contents of the required submission.''

On January 31, 2008, Massachusetts submitted a SIP revision to EPA addressing the CAA Section 110(a)(2)(D)(i) ''good neighbor'' requirements for the 1997 ozone NAAQS. The Commonwealth's submittal noted that EPA's 2006 Guidance indicates that states subject to EPA's CAIR can meet their CAA Section 110(a)(2)(D)(i) ''good neighbor'' obligations with a state-adopted, SIP-approved CAIR regulation. Massachusetts submitted a CAIR regulation to EPA on March 30, 2007, and EPA approved it into the Massachusetts SIP on December 3, 2007. *See* 72 FR 67854. Massachusetts noted

[1] Memorandum from William T. Harnett entitled ''Guidance for State Implementation Plan (SIP) Submissions to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-hour ozone and $PM_{2.5}$National Ambient Air Quality Standards'' (Aug. 15, 2006).

[2] *See North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), amended on rehearing, 550 F.3d 1176 (2008).

[3] 531 F.3d at 909.

[4] *Id.*

[5] The original CSAPR did not address the 2008 8-hour ozone NAAQS.

that it doubted that the CAIR rule would be adequate to ensure all areas in the Eastern U.S. would meet the 1997 ozone NAAQS by the required attainment dates, and, therefore, supplemented its submittal with information about additional controls measures it had adopted, or planned to adopt, that stemmed from a planning effort overseen by the Ozone Transport Commission (OTC).

Although Massachusetts was identified as a state that contributed significantly to ozone nonattainment in another state, and, therefore, was required under CAIR to reduce ozone-season NO_X emissions, EPA's August 2011 CSAPR rule reached a different conclusion based on an updated analysis of air-quality and emissions data. *See* 76 FR 48299. Specifically, Table V.D–7 of the CSAPR rule indicates that Massachusetts' largest downwind contribution to nonattainment for ozone was 0.0 ppb, and its largest downwind contribution to maintenance for ozone was 0.6 ppb. *Id.* at 48245. These levels are below the 1 percent of the standard (0.8 ppb) that EPA established as the contribution threshold for the 1997 ozone NAAQS. Accordingly, EPA concluded in CSAPR that Massachusetts does not significantly contribute to nonattainment or interfere with maintenance of the 1997 ozone NAAQS. *Id.* at 48236 (explaining that states whose contributions are below the threshold do not violate the Good Neighbor provision). In light of the analysis of ozone transport contained in the CSAPR rule, the final determination pertaining to Massachusetts in that action, and the Commonwealth's continued adoption of VOC and NO_X control strategies as noted in their January 31, 2008, Transport SIP submittal, we are proposing to find that Massachusetts has met its CAA Section 110(a)(2)(D)(i)(I) ''good neighbor'' SIP obligation for the 1997 ozone NAAQS.

B. Background and Evaluation of the Transport SIP for the 2008 Ozone Standard

On March 12, 2008, EPA revised the primary and secondary ozone standards from 0.08 parts per million (ppm) to 0.075 ppm. *See* 73 FR 16436. As discussed above, upon promulgation of a new or revised NAAQS, states have three years to submit the SIP revision under section 110(a)(2) of the Act, including ''good neighbor'' SIPs. The CAA gives EPA a backstop role to issue federal implementation plans (FIPs), as appropriate, for states that do not have ''good neighbor'' provisions, or other required provisions, approved in their SIP.

To meet this backstop role for the 2008 ozone NAAQS, EPA updated the CSAPR ozone-season program by issuing a final rule on October 26, 2016, known as the CSAPR Update. *See* 81 FR 74504. The CSAPR Update addressed the summertime (May–September) transport of ozone in the eastern United States that crosses state lines to help downwind states meet and maintain the 2008 ozone NAAQS.[6] The CSAPR Update used the same framework that was used by EPA in developing CSAPR.[7] Prior to this, on July 13, 2015, EPA published a rule finding that 24 states, including Massachusetts, failed to make complete submissions addressing the requirements of section 110(a)(2)(D)(i)(I) regarding the 2008 ozone NAAQS. *See* 80 FR 39961.

Through several previous rulemakings,[8] EPA, working in partnership with states, established a four-step interstate-transport framework to address the requirements of the ''good neighbor'' provision for the ozone NAAQS.[9] The four steps are: Step 1—Identify downwind receptors that are expected to have problems attaining or maintaining the NAAQS; step 2—determine which upwind states contribute enough to these identified downwind air quality problems to warrant further review and analysis; step 3—identify the emissions reductions necessary to prevent an identified upwind state from contributing significantly to those downwind air quality problems; and step 4—adopt permanent and enforceable measures needed to achieve those emissions reductions.

To apply the first and second steps of the four-step interstate-transport framework to the 2008 ozone NAAQS, EPA evaluated modeling projections for air-quality monitoring sites in 2017 and considered current (at the time) ozone monitoring data at these sites to identify receptors[10] anticipated to have problems attaining or maintaining the 2008 ozone NAAQS. Next, EPA used air-quality modeling to assess contributions from upwind states to these downwind receptors and evaluated the contributions relative to a screening threshold of one percent (1%) of the NAAQS. States with contributions that equaled or exceeded the 1% threshold were identified as warranting further analysis for ''significant contribution to nonattainment'' or ''interference with maintenance'' of the NAAQS. In the CSAPR Update, EPA found that Massachusetts did not contribute at or above the 1% threshold to any downwind nonattainment or maintenance receptor. *See* 81 FR 74506. Therefore, EPA did not issue FIP requirements for sources in Massachusetts as part of CSAPR Update. *See id.* at 74553.

On June 6, 2014, Massachusetts submitted most of its infrastructure SIP for the 2008 ozone NAAQS to EPA. On December 21, 2016, EPA fully approved most, and conditionally approved some portions, of that submittal. *See* 81 FR 93627. However, that submittal did not include the ''good neighbor'' provisions of section 110(a)(2)(D)(i)(I). On February 9, 2018, Massachusetts submitted a SIP revision to address this unmet SIP obligation for the 2008 ozone NAAQS. In today's action, we are proposing to approve that submittal.

In its February 2018, submittal, the Commonwealth noted that the CSAPR Update states that the largest modeled contribution of emissions from Massachusetts to nonattainment and maintenances receptors are well below the threshold of 1% of the NAAQS. Massachusetts also pointed to the declining trend in ozone-precursor emissions that has occurred in the Commonwealth to support its view that Massachusetts is unlikely to cause future problems to downwind attainment or maintenance receptors. Moreover, we note that, in the CSAPR Update, EPA already ''determined that emissions from [Massachusetts] do not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in downwind states'' and that EPA ''need not require further emission reductions from sources in [Massachusetts] to address the good

[6] In the CSAPR Update, EPA issued FIPs to address CAA section 110(a)(2)(D)(i) obligations for 22 eastern states but determined that no FIP was needed for Massachusetts.

[7] Key elements of the four-step interstate transport framework have been upheld by the Supreme Court in *EPA* v. *EME Homer City Generation, L.P.,* 134 S. Ct. 1584 (2014).

[8] NO_X SIP Call. 63 FR 57356 (October 27, 1998); Clean Air Interstate Rule (CAIR). 70 FR 25162 (May 12, 2005); Cross-State Air Pollution Rule (CSAPR). 75 FR 48208 (August 8, 2011); and CSAPR Update. 81 FR 74504 (October 26, 2016).

[9] The four-step interstate framework has also been used to address requirements of the good neighbor provision for some previous particulate matter (PM) NAAQS.

[10] Within the CSAPR framework, the term ''receptor'' indicates a monitoring site. Under CSAPR Update, nonattainment receptors are downwind monitoring sites that are projected to have an average design value that exceed the NAAQS and that have a current monitored design value above the NAAQS, while maintenance receptors are downwind monitoring sites that are projected to have maximum design values that exceed the NAAQS.

neighbor provision as to the 2008 ozone NAAQS.'' 81 FR at 74506.

In light of the above, we propose that Massachusetts has met its CAA Section 110(a)(2)(D)(i)(I) ''good neighbor'' SIP obligation for the 2008 ozone NAAQS.

C. Background and Evaluation of the Massachusetts Transport SIP for the 2015 Ozone Standard

EPA has released several documents relevant to evaluating interstate transport with respect to the 2015 ozone NAAQS. First, on January 6, 2017, EPA published a notice of data availability (NODA) for preliminary interstate ozone-transport modeling with projected ozone design values for 2023.[11] The year 2023 aligns with the expected attainment year for Moderate ozone nonattainment areas under the 2015 ozone standard. On October 27, 2017, EPA issued a memorandum (2017 memorandum) containing updated modeling data for 2023, with changes made in response to comments on the NODA.[12] The 2017 memorandum also included data for the 2023 modeling year. Although it stated that the modeling may be useful for states for developing SIPs addressing ''good neighbor'' obligations for the 2008 ozone NAAQS, the 2017 memorandum did not address the 2015 ozone NAAQS.

On March 27, 2018, EPA issued a memorandum (March 2018 memorandum) indicating that the same 2023 modeling data released in the 2017 memorandum may also be useful for evaluating potential downwind air-quality problems with respect to the 2015 ozone NAAQS (step 1 of the four-step framework).[13] The March 2018 memorandum included contribution-modeling results to help states evaluate their impact on potential downwind air-quality problems (step 2 of the four-step framework). In August and October 2018, EPA issued two more memoranda that provided guidance for developing ''good neighbor'' SIPs for the 2015 ozone NAAQS regarding (1) potential contribution thresholds that may be appropriate to apply in step 2 and (2) considerations for identifying downwind areas that may have problems maintaining the standard (*i.e.,* prong 2) at step 1 of the framework.[14]

The March 2018 memorandum described the updated photochemical and source-apportionment modeling used to project ambient ozone concentrations for 2023 and the state-by-state impacts on those concentrations. As described in the 2017 and March 2018 memoranda, EPA used the Comprehensive Air Quality Model with Extensions (CAMx version 6.40) to model average and maximum design values in 2023 to identify potential nonattainment and maintenance receptors for the 2015 ozone NAAQS. The March 2018 memorandum presented design values calculated in two ways: (1) Following the EPA's historic ''3 x 3'' approach [15] to evaluating all sites, and (2) following a modified approach for coastal monitoring sites in which ''overwater'' modeling data were not included in the calculation of future-year design values (known as the ''no water approach'').

For identifying potential nonattainment and maintenance receptors in 2023, EPA applied the same approach as that used in the CSAPR Update. Specifically, EPA identified nonattainment receptors as those monitors with both measured values [16] and projected 2023 average design values exceeding the NAAQS. The EPA identified maintenance receptors as those monitors with projected maximum design values exceeding the NAAQS. This included monitoring sites with measured values below the NAAQS, but with projected average and maximum design values above the NAAQS, and monitoring sites with projected average design values below the NAAQS, but with projected maximum design values above the NAAQS. Data for all monitoring sites projected to be nonattainment or maintenance receptors based on the updated 2023 modeling is included in Attachment B of the March 2018 memorandum.

After identifying potential downwind nonattainment and maintenance receptors, EPA performed nationwide, state-level ozone source-apportionment modeling to estimate the expected impact from each state to each nonattainment and maintenance receptor.[17] For more information, see the 2017 and March 2018 memoranda, the NODA for the preliminary interstate transport assessment, and the supporting technical documents included in the docket for today's action.

As noted previously, on August 31, 2018, EPA issued a memorandum (the August 2018 memorandum) providing guidance concerning contribution thresholds that may be appropriate to apply with respect to the 2015 ozone NAAQS in step 2. Consistent with the process for selecting the 1% threshold in CSAPR and the CSAPR Update, the memorandum included analytical information regarding the degree to which potential air-quality thresholds would capture the collective amount of upwind contribution from upwind states to downwind receptors for the 2015 ozone NAAQS. The August 2018 memorandum indicated that, based on EPA's analysis of its most recent modeling data, the amount of upwind collective contribution captured using a 1 ppb threshold is generally comparable, overall, to the amount captured using a threshold equivalent to 1% of the 2015 ozone NAAQS. Accordingly, EPA indicated that it may be reasonable and appropriate for states to use a 1 ppb contribution threshold, as an alternative to the 1% threshold, at step 2 of the four-step framework in developing their SIP revisions addressing the good neighbor provision for the 2015 ozone NAAQS.[18]

Although the March 2018 memorandum presented information regarding EPA's latest analysis of ozone transport, EPA has not made any final determinations regarding how states should identify downwind receptors with respect to the 2015 ozone NAAQS at step 1 of the four-step framework. Rather, EPA noted that, in developing their SIPs, states have flexibility to

[11] *See* Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 Ozone National Ambient Air Quality Standard (NAAQS), 82 FR 1733 (January 6, 2017).

[12] *See* Information on the Interstate Transport State Implementation Plan Submissions for the 2008 Ozone National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I) (Oct. 27, 2017), available in the docket for this action or at *https://www.epa.gov/interstate-air-pollution-transport/interstate-air-pollution-transport-memos-and-notices.*

[13] *See* Information on the Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I) (Mar. 27, 2018), available in the docket for this action or at *https://www.epa.gov/interstate-air-pollution-transport/interstate-air-pollution-transport-memos-and-notices.*

[14] *See* Analysis of Contribution Thresholds for Use in Clean Air Act Section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards (Aug. 31, 2018) (''August 2018 memorandum''); Considerations for Identifying Maintenance Receptors for Use in Clean Air Act Section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards (Oct. 19, 2018), available in the docket for this action or at *https://www.epa.gov/airmarkets/memo-and-supplemental-information-regarding-interstate-transport-sips-2015-ozone-naaqs.*

[15] *See* March 2018 memorandum, p. 4.

[16] The EPA used 2016 ozone design values, based on 2014–2016 measured data, which were the most current data at the time of the analysis. *See* attachment B of the March 2018 memorandum, p. B–1.

[17] As discussed in the March 2018 memorandum, the EPA performed source-apportionment model runs for a modeling domain that covers the 48 contiguous United States and the District of Columbia, and adjacent portions of Canada and Mexico.

[18] *See* August 2018 memorandum, p. 4.

follow different analytical approaches than EPA if their chosen approach has adequate technical justification and is consistent with the requirements of the CAA.

On September 27, 2018, Massachusetts submitted a SIP revision addressing the infrastructure SIP requirements of section 110(a)(2), including the section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 ozone NAAQS.[19] Massachusetts relied on the results of EPA's modeling for the 2015 ozone NAAQS (in the March 2018 memorandum) to identify downwind nonattainment and maintenance receptors that may be impacted by emissions from sources in the Commonwealth. Based on Massachusetts' review of EPA's modeling assumptions, model performance evaluation, and the modifications made in response to public comments, the Commonwealth determined that EPA's future-year projections were appropriate for purposes of evaluating Massachusetts' impact on attainment and maintenance of the 2015 ozone NAAQS in other states. Thus, the Commonwealth concurred with EPA's photochemical modeling results that indicate Massachusetts' greatest impact on any potential downwind nonattainment or maintenance receptor would be 0.24 ppb.

Massachusetts compared these values to a screening threshold of 0.70 ppb, representing 1% of the 2015 ozone NAAQS, and concluded that because none of the Commonwealth's impacts exceed this threshold, emissions from Massachusetts sources will not significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state.

The March 2018 memorandum also provided contribution data regarding the impact of other states on the potential receptors. To evaluate the Commonwealth's 2015 ozone NAAQS interstate-transport SIP submission, EPA used the 1% threshold to conclude that the state's impact will not significantly contribute to nonattainment or interfere with maintenance of the NAAQS in any other state. EPA notes that, consistent with the August 2018 memorandum, it may be reasonable for states to use a 1-ppb contribution threshold as an alternative to a 1% threshold at step 2 of the four-step framework. However, for the reasons discussed below, it is unnecessary for EPA to determine the appropriateness of applying a 1-ppb threshold for purposes of today's action.

EPA's updated 2023 modeling discussed in the March 2018 memorandum indicates that Massachusetts' largest impact on any potential downwind nonattainment or maintenance receptor is 0.24 ppb at the Queens, New York, monitor. This value is less than 0.70 ppb (1% of the 2015 ozone NAAQS),[20] and demonstrates that emissions from Massachusetts are not linked to any projected 2023 downwind nonattainment and maintenance receptors identified in the March 2018 memorandum. Therefore, EPA proposes to find that Massachusetts will not significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state.

III. Proposed Action

EPA is proposing to approve Massachusetts' SIP revisions that were submitted to address prongs 1 and 2 of the interstate transport requirements for CAA section 110(a)(2)(D)(i)(I) for the 1997, 2008, and 2015 ozone NAAQS. EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters.[21] These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Volatile organic compounds.

[19] As noted earlier, in this action, EPA is only addressing the requirements of section 110(a)(2)(D)(i)(I). EPA will address the remaining infrastructure requirements for the 2015 ozone NAAQS in a separate rulemaking(s).

[20] Because none of Massachusetts' impacts exceed 0.70 ppb, they necessarily also do not exceed the 1ppb contribution threshold discussed in the August 2018 memorandum.

[21] EPA is not reopening for comment final determinations made in CSAPR or in the CSAPR Update or the modeling conducted to support those rulemakings.

Dated: August 7, 2019.

Deborah Szaro,

Acting Regional Administrator, EPA Region 1.

[FR Doc. 2019–17406 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2019–0426, FRL–9998–09–Region 10]

Air Plan Approval: Lane County, Oregon; 2019 Permitting Rule Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve revisions to the Oregon State Implementation Plan (SIP) submitted on June 13, 2019. The proposed revisions, applicable in Lane County, Oregon, update regulations contained in the SIP to make minor syntax and renumbering changes, add a reference to the electronic public notice option, and update citations to reference materials such as the Code of Federal Regulations (CFR) and the most recent Oregon Source Sampling Manual. The EPA reviewed the submitted revisions and proposes to find they are consistent with Clean Air Act (CAA) requirements.

DATES: Comments must be received on or before September 13, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2019–0426, at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, EPA Region 10, 1200 Sixth Avenue—Suite 155, Seattle, WA 98101, at (206) 553–0256, or *hunt.jeff@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''us,'' or ''our'' is used, it means the EPA.

I. Background

Each state has a SIP containing the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS) established by the EPA for the criteria pollutants (carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, sulfur dioxide). The SIP contains such elements as air pollution control regulations, emission inventories, attainment demonstrations, and enforcement mechanisms. Section 110 of the CAA requires each state to periodically revise its SIP. As a result, the SIP is a living compilation of regulatory and non-regulatory elements that are updated to address federal requirements and changing air quality issues in the state.

The Oregon Department of Environmental Quality (ODEQ) implements and enforces the Oregon SIP through rules set out in Chapter 340 of the Oregon Administrative Rules (OAR). Chapter 340 rules apply in all areas of the state, except where the Oregon Environmental Quality Commission (EQC) has designated a local agency as having primary jurisdiction.

Lane Regional Air Protection Agency (LRAPA) has been designated by the EQC to implement and enforce state rules in Lane County, and to adopt local rules that apply within Lane County. LRAPA may promulgate a local rule in lieu of a state rule provided: (1) It is as strict as the corresponding state rule; and (2) it has been submitted to and not disapproved by the EQC. This delegation of authority in the Oregon SIP is consistent with CAA section 110(a)(2)(E) requirements for state and local air agencies.

On May 16, 2019, the EQC adopted revised air quality regulations applicable in Lane County that became effective May 17, 2019. On June 13, 2019, the state submitted certain of these rule revisions to the EPA for approval into the Oregon SIP. The submitted changes account for electronic public notice of proposed major source permits, add references to stationary source sampling requirements, make use of plain language, and correct errors. We note that some of the adopted changes were not submitted for SIP approval because they administer the new, state-only air toxics permitting program known as Cleaner Air Oregon, established in OAR Chapter 340, Division 245. Cleaner Air Oregon is not part of the federally-approved SIP.

II. Evaluation of Submission

A complete analysis of the LRAPA regulatory changes is included in the docket for this action. As detailed in the analysis and discussed briefly, not all the LRAPA regulatory changes were submitted for incorporation in the SIP. Listed is a summary of the major changes.

A. Title 12: General Provisions and Definitions

Title 12 contains general procedures and definitions used in LRAPA's air quality program. LRAPA made minor changes to clarify rule language throughout the definitions section of this title. LRAPA added a new definition for ''toxic air contaminant'' to account for the new state air toxics permitting program and made conforming changes to related definitions in title 12. However, these revisions have limited impact on the federally-approved Oregon SIP because the revisions primarily relate to the new, state-only air toxics rules which are not part of the SIP and were not submitted to the EPA for approval.

Title 12 also includes key reference materials used throughout LRAPA's air quality rules. The submission revises citation dates for these reference materials. First, all references to federal requirements in the CFR now refer to the July 1, 2018 version. Second, all references to the Oregon Source Sampling Manual now refer to the November 2018 edition (previously submitted for approval into the SIP, see 84 FR 33883, July 16, 2019).

We reviewed the submitted changes to title 12 and propose to approve and incorporate them by reference into the Oregon SIP, except all references to ''toxic air contaminants'' and the state-only air toxics permitting program set forth in OAR Chapter 340, Division 245, because these provisions were not submitted to the EPA for approval.

B. Title 15: Enforcement Procedure and Civil Penalties

Title 15 contains enforcement procedures and civil penalties for violations of environmental regulations. In the submission, LRAPA made minor

edits to this title for clarity and to correct errors. For example, LRAPA replaced the phrase ''pursuant to'' with ''under'' because the word has a plainer meaning and aligns with the recent changes to OAR Chapter 340. In addition, LRAPA corrected references to the federally-defined term ''Best Available Control Technology'' to match the recent revision to OAR Chapter 340.

We reviewed the submitted changes and propose to find that title 15 continues to provide LRAPA with adequate authority to enforce the SIP as required by section 110 of the CAA and 40 CFR 51.230(b). Consistent with our prior action on title 15 on February 20, 2019, we propose to approve the changes to this title only to the extent the provisions relate to enforcement of the requirements contained in the Oregon SIP (84 FR 5000). We are not proposing to incorporate the changes by reference into the CFR, however, because the EPA relies on its independent enforcement procedures and penalty provisions in bringing enforcement actions and assessing penalties under the CAA.

C. Title 31: Public Participation

Title 31 contains rules to notify the public of certain permit actions and give the public an opportunity to participate in the permitting process. In the submission, LRAPA added electronic noticing (termed e-notice) for draft major new source review (NSR) permits consistent with recent EPA rules published on October 18, 2016 and intended to modernize the process (81 FR 71613).

LRAPA also made updates to this title to address the new, state-only air toxics permitting program. However, the state submitted these public participation rule changes only to the extent the rules apply to (1) pollutants for which NAAQS have been established (criteria pollutants) and precursors to those criteria pollutants as determined by the EPA for the applicable geographic area; and (2) any additional pollutants that are required to be regulated under part C of title I of the CAA, but only for the purposes of meeting or avoiding the requirements of part C of title I of the CAA.

We most recently approved revisions to title 31 on October 5, 2018 (83 FR 50274). We found that title 31 was consistent with the CAA and regulatory requirements for public notice of new source review actions in 40 CFR 51.161 Public availability of information, 40 CFR 51.165 Permit requirements, and 40 CFR 51.166 Prevention of significant deterioration of air quality. After reviewing the submitted changes, we find that LRAPA's public participation rules continue to meet the CAA and the EPA's NSR public notice requirements.

D. Title 37: Air Contaminant Discharge Permits

The Oregon Air Contaminant Discharge Permit (ACDP) program is both the federally-enforceable non-title V operating permit program, and the administrative mechanism used to implement the notice of construction and NSR programs. There are six types of ACDPs under state rules: Construction, General, Short Term Activity, Basic, Simple, and Standard. LRAPA made changes to this title to align with changes to OAR Chapter 340 to use plain language, clarify requirements, and reference the new, state-only air toxics permitting program. LRAPA also revised the applicability and jurisdiction section of this title to spell out that a source may not continue to operate if the source's ACDP expires, or is terminated, denied, or revoked.

Certain rules in title 37 are used to implement both the SIP-approved permitting programs and the new, state-only air toxics permitting program. In the submission, the state made clear that it requested approval of the submitted changes to title 37 for purposes of SIP permitting only.[1] We reviewed the submitted changes and find that the program remains consistent with section 110 of the CAA and the EPA's implementing regulations.

III. Proposed Action

The EPA proposes to approve, and incorporate by reference into the Oregon SIP, the submitted changes to LRAPA's regulations, state effective May 17, 2019:

- Title 12 General Provisions and Definitions (005, 020, 025);
- Title 31 Public Participation (0020, 0030, 0040, 0050); and
- Title 37 Air Contaminant Discharge Permits (0010, 0020, 0030, 0040, 0090, 8020).[2]

The EPA also proposes to approve, but not incorporate by reference, the submitted changes to the following sections, state effective May 17, 2019:

- Title 15 Enforcement Procedure and Civil Penalties (005, 018, 020, 025, 030, 045, 055, 060), only to the extent the rules relate to enforcement of the requirements contained in the Oregon SIP.

IV. Oregon Notice Provision

Oregon Revised Statute 468.126 prohibits the ODEQ from imposing a penalty for violation of an air, water or solid waste permit unless the source has been provided five days' advanced written notice of the violation and has not come into compliance or submitted a compliance schedule within that five-day period. By its terms, the statute does not apply to Oregon's title V program or to any program if application of the notice provision would disqualify the program from federal delegation. Oregon has previously confirmed that, because application of the notice provision would preclude EPA approval of the Oregon SIP, no advance notice is required for violation of SIP requirements.

V. Incorporation by Reference

In this rule, the EPA is proposing to include, in a final rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the provisions described in Section III. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735,

[1] The state submitted ACDP permitting rule revisions only to the extent that the rules apply to (1) pollutants for which NAAQS have been established (criteria pollutants) and precursors to those criteria pollutants as determined by the EPA for the applicable geographic area; and (2) any additional pollutants that are required to be regulated under part C of title I of the CAA, but only for the purposes of meeting or avoiding the requirements of part C of title I of the CAA.

[2] Titles 12, 31, and 37 are proposed to be approved only to the extent the rules apply to (1) pollutants for which NAAQS have been established (criteria pollutants) and precursors to those criteria pollutants as determined by the EPA for the applicable geographic area; and (2) any additional pollutants that are required to be regulated under Part C of title I of the CAA, but only for the purposes of meeting or avoiding the requirements of Part C of title I of the CAA.

October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because it does not involve technical standards; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and record keeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: July 31, 2019.

Chris Hladick,

Regional Administrator, Region 10.

[FR Doc. 2019–17351 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–R04–OAR–2019–0374; FRL–9998–31–Region 4]

Air Plan Approval and Air Quality Designation; FL; Redesignation of the Duval County Ozone Unclassifiable Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On June 19, 2019, the State of Florida, through the Florida Department of Environmental Protection (FDEP), submitted a request for the Environmental Protection Agency (EPA) to redesignate the Duval County, Florida ozone unclassifiable area (hereinafter referred to as the ''Duval County Area'' or ''Area'') to attainment for the 2015 primary and secondary 8-hour ozone national ambient air quality standards (NAAQS). EPA now has sufficient data to determine that the Duval County Area is in attainment of the 2015 primary and secondary 8-hour ozone NAAQS. Therefore, EPA is proposing to approve the State's request and redesignate the Area to attainment/unclassifiable for the 2015 primary and secondary 8-hour ozone NAAQS based upon valid, quality-assured, and certified ambient air monitoring data showing that the Area is in compliance with the 2015 primary and secondary 8-hour ozone NAAQS.

DATES: Comments must be received on or before September 13, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2019–0374 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Madolyn Sanchez, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Ms. Sanchez can be reached by telephone at (404) 562–9644 or via electronic mail at *sanchez.madolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Clean Air Act (CAA or Act) establishes a process for air quality management through the establishment and implementation of the NAAQS. After the promulgation of a new or revised NAAQS, EPA is required to designate areas, pursuant to section 107(d)(1) of the CAA, as attainment, nonattainment, or unclassifiable. On October 1, 2015, EPA published a final rule revising the primary and secondary 8-hour NAAQS for ozone to a level of 70 parts per billion (ppb), based on a 3-year average of the annual fourth-highest daily maximum 8-hour ozone concentrations. *See* 80 FR 65292 (October 26, 2015). EPA established the standards based on significant evidence and numerous health studies demonstrating that serious health effects are associated with exposures to ground-level ozone.

The process for designating areas following promulgation of a new or revised NAAQS is contained in section 107(d)(1) of the CAA. On June 4, 2018 (83 FR 25776), EPA published a final rule designating certain areas across the country, including the Duval Area, as nonattainment, unclassifiable, or attainment/unclassifiable [1] for the 2015

[1] For the ozone initial area designations in 2018, EPA used a designation category of ''attainment/unclassifiable'' for areas that had monitors showing attainment of the standard and were not contributing to nearby violations and for areas that did not have monitors but for which EPA had reason to believe were likely attaining the standard and not contributing to nearby violations. EPA used the category ''unclassifiable'' for areas in which EPA could not determine, based upon available information, whether or not the NAAQS was being

Continued

primary and secondary 8-hour ozone NAAQS based upon air quality monitoring data from monitors for calendar years 2015–2017.[2] The monitors in the Duval County Area had incomplete data for the 2015–2017 timeframe. Therefore, EPA designated Duval County as unclassifiable for the 2015 primary and secondary 8-hour ozone NAAQS.

As discussed in section III below, the monitors in the Duval County Area now have sufficient data to determine that the Area is attaining the 2015 primary and secondary 8-hour ozone NAAQS. Therefore, on June 19, 2019, Florida submitted a request for EPA to redesignate the Duval County Area to attainment for the 2015 primary and secondary 8-hour ozone NAAQS.[3]

II. What are the criteria for redesignating an area from unclassifiable to attainment/unclassifiable?

Section 107(d)(3) of the CAA provides the framework for changing the area designations for any NAAQS pollutants. Section 107(d)(3)(A) provides that the Administrator may notify the Governor of any state that the designation of an area should be revised ''on the basis of air quality data, planning and control considerations, or any other air quality-related considerations the Administrator deems appropriate.'' The Act further provides in section 107(d)(3)(D) that even if the Administrator has not notified a state Governor that a designation should be revised, the Governor of any state may, on the Governor's own motion, submit a request to revise the designation of any area, and the Administrator must approve or deny the request.

When approving or denying a request to redesignate an area, EPA bases its decision on the air quality data for the area as well as the considerations provided under section 107(d)(3)(A).[4] In keeping with section 107(d)(1)(A), areas that are redesignated to attainment/unclassifiable must meet the requirements for attainment areas and thus must meet the relevant NAAQS. In addition, the area must not contribute to ambient air quality in a nearby area that does not meet the NAAQS. The relevant monitoring data must be collected and quality-assured in accordance with 40 CFR part 58 and recorded in the EPA Air Quality System (AQS) database. The designated monitors generally should have remained at the same location for the duration of the monitoring period upon which the redesignation request is based.[5]

III. What is EPA's rationale for proposing to redesignate the area?

In order to redesignate the Area from unclassifiable to attainment/unclassifiable for the 2015 primary and secondary 8-hour ozone NAAQS, the 3-year average of annual fourth-highest daily maximum 8-hour ozone concentration values (*i.e.,* design value) over the most recent 3-year period must be less than or equal to 70 ppb at all monitoring sites in the Area over the full 3-year period, as determined in accordance with 40 CFR 50.19 and Appendix U of Part 50. EPA reviewed ozone monitoring data from the monitoring stations in the Duval County Area for the 2015 primary and secondary 8-hour ozone NAAQS for the 3-year period from 2016–2018. These data have been quality-assured, certified, and recorded in AQS by Florida, and the monitoring locations have not changed during the monitoring period. As summarized in Table 1, the design values for all of the monitors in the Area for the 2016–2018 period are well below the 2015 primary and secondary 8-hour ozone NAAQS.

TABLE 1—2015 8-HOUR OZONE DESIGN VALUES FOR THE MONITORS IN THE DUVAL COUNTY AREA FOR 2016–2018

AQS site No.	Site name	2016–2018 Ozone design value (ppb)
12–031–0077	Sheffield Elementary.	58
12–031–0100	Mayo Clinic	60
12–031–0106	Cisco Drive	61

Because the 3-year design values, based on complete, valid, certified, and quality-assured data, demonstrate that the Area meets the 2015 primary and secondary 8-hour ozone standards, EPA is proposing to redesignate the Duval County Area from unclassifiable to attainment/unclassifiable for the 2015 primary and secondary 8-hour ozone NAAQS.

IV. Proposed Action

EPA is proposing to approve Florida's June 19, 2019, redesignation request and to redesignate the Duval County Area from unclassifiable to attainment/unclassifiable for the 2015 primary and secondary 8-hour ozone NAAQS. If finalized, approval of the redesignation request would change the legal designation, found at 40 CFR part 81, of Duval County from unclassifiable to attainment/unclassifiable for the 2015 primary and secondary 8-hour ozone NAAQS.

V. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment/unclassifiable is an action that affects the status of a geographical area and does not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment/unclassifiable does not create any new requirements. Accordingly, this proposed action merely proposes to redesignate an area to attainment/unclassifiable and does not impose additional requirements. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because redesignations are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive

met and/or EPA had not determined the area to be contributing to nearby violations. EPA reserves the ''attainment'' category for when EPA redesignates a nonattainment area that has attained the relevant NAAQS and has an approved maintenance plan.

[2] This action, combined with final rules published on November 16, 2017 (82 FR 54232) and July 25, 2018 (83 FR 35136), completed the 2015 8-hour ozone NAAQS designations for all areas.

[3] Although Florida requested redesignation of the Area to ''attainment,'' EPA is proposing to redesignate the area to ''attainment/unclassifiable'' because, as noted above, EPA reserves the ''attainment'' category for when EPA redesignates a nonattainment area that has attained the relevant NAAQS and has an approved maintenance plan.

[4] While CAA section 107(d)(3)(E) also lists specific requirements for redesignations, those requirements only apply to redesignations of nonattainment areas to attainment and therefore are not applicable in the context of a redesignation of an area from unclassifiable to attainment/unclassifiable.

[5] *See* Memorandum from John Calcagni, Director, EPA Air Quality Management Division, entitled ''Procedures for Processing Requests to Redesignate Areas to Attainment'' (September 4, 1992).

Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Will not have disproportionate human health or environmental effects under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control.

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

Dated: August 5, 2019.

Mary S. Walker,

Regional Administrator, Region 4.

[FR Doc. 2019–17474 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[EPA–HQ–OLEM–2018–0524; FRL–9997–74–OLEM]

RIN 2050–AG98

Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Enhancing Public Access to Information; Reconsideration of Beneficial Use Criteria and Piles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action, EPA is proposing the following targeted changes to the April 17, 2015 Coal Combustion Residuals Final Rule based on stakeholder input: Revisions to the annual groundwater monitoring and corrective action report requirements, establishing an alternate risk-based groundwater protection standard for boron, and revisions to the publicly accessible CCR website requirements. The Agency is also proposing to address two provisions of the final rule that were remanded back to EPA on August 21, 2018 by the U.S. Court of Appeals for the D.C. Circuit. First, EPA is proposing to revise the CCR beneficial use definition by replacing the mass-based numerical threshold with specific location-based criteria as the trigger for an environmental demonstration. Second, EPA is proposing to introduce a single approach to consistently address the potential environmental and human health issues associated with piles of CCR, regardless of the location of the pile and whether the CCR is destined for disposal or beneficial use.

DATES: *Comments.* Comments must be received on or before October 15, 2019. *Public Hearing.* The EPA will hold a public hearing on October 2, 2019, in the Washington, DC metropolitan area.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2018–0524, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Land and Emergency Management Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery/Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

The hearing will be held in the Washington, DC metropolitan area. The exact location of the hearing will be posted in the docket for this proposal and on EPA's CCR website (*https://www.epa.gov/coalash*) in advance of the hearing. The hearing will convene at 9:00 a.m. (local time) and will conclude at 8:00 p.m. (local time).

Please note that if this hearing is held at a U.S. government facility, individuals planning to attend the hearing should be prepared to show valid picture identification to the security staff in order to gain access to the meeting room. Please note that the REAL ID Act, passed by Congress in 2005, established new requirements for entering federal facilities. For purposes of the REAL ID Act, EPA will accept government-issued IDs, including driver's licenses, from the District of Columbia and all states and territories except from American Samoa. If your identification is issued by American Samoa, you must present an additional form of identification to enter the federal building where the public hearing will be held. Acceptable alternative forms of identification include: Federal employee badges, passports, enhanced driver's licenses, and military identification cards. For additional information for the status of your state regarding REAL ID, go to: *https://www.dhs.gov/real-id-enforcement-brieffrequently-asked-questions.* Any objects brought into the building need to fit through the security screening system, such as a purse, laptop bag, or small backpack. Demonstrations will not be allowed on federal property for security reasons.

FOR FURTHER INFORMATION CONTACT: Jesse Miller, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304–P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (703) 308–1180; email address: *miller.jesse@epa.gov.* For more information on this rulemaking please visit *https://www.epa.gov/coalash.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2018–0524, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to

make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

B. Participation in Public Hearing

The EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the hearing, please use the online registration form available on EPA's CCR website (*https://www.epa.gov/coalash*) or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to register to speak at the hearing. The last day to pre-register to speak at the hearing will be September 26, 2019. On September 30, 2019, the EPA will post a general agenda for the hearing on EPA's CCR website (*https://www.epa.gov/coalash*).

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule. Additionally, requests to speak will be taken the day of the hearing at the hearing registration desk. The EPA will make every effort to accommodate all speakers who arrive and register, although preferences on speaking times may not be able to be fulfilled.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) or in hard copy form. If EPA is anticipating a high attendance, the time allotment per testimony may be shortened to no shorter than 3 minutes to accommodate all those wishing to provide testimony and have pre-registered. All comments and materials received at the public hearing will be placed in the docket for this rule, as well as a transcript from this hearing. While EPA will make every effort to accommodate all speakers who arrive and register the day of the hearing, opportunities to speak may be limited based upon the number of preregistered speakers. Therefore, EPA strongly encourages anyone wishing to speak to preregister.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public hearing. Commenters should notify the person listed in the **FOR FURTHER INFORMATION CONTACT** section if they will need specific equipment or if there are other special needs related to providing comments at the hearings. Verbatim transcripts of the hearings and written statements will be included in the docket for the rulemaking.

Please note that any updates made to any aspect of the hearing is posted online at *https://www.epa.gov/coalash*. While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

The EPA will not provide audiovisual equipment for presentations unless we receive special requests in advance. Commenters should notify the person listed in the **FOR FURTHER INFORMATION CONTACT** section when they pre-register to speak that they will need specific equipment. If you require the service of a translator or special accommodations, such as audio description, please pre-register for the hearing and describe your needs by September 26, 2019. We may not be able to arrange accommodations without advanced notice.

C. Submitting CBI

Do not submit information that you consider to be CBI electronically through *https://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address: ORCR Document Control Officer, Mail Code 5305–P, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; Attn: Docket ID No. EPA–HQ–OLEM–2018–0524.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or DC–ROM that you mail to the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD–ROM or disk that does not contain CBI, mark the outside of the disk or CD–ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

D. Docket

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OLEM–2018–0524. The EPA has previously established a docket for the April 17, 2015, CCR final rule under Docket ID No. EPA–HQ–RCRA–2009–0640, and the docket number supporting the March 15, 2018 proposed rule is EPA–HQ–OLEM–2017–0286. All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *https://www.regulations.gov* or in hard copy at the EPA Docket Center (EPA/DC), EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

II. General Information

A. Does this action apply to me?

This rule applies to the disposal and beneficial use of CCR generated by electric utilities and independent power producers that fall within the North American Industry Classification System (NAICS) code 221112 and may affect the following entities: Electric utility facilities and independent power producers that fall under the NAICS code 221112. This discussion is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This discussion lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine this proposal, as well as the applicability criteria found in § 257.50 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult

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

B. What action is the Agency taking?

The EPA is proposing to amend the regulations governing the disposal of CCR in landfills and surface impoundments in order to address certain issues raised by stakeholders that have arisen since the April 15, 2015 publication of the CCR rule and which were not addressed in the March 15, 2018 proposal (83 FR 11584) or the July 30, 2018 final rule (83 FR 36435). These issues are presented in Units IV through VIII of this proposal.

In this proposal, EPA is not reconsidering, proposing to reopen, or otherwise soliciting comment on any other provisions of the final CCR rule beyond those specifically identified in this proposal. The EPA will not respond to comments submitted on any issues other than those specifically identified in this proposal and they will not be considered part of the rulemaking record.

C. What is the Agency's authority for taking this action?

These regulations are established under the authority of sections 1008(a), 2002(a), 4004, 4005 and 7004(b) of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA) and the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016, 42 U.S.C. 6907(a), 6912(a), 6944, 6945 and 6974(b).

D. What are the incremental costs and benefits of this action?

This action is expected to result in net costs amounting to between $0.43 million and $3.8 million per year. Further information on the economic effects of this action can be found in Unit IX of this preamble.

III. Background

On April 17, 2015, EPA finalized national regulations to regulate the disposal of CCR as solid waste under subtitle D of the Resource Conservation and Recovery Act (RCRA) titled, ''Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals from Electric Utilities,'' (80 FR 21302) (2015 CCR rule or CCR rule). The CCR rule established national minimum criteria for existing and new CCR landfills, existing and new CCR surface impoundments, and all lateral expansions of these types of CCR units that are codified in Subpart D of Part 257 of Title 40 of the Code of Federal Regulations (CFR).[1] The criteria consist of location restrictions, design and operating criteria, groundwater monitoring and corrective action, closure requirements and post-closure care, and recordkeeping, notification and internet posting requirements. The rule also required any existing unlined CCR surface impoundment that is contaminating groundwater above a regulated constituent's groundwater protection standard to stop receiving CCR and either retrofit or close, except in limited circumstances.

The 2015 CCR rule was challenged by several different parties, including a coalition of regulated entities and a coalition of environmental organizations. See *USWAG et al* v. *EPA,* No. 15–1219 (D.C. Cir.). Four of the claims, a subset of the provisions challenged by the industry and environmental Petitioners, were settled. As part of that settlement, on April 18, 2016, EPA requested the Court to remand the four claims back to the Agency. On June 14, 2016, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit Court of Appeals) granted EPA's motion.

On September 13, 2017, EPA granted petitions from the Utility Solid Waste Activities Group (USWAG) and AES Puerto Rico LLP, requesting the Agency initiate rulemaking to reconsider certain provisions of the 2015 final rule.[2] The EPA determined that it was appropriate and in the public interest to reconsider certain provisions of the 2015 CCR rule, in light of the issues raised in the petitions and the new authorities in the WIIN Act. In light of that decision, EPA requested that the D.C. Circuit Court of Appeals hold the case in abeyance until the Agency had completed its reconsideration. The EPA subsequently requested that the Court remand certain provisions of the 2015 CCR rule on the ground that the Agency is reconsidering the provisions. Included in that request were two sets of provisions related to the beneficial use of CCR: (1) The 12,400-ton threshold in the beneficial use definition, and (2) the requirements for ''piles'' of CCR located on-site of a utility and those that are located off-site but destined for beneficial use. In October 2017, the D.C. Circuit Court of Appeals directed EPA to file a status report with the Court indicating its schedule for addressing issues contained in the petitions for reconsideration. In the status report filed in November 2017, EPA stated that it anticipated it would complete its reconsideration of all provisions in two phases. The first phase would be proposed in March 2018 and finalized no later than June 2019 and the second phase would be proposed no later than September 30, 2018 and finalized no later than December 2019. The EPA proposed the Phase One rule on March 15, 2018 (83 FR 11584) and on July 30, 2018, finalized several revisions included in the Phase One proposal (83 FR 36435). In the July 30, 2018, final rule, EPA adopted two alternative performance standards that either Participating State Directors in states with approved CCR permit programs (participating states) or EPA where EPA is the permitting authority to (1) suspend groundwater monitoring requirements if there is evidence that there is no potential for migration of hazardous constituents to the uppermost aquifer during the active life and post-closure care of the CCR unit; and (2) issue technical certifications in lieu of the current requirements to have professional engineers issue certifications. The Agency also established health-based groundwater protection standards (GWPS) for four constituents (cobalt, lead, lithium and molybdenum) that do not have established Maximum Contaminant Levels. Finally, the Agency extended the deadline by which facilities must cease the placement of waste in CCR units closing for cause in two situations: Where the facility has detected a statistically significant increase above a GWPS from an unlined surface impoundment; and where the unit is unable to comply with the aquifer location restriction. In both of these situations, the deadline for waste placement was revised to October 31, 2020. Provisions included in the March 15, 2018 proposal that were not included in July 30, 2018 final rule will be addressed in a subsequent action.

On August 21, 2018, the D.C. Circuit Court of Appeals issued its decision. Of greatest relevance to this proposed rule, the Court granted EPA's request to remand the challenged beneficial use provisions back to EPA in order to allow the Agency to complete its administrative reconsideration.

IV. Proposal To Revise the Beneficial Use Criteria

In the 2015 CCR rule, EPA established a Beneficial Use definition to distinguish between legitimate beneficial uses of CCR and the disposal of CCR. The Beneficial Use definition is comprised of four criteria: (1) The CCR must provide a functional benefit; (2)

[1] Unless otherwise noted, all part and section references in this preamble are to Title 40 of the CFR.

[2] The USWAG and AES Puerto Rico rulemaking petitions are available in the docket to this rulemaking.

the CCR must substitute for the use of a virgin materials, conserving natural resources that would otherwise need to be obtained through practices such as extraction; (3) the use of the CCR must meet relevant product specifications, regulatory standards, or design standards, when available, and where such specifications or standards have not been established, CCR may not be used in excess quantities; and (4) when unencapsulated use of CCR involves placement on the land of 12,400 tons or more in non-roadway applications, the user must demonstrate and keep records, and provide such documentation upon request, that environmental releases to groundwater, surface water, soil, and air are comparable to or lower than those from analogous products made without CCR, or that environmental releases to groundwater, surface water, soil, and air will be at or below relevant regulatory and health-based benchmarks for human and ecological receptors during use. See, § 257.53 and 80 FR 21349–54 (April 15, 2015). Criteria one through three of the Beneficial Use definition still remain as finalized in the 2015 CCR rule. In this action, EPA is proposing to eliminate the mass-based numerical threshold used to trigger an environmental demonstration, and replace it with specific location-based criteria derived from the existing location criteria for CCR disposal units. The EPA is also soliciting comments and information that could be used to select a new mass-based numerical threshold.

The EPA's current regulations at § 257.53 require that to be considered a ''beneficial use,'' when unencapsulated CCR is placed on the land in amounts greater than 12,400 tons, in non-roadway applications, the user must demonstrate that releases to environmental media (*i.e.,* groundwater, surface water, soil, air) are comparable to or lower than those from analogous products made without CCR or that releases to environmental media will be at or below relevant regulatory and health-based benchmarks for human and ecological receptors during use. The Agency established this environmental criterion to ensure that unencapsulated uses of CCR would be conducted in an environmentally protective manner. This fourth criterion was designed to address both the concern that large-scale fills were effectively operating as landfills and the documented risks associated with the placement of unencapsulated CCR in or near water sources. See 80 FR 21351–52 (April 15, 2015). A numerical threshold was established to determine when further analysis was warranted. The 12,400-ton threshold criterion was based on data collected in response to the 2010 Steam Electric Power Generating Effluent Guidelines Questionnaire (''the Effluent Guidelines Questionnaire''),[3] representing the smallest size CCR landfill. The EPA selected this threshold largely because the 2014 risk assessment demonstrated that at these volumes the potential risks warrant regulation. See 80 FR 21352 (April 15, 2015). In addition, EPA noted that the threshold of 12,400 tons was generally consistent with three state regulations identified in a 2013 Notice of Data Availability: [4] North Carolina and Wisconsin, which had established 5,000 cubic yards of CCR as a threshold, and West Virginia which had a threshold of 10,000 cubic yards (which equates to about 6,000–12,000 tons). See 80 FR 21351 (April 15, 2015).

After the final rule was issued, EPA received a letter [5] alleging that the 12,400-ton criterion was based on erroneous data that had been submitted to the Agency (available in the docket for the 2015 CCR rule). The letter concluded that the facility had incorrectly reported data in cubic yards rather than in cubic feet as requested in the survey questionnaire form. Based on their calculations, the letter claimed that the smallest landfill in the survey questionnaire data is approximately 74,800 tons and requested that EPA update the fourth beneficial use criterion to reflect this higher value.

The petition for rulemaking [6] submitted by USWAG included a request to correct the numerical threshold for the beneficial use definition (based on the letter previously discussed). Considering the numerical threshold issue raised by the petitioner, EPA has preliminarily determined that it is appropriate and in the public interest to reconsider the numerical threshold criterion in the final rule.

As part of this reconsideration, EPA conducted a focused review of currently available data from three sources: (1) Data collected in response to the Effluent Guidelines Questionnaire; (2) available risk information from the risk assessment for the 2015 rule; and (3) information from state beneficial use programs.[7]

Effluent Guidelines Questionnaire Data. The Agency first reviewed the reported landfill data received in response to the Effluent Guidelines Questionnaire. After reviewing this data, EPA identified several additional data points in which some facilities mistakenly reported data in cubic yards rather than cubic feet. While this dataset can still provide useful information on typical landfill sizes, EPA was not able to independently confirm the accuracy of every individual value. A review of the full database would not be practicable; at a minimum it would require EPA to contact each facility that provided information to confirm whether the facility had made any errors in reporting its data. No member of the public or stakeholders provided additional data to support the contention that the smallest CCR landfill is approximately 74,800 tons, or information that would allow EPA to independently confirm that value.

Available Risk Information. The Agency next reviewed the results of the 2014 Human and Ecological Risk Assessment of Coal Combustion Residuals (''the 2014 Risk Assessment'') to determine whether the model results for landfills could be used to draw conclusions about structural fill and other unencapsulated uses of CCR.[8] The EPA focused on the model runs for arsenic (III), which was found to be the primary risk driver associated with unlined landfills in the 2014 Risk Assessment. To identify the relevant subset of model runs, EPA queried the risk assessment results for unlined landfills with no surface water interception and plumes that reached the receptor within the 10,000-year evaluation window (*i.e.,* non-zero risk). These limits were placed to eliminate confounding factors that could obscure trends.

The EPA plotted the queried data to visualize any relationships that exist between risk and distance to receptor (meters), total mass disposed (tons), or mass disposed per area (tons/acre). Significant relationships were identified for distance to receptor and total mass disposed, but not for mass disposed per

[3] Additional information on this questionnaire can be found on EPA's website: *https://www.epa.gov/eg/steam-electric-power-generating-effluent-guidelines-questionnaire.*

[4] 78 FR 46943–44 (August 2, 2013).

[5] See letter from Kenneth Kastner, Hogan Lovells US LLP, on behalf of Headwaters Resources, Inc., to U.S. Environmental Protection Agency, dated April 1, 2015; available in the docket to this rulemaking.

[6] USWAG's petition for rulemaking is available in the docket to this rulemaking.

[7] Many state environmental agencies have requirements and programs to manage the beneficial use of non-hazardous solid waste including coal combustion residuals.

[8] The Agency's review is documented in the *Analysis of Model Results from 2014 Risk Assessment of Coal Combustion Residuals: Impacts of Total Mass Disposed and Distance to Receptor on Risk,* which is available in the docket for this rulemaking.

area. Although the identified relationships are relevant to unencapsulated beneficial uses, the data used to identify these relationships are based on the characteristics of existing landfills. However, unencapsulated beneficial uses are not subject to the same siting and construction requirements as the landfills modeled in the 2014 Risk Assessment. As a result, unencapsulated beneficial uses of an equivalent size have the potential to be placed closer to receptors, in more permeable soils or in other areas that will tend to increase risk. Therefore, the potential high-end risks associated with unencapsulated uses will tend to be higher than those modeled for landfills. This makes it difficult to extrapolate the landfill data to unencapsulated uses and to identify a numerical cutoff for proximity or size at which these uses will start to pose concern. Therefore, EPA concluded these data cannot be used directly to select national beneficial use criteria.

State Beneficial Use Programs. From the sources discussed above, EPA identified relationships between risk and both the tonnage of CCR placed in the environment and the distance from the CCR to receptors, but the Agency was unable to use these data as the basis for national-scale beneficial use criteria. Therefore, the Agency reviewed existing state beneficial use programs to understand the basis for similar state criteria. The Agency reviewed the 2012 ASTSWMO Beneficial Use Coal Combustion Residuals Survey Report (''the 2012 ASTSWMO Report'').[9] The 2012 ASTSWMO Report summarizes the results from a survey conducted in October 2011 through March 2012 to which 46 states responded and includes information from their 2006 Beneficial Use Survey Report. The 2012 ASTSWMO Report states that 35 out of 46 States restrict the beneficial use of CCR by statute, regulation, policy, or local ordinance. The Agency initially focused on six states (*i.e.,* Alaska, Illinois, North Carolina, South Carolina, Wisconsin, and West Virginia) that reported the use of numerical criteria to distinguish between small- and large-scale fills in the 2012 ASTSWMO Report. The EPA also gathered additional information on state beneficial use regulations through state websites and follow-up telephone calls with some states. Specifically, the Agency reviewed six additional state beneficial use programs that either were mentioned in submitted comments on the June 2010 proposed rule or were recommended for consideration by one of the other states reviewed (*i.e.,* Kentucky, Maryland, New York, Pennsylvania, Virginia, and Wyoming).

Of the six states (Alaska, North Carolina, South Carolina, Illinois, Wisconsin, and West Virginia) identified in the 2012 ASTSWMO Report, four have requirements based on the amount of CCR applied in a fill project by total mass (Illinois—10,000; and North Carolina—80,000 tons), mass per area (North Carolina—8,000 tons/acre) or volume (Wisconsin—5,000 and West Virginia—10,000 cubic yards).[10] Of the other six states (Kentucky, Maryland, New York, Pennsylvania, Virginia, and Wyoming) reviewed that were not from the 2012 ASTSWMO Report, only one additional state (Pennsylvania) has requirements based by total mass (100,000 tons) and mass per area (10,000 tons/acre). Uses at or greater than these amounts trigger some form of design, operation, construction and/or maintenance requirements or some form of notification to the state, landowner, deed record office and/or the public. Only one state (West Virginia) prohibited all fill uses above the established criteria (10,000 cubic yards). Based on EPA's review of these specific state beneficial use programs, none of the identified size criteria are based on an analysis of the potential risks associated with the specified mass or volume. Instead, these values are based on considerations such as the size of previously completed fill projects or consensus values agreed upon by state, industry and citizen groups. However, many of these states have additional criteria in place for fill applications that either directly or indirectly address potential risks. Under these state programs, the proposed use of CCR is prohibited if the placement of CCR does not meet these additional criteria, regardless of the amount of CCR used. In describing state programs in this section, the Agency uses the state terminology for clarity. These additional criteria include:

- Three states (Wisconsin, North Carolina, and Pennsylvania) require placement of the CCR to be a minimum distance above the groundwater table. One state (Wisconsin) requires placement to be 5 feet above the groundwater table and another (Pennsylvania) requires it to be 8 feet above the groundwater table. The third state (North Carolina) prohibits placement within 4 feet of the seasonal high groundwater table.
- Three states (Wisconsin, Illinois, and Pennsylvania) require chemical analysis of either the CCR bulk content or leachate to demonstrate that concentrations either present in or released from the ash are below specified levels.
- Two states (North Carolina and Pennsylvania) require a minimum setback distance from wetlands—one of 50 feet and another of 100 feet. One of the states (Pennsylvania) also has a limit of 300 feet from an ''exceptional value wetland.''
- Two states (North Carolina and Pennsylvania) prohibit placement within the 100-year flood plain.
- Two states (North Carolina and Pennsylvania) limit placement near water bodies, requiring a setback distance of 50 and 100 feet (respectively) from any surface water body. One of the states (Pennsylvania) also has a limit of 300 feet from any exceptional quality water body.
- Two states (North Carolina and Wisconsin) impose restrictions on proximity to residences. One state (North Carolina) required a minimum setback distance of 300 feet from any private dwelling or 50 feet from any property boundary. The other (Wisconsin) prohibited placement of CCR in any area zoned for residential use.
- Two states (Wisconsin and Pennsylvania) require a minimum setback distance, one of 200 feet and another of 300 feet from water supply wells.
- One state (Pennsylvania) requires a setback of 100 feet from sinkholes or any area draining to a sinkhole.
- One state (Pennsylvania) requires a setback of 25 feet from bedrock outcrops.

Several of the remaining states evaluate all uses including fill uses on a case-by-case basis, regardless of size, typically requiring a site-specific assessment that considers potential risks before approving the placement of unencapsulated CCR in fill applications. Based on the 2012 and 2006 ASTSWMO reports, and additional state beneficial use programs looked at by EPA, factors that these states consider in their review include: Test data on the chemical and physical characteristics of the wastes; benefit assessment based on suitable physical, chemical, or agronomic properties of the wastes; special conditions that limit use; and evaluations of potential risks to human health.

[9] ASTSWMO, ''Beneficial Use of Coal Combustion Residuals Survey Report'', September 2012, which is available in the docket to this rulemaking.

[10] With a typical compacted density for fly ash between 1,120 to 1,500 kg/m^3, the reported volumetric limits correspond to an upper bound somewhere between 4,700 and 12,600 tons. This range is similar to the lower end of mass limits reported by other states.

The EPA solicits comments and information on specific state criteria that would represent an appropriate trigger for an environmental demonstration such as, numerical limits, setbacks (to wetlands, private residences), proximity to water (water body, water supply well), specific criteria for CCR use, and any other requirements that state beneficial use programs have in place (*e.g.,* specific areas prohibited from CCR use) to supplement the information on the group of 12 states reviewed by the Agency.

Based on the Agency's review of these sources of information, EPA is proposing to eliminate the mass-based numerical threshold and replace it with specific location-based criteria, derived from the existing location criteria for CCR disposal units, to trigger an environmental demonstration. As discussed further below, the available information does not appear to provide strong support for a single numerical mass-based threshold as a general matter; however, EPA solicits comments on whether to retain a mass-based threshold. Assuming EPA determines a threshold to be appropriate, EPA also solicits comments on whether an appropriate value for a mass threshold to trigger an environmental demonstration should be based on the state beneficial use programs' lower tonnage thresholds, discussed above, or to retain the current 12,400-ton numerical criterion. The EPA also requests comment on whether a combination of the mass-based threshold and location-based criteria would be an appropriate trigger to require an environmental demonstration for unencapsulated uses. Generally, having some type of threshold is a reasonable approach since there may potentially be some relatively small volume uses or dry locations where an environmental demonstration is not necessary. The Agency notes that two of the four proposed approaches discussed in this preamble would be of particular interest to those entities that use small volumes of CCR. Both of these approaches include a numerical threshold where unencapsulated uses involving an amount of CCR less than the threshold would not trigger the need for an environmental demonstration. Nevertheless, EPA also solicits comment on whether the environmental demonstration required under the beneficial use definition's fourth criterion should be conducted for all unencapsulated CCR uses. All four of these approaches are discussed below.

A. Location-Based Criteria Instead of a Mass-Based Numerical Value

Based on the above considerations, EPA is proposing to eliminate the mass-based numerical threshold and instead replacing it with specific location-based criteria, which are largely derived from the current location criteria for CCR disposal units, to trigger an environmental demonstration. The specific location-based criteria EPA is proposing in this action are: Distance from the uppermost aquifer; placement in a wetland; placement in an unstable area; placement in a flood plain; distance from a fault area; and placement in a seismic zone. The EPA considered information developed for the 2015 CCR rule and the state beneficial use programs discussed above. As mentioned previously, modeled risks in the 2014 Risk Assessment show that where the CCR is placed in the environment can be a sensitive variable. In addition, the conditions in certain areas, such as wetlands or other areas addressed by the current CCR location criteria for disposal units, are generally recognized as having the potential to impact the structural integrity of a disposal unit negatively and as such, increase the risks to human health or the environment, *e.g.,* through leaching of contaminants into groundwater. Several states have established requirements to protect specific sensitive areas found in each state, by prohibiting CCR from being placed for fill uses. Some of these requirements are also similar to the existing location restrictions for CCR units, *e.g.,* address the same site conditions. Based on these considerations, EPA is proposing to revise the fourth criterion of the Beneficial Use definition by adopting certain location criteria (based on the location criteria for CCR disposal units) as triggers for the environmental demonstration. Before the placement of any amount of unencapsulated CCR in areas meeting the location-based criteria can occur for a proposed use, an affirmative demonstration that releases to environmental media (*i.e.,* groundwater, surface water, soil and air) are comparable to or lower than those from analogous products made without CCR, or will be at or below relevant regulatory and health-based benchmarks for human and ecological receptors during use, is necessary in order to be considered a ''beneficial use.'' The EPA is proposing the following location-based criteria: Distance from the uppermost aquifer; placement in a wetland; placement in an unstable area; placement in a flood plain; distance from a fault area; and placement in a seismic zone. The EPA solicits comment on additional location criteria based on state beneficial use programs for distance from a water body and distance from a water supply well.

1. Distance From the Uppermost Aquifer

The current CCR regulations restrict placement of CCR units within 1.52 meters (five feet) of the upper limit of the uppermost aquifer or to demonstrate that there will not be an intermittent, recurring, or sustained direct hydraulic connection between any portion of the base of the CCR unit and the uppermost aquifer due to normal fluctuations in groundwater elevations (including groundwater elevations during the wet season). See § 257.60(a). For placement of CCR in fill applications, state programs have similar requirements, but they are specific to groundwater. Two states (Wisconsin and Pennsylvania) prohibit placement of CCR within 5 and 8 feet (respectively) of the groundwater table, while a third state (North Carolina) prohibits placement within 4 feet of the seasonal high groundwater table. The EPA is proposing a location-based criterion that when unencapsulated CCR is placed at a site for beneficial use within 5 feet of the upper limit of the uppermost aquifer that the environmental demonstration under the existing regulation would be triggered to assess the potential environmental releases from the CCR use under consideration. The EPA chose this value to be consistent with the current federal location criteria for CCR disposal units. The EPA solicits comments on (i) adopting a location criterion based on the distance to the uppermost aquifer and whether North Carolina's 4 feet of the seasonal groundwater table, the 8-foot value in Pennsylvania's requirements or Wisconsin's criterion of 5-feet from the groundwater table is more appropriate; and (ii) whether there are other existing state restrictions that are appropriate for EPA to consider in establishing a criterion for distance to the groundwater table to trigger an environmental demonstration.

2. Placement in a Wetland

The current regulations restrict placement of CCR units in wetlands except if the owner or operator makes specific demonstrations that the CCR unit will not degrade sensitive wetland ecosystems. See in § 257.61. The current regulations define a wetland by reference to the definition in § 232.2. For placement of CCR in fill applications, two states (North Carolina and Pennsylvania) require a minimum

setback distance from wetlands of 50 and 100 feet (respectively), and 300 feet from an exceptional value wetland. The EPA is proposing to adopt a provision that when unencapsulated CCR is placed at a site for beneficial use in a wetland that the environmental demonstration would be triggered to assess potential environmental releases from the proposed CCR use. This means that an environmental demonstration is required before the placement of any amount of unencapsulated CCR can occur for a proposed use in a wetland. The EPA considered this criterion to ensure consistency with the location criteria for CCR disposal units. However, EPA requests comment on whether a different definition of a wetland is more appropriate in this context. The EPA also solicits comments on (i) adopting a location criterion based on a distance to wetlands; (ii) whether the 50-foot value in North Carolina, the 100-foot value in Pennsylvania's requirements or the criterion of 300 feet from an exceptional value wetland is a more appropriate distance; (iii) whether prohibiting the placement of CCR for beneficial use in wetlands is more consistent with the CCR disposal regulations; and (iv) whether other state restrictions exist that are appropriate for EPA to consider in establishing a criterion for distance to wetland in triggering an environmental demonstration.

3. Placement in an Unstable Area

The current CCR disposal regulations restrict the placement of CCR in sites classified as unstable areas unless the owner or operator demonstrates that engineering measures have been incorporated into the unit's design to ensure the structural components will not be disrupted. See § 257.64. In the current rule, unstable areas are locations that are susceptible to natural or human-induced events or forces capable of impairing the integrity of some or all of the structural component responsible for preventing releases from a CCR unit. See § 257.53. For CCR fill applications, one state (Pennsylvania) prohibits placement within 100 feet of a sinkhole or any area draining to a sinkhole. Sinkholes are commonly found in unstable areas, such as karst terrains, where the types of rock below the land surface can naturally be dissolved by groundwater circulating through the rock [11] that can result in a collapse of the land surface. The EPA is proposing to adopt a provision that when unencapsulated CCR is placed for beneficial use in an unstable area, the environmental demonstration would be triggered. This means that an environmental demonstration is required before the placement of any amount of unencapsulated CCR can occur for a proposed use in an unstable area. The environmental demonstration is reasonable in order to assess any environmental releases that may result from the shifting of the placed CCR and potential structural failure of any engineering controls (*e.g.,* tears in liners), if employed, that could cause contaminants to leach into groundwater from the movement of the unstable area. The EPA solicits comments on (i) adopting a location criterion based on placement in an unstable area; (ii) whether prohibiting the placement of CCR for beneficial use in unstable areas is more consistent with the CCR disposal regulations and the Pennsylvania requirement; and (iii) whether other state provisions are appropriate for EPA to consider in establishing a criterion for placement of unencapsulated CCR for beneficial use in sites classified as unstable areas.

4. Placement in a Flood Plain

In the current CCR rule (as well as part 258 requirements for municipal solid waste landfills), EPA restricts siting of disposal units in the 100-year flood plain. See §§ 257.3–1 and 258.11. For CCR fill applications, two states (North Carolina and Pennsylvania) prohibit the placement of CCR within a 100-year flood plain. The EPA is proposing to incorporate a similar provision when unencapsulated CCR is placed at a site for beneficial use in the 100-year flood plain that the environmental demonstration would be triggered due to the potential environmental releases posed by flooding in these areas. The EPA solicits comments on (i) adopting a location criterion based on placement of CCR in a flood plain; and (ii) whether prohibiting the placement of unencapsulated CCR for beneficial use within a 100-year flood plain is more consistent the current CCR rule (as well as part 258 requirements for municipal solid waste landfills) and with some state restrictions.

5. Distance From a Fault Area

In addition to these location criteria, the current regulations prohibit the location of CCR units within 60 meters (200 feet) of a fault that has had displacement in Holocene time, unless the owner or operator demonstrates that an alternate setback distance of less than 200 feet will prevent damage to the structural integrity of the unit. See § 257.62. None of the reviewed states included a similar location restriction. However, a few of the reviewed states are located in areas with significant seismic activity. The EPA is proposing to adopt a provision that when unencapsulated CCR is placed for beneficial use within 200 feet of a fault and within a seismic impact zone that the environmental demonstration would be triggered. The environmental demonstration is reasonable in order to assess any environmental releases resulting from the shifting of the placed CCR and potential failure of any engineering controls (*e.g.,* tears in the liners), if employed, that could cause contaminants to leach into the groundwater from the seismic activity. Therefore, while this consideration may not be of significance for the other individual states that EPA reviewed, the Agency considers this to be relevant and appropriate on a national scale because many states across the nation have these types of areas. The EPA solicits comments on (i) adopting a location criterion based on a distance of within 200 feet from a fault area to trigger an environmental demonstration; and (ii) whether prohibiting the placement of CCR for beneficial use within fault areas is more consistent with the CCR disposal regulations.

6. Placement in a Seismic Zone

The current CCR disposal rule also prohibits the location of CCR units within seismic impact zones unless the owner or operator makes a demonstration that all containment structures are designed to resist the maximum horizontal acceleration in lithified earth materials from a probable earthquake. See § 257.63. None of the reviewed states included a similar location restriction. However, a few of the reviewed states are located in areas with significant seismic activity. The EPA is proposing to adopt a provision that when unencapsulated CCR is placed for beneficial use within a seismic impact zone that the environmental demonstration would be triggered. Fill applications typically involve the placement of large amounts of CCR and in some situations may require the use of engineering controls, such as liners. As with landfills, large-scale fill applications located in seismic areas can encounter structural stability issues (*i.e.,* the placed CCR shifts and engineering controls fail), (*e.g.,* tears in the liner). The environmental demonstration is reasonable in order to assess any environmental releases resulting from a probable earthquake that may cause the placed CCR to shift

[11] U.S. Geological Survey. ''What is a sinkhole?'' A copy of the USGS web page is available in the docket to this rulemaking.

and potential failure of any engineering controls (*e.g.,* tears in the liners), if employed, that could cause contaminants to leach into the groundwater from the seismic activity. Therefore, while this consideration may not be of significance for the other individual states that EPA reviewed, the Agency considers this to be relevant and appropriate on a national scale because many states across the nation have these types of areas. The EPA solicits comments on (i) adopting a location criterion based on placement of CCR in a seismic zone to trigger an environmental demonstration; and (ii) whether prohibiting the placement of CCR for beneficial use within seismic impacts zones is more consistent with the CCR disposal regulations.

The EPA also considered adopting the following additional location criteria, largely-based on state beneficial use program provisions: Distance from a water body and distance from a water supply well.

7. Distance From a Water Body

For placement of CCR in fill applications, two states (North Carolina and Pennsylvania) require a minimum setback distance within 50 and 100 feet from a water body; and within 300 feet of an exceptional value or high-quality water body. The modeled risks in the 2014 Risk Assessment show that distance to receptor is a sensitive variable. Therefore, EPA solicits comment on adopting a provision that when unencapsulated CCR is placed at a site for beneficial use within 50 feet from a water body the environmental demonstration under the existing regulation would be triggered to assess environmental releases. The EPA intends the term ''water body'' to mean perennial and intermittent streams and rivers. This criterion generally would be consistent with the approach taken by North Carolina and Pennsylvania. This value, which represents the least restrictive state requirement, will ensure that the federal provision is not inconsistent with existing state programs, as a regulated entity could always comply with both the EPA and the state provision, including any more stringent state requirement. The EPA solicits comments on (i) adopting a location criterion based on a distance from a water body; (ii) whether the 50-foot criterion in North Carolina, the 100-foot criterion in Pennsylvania's requirements or the criterion prohibiting placement within 300 feet of an exceptional value or high-quality water body (also in Pennsylvania's requirements) is more appropriate; and (iii) whether other state restrictions exist that are appropriate for EPA to consider in establishing a criterion for distance to water bodies to trigger an environmental demonstration. The EPA is considering such a provision and could finalize it without a subsequent proposal.

8. Distance From a Water Supply Well

For placement of CCR in fill applications, three states (Wisconsin, North Carolina and Pennsylvania) require a minimum setback of 200 and 300 feet from water supply wells. Modeled risks in the 2014 Risk Assessment show that distance to receptor is a sensitive variable. Therefore, EPA solicits comments on adopting a provision that when unencapsulated CCR is placed at a site for beneficial use within 200 feet from a water supply well the environmental demonstration would be triggered to assess the risks to potential receptors. The EPA considered this criterion to ensure consistency with existing state programs. This value, which represents the least restrictive state requirement, will ensure that the federal provision is not inconsistent with existing State programs, as a regulated entity could always comply with both the EPA and the State provision, including any more stringent state requirement. The EPA solicits comments on (i) adopting a location standard based on a distance from a water supply well; (ii) whether either the 200-foot distance in North Carolina or 300-foot distance in both North Carolina's and Pennsylvania's requirements is more appropriate; and (iii) whether other state restrictions exist that are appropriate for EPA to consider in establishing a criterion for distance to water supply well to trigger an environmental demonstration. The EPA is considering such a provision and could finalize it without a subsequent proposal.

The EPA solicits comments on (i) revising the fourth criterion's trigger for an environmental demonstration from a mass-based threshold amount to any or all of the above location criteria; (ii) information on other state beneficial use programs with location-based provisions; (iii) the potential impacts to state beneficial use programs in setting location criteria based on the location criteria for CCR disposal units in the 2015 CCR Rule; and (iv) whether prohibiting the placement of CCR for beneficial use within wetlands, seismic impacts zones, unstable areas, and flood plains is more consistent with the CCR disposal regulations. In response to concerns from commenters that there may be some situations where the location-based criteria prevent placement of CCR in appropriate uses, the Agency also solicits comment and information on these specific situations where EPA should consider exemptions for any of the proposed location-based criteria.

B. Mass-Based Numerical Value

As discussed previously, EPA also considered selecting a new value to replace the existing 12,400-ton numerical threshold based on the numerical values that state beneficial use programs have in place and the available risk information. Of the state programs EPA looked at, several state programs have values lower than the existing 12,400-ton threshold based on mass (Illinois 10,000 tons); or by volume (Wisconsin 5,000 cubic yards; West Virginia 10,000 cubic yards). North Carolina and Pennsylvania have both lower and upper values based on mass per unit area (8,000 tons per acre; 10,000 tons per acre); and mass of total CCR used in a fill project (80,000 tons; 100,000 tons). As discussed earlier, none of the numerical criteria in the identified State programs were based on an analysis of the potential risks associated with the specified mass or volume. Instead, the States based the values on considerations such as the size of previously completed fill projects or consensus values agreed upon by state, industry and citizen groups.

The current mass-based criteria of 12,400 tons is similar to the lower end of identified state limits. Although the analysis of model runs from the 2014 Risk Assessment demonstrates that potential risks will tend to decrease as the mass of CCR decreases, the Agency cannot define an exact relationship between risk and small changes in mass for prospective uses. The EPA identified individual model runs with risks above 1×10^{-5} for the smallest modeled landfill of 8,023 tons; however, it is not possible to estimate the likelihood that such risks will occur at these lower tonnages based on the limited number of model runs for small landfills. As EPA acknowledged in the 2015 CCR rule, the following factors are more critical than the volumes of CCR in whether the use may present a risk of concern: ''the characteristics of the CCR, the amount of material and the manner in which it is placed, and (perhaps most important) the site conditions.'' See 80 FR 21348 (April 15, 2015). Thus, for these smaller uses, EPA explained that the Agency ''. . . expects potential users of unencapsulated CCR below this threshold to work with the states to determine the potential risks of the proposed use at the site and to adopt the appropriate controls necessary to

address risks'' See 80 FR 21352 (April 15, 2015).

The EPA also is aware that Alaska and Virginia have already taken steps to adopt the 12,400-ton threshold into their state regulations. Because EPA anticipates that there will likely be little practical difference between the current threshold of 12,400 tons and the lower end of the state limits in terms of the number of fill applications that would be affected, EPA considered retaining the existing value in the interest of minimizing disruption to the states and industry. However, EPA solicits comment on whether that preliminary conclusion is accurate, as well as the potential impact of this consideration on state programs (*e.g.,* whether other states have not incorporated the current requirement).

The available information does not appear to provide strong support for a new numerical value to replace the existing 12,400-ton mass-based threshold. Nevertheless, EPA is still considering whether to adopt a new numerical value for the existing mass-based threshold. The EPA, therefore, solicits comments on whether (i) the state beneficial use programs' tonnage thresholds discussed above are appropriate for revising the numerical criterion to trigger an environmental demonstration; (ii) the existing 12,400 ton-numerical threshold is appropriate and reasonable; (iii) the Agency's preliminary conclusion that retaining the existing numerical value minimizes disruption; and (iv) whether there are potential impacts to state beneficial use programs. The EPA is also requesting (i) information on other numerical criterion that states use to trigger other requirements, either those listed in this proposal or other state beneficial use programs that EPA did not review, that would also represent an appropriate trigger for further analysis of unencapsulated uses; and (ii) other state criteria, either those listed in this proposal or incorporated in other state beneficial use programs, that would also form an appropriate basis for national criteria to trigger an environmental demonstration.

C. Use Both Mass- and Location-Based Criteria

The EPA also requests comment on whether to adopt a combination of the mass-based threshold and location-based criteria to trigger an environmental demonstration for unencapsulated uses. Under such an approach, the environmental demonstration for unencapsulated uses would be triggered by either a mass-based threshold or any of the location-based criteria. Under such an approach, uses that exceed a mass-based threshold would need to conduct an environmental demonstration, even if they did not involve placement in areas that meet the location criterion. The EPA, therefore, requests comment on whether the thresholds from the state beneficial use programs listed above or other states not listed above would represent an appropriate basis on which to trigger the environmental demonstration.

The EPA also solicits comment on any alternative approaches to combining the mass- and location-based criteria to ensure that both the largest uses and those with the greatest potential for risk would conduct an environmental demonstration.

D. All Unencapsulated Uses Demonstrate Environmental Analysis

In general, having some type of threshold is a reasonable approach since there may potentially be some relatively small volume uses or dry locations where an environmental demonstration is not necessary. Nevertheless, EPA also solicits comment on whether the environmental analysis of the beneficial use definition's fourth criterion should be demonstrated in all cases rather than limiting the fourth criterion to only the largest or most environmentally concerning beneficial use circumstances. Under such an approach, every unencapsulated beneficial use of CCR in non-roadway applications would have to make an appropriate environmental demonstration of whether releases to environmental media from the beneficial use are likely to be of concern. Under this approach, it is possible that the Agency could also develop additional guidance [12] and offer technical direction regarding the nature and extent of the environmental demonstration that would be needed depending on the site-specific considerations related to the particular proposed beneficial use of CCR in question. The EPA also solicits comment on the use of guidance to determine what an appropriate environmental demonstration would be in particular site-specific circumstances. The EPA is considering all such approaches or provisions and could finalize it without a subsequent proposal.

The EPA also solicits comment on whether the regulations should impose a notification requirement upon a person placing unencapsulated CCR on the land in accord with the regulatory criteria. Many state programs require notice to the state, landowner, deed record office and/or the public. The EPA is considering such a provision and could finalize it without a subsequent proposal.

E. Applicability of the Revised BU Definition

The EPA proposes that all beneficial use applications or projects not completed before the effective date of a final rule would be subject to the revised beneficial use criteria. This is consistent with what the Agency required in the 2015 final rule in terms of applicability of the new beneficial use definition. The EPA solicits comment on whether this approach is reasonable and whether there are other factors, such as a project's completion timeframe, that should also be considered into the Agency's applicability approach.

V. Proposal To Revise Requirements Applicable to Piles

Under the current regulation, CCR piles are defined as any ''non-containerized accumulation of solid, non-flowing CCR that is placed on the land.'' See § 257.53. This definition closely mirrors the RCRA definition of disposal, which is defined in part as the ''placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including ground waters.'' See 42 U.S.C. 6903(3). Under this regulation, CCR piles constitute disposal and are consequently subject to all regulatory criteria applicable to CCR landfills. In contrast, activities that meet the definition of a beneficial use are not considered disposal, even if they involve the direct placement on the land of ''non-containerized'' CCR. See §§ 257.50(g) and 257.53 (definitions of CCR landfill and CCR pile); 80 FR 21327–30 (April 17, 2015). Since promulgation of the 2015 CCR rule, questions have been raised about the requirements that apply to piles of unencapsulated CCR placed on the land prior to beneficial use.

The current regulation distinguishes piles of CCR *on-site* (at an electric utility or independent power producer site) from temporary piles of CCR *off-site* (at

[12] In 2016, EPA released the ''Methodology for Evaluating Beneficial Uses (BU) of Industrial Non-Hazardous Waste Secondary Materials'' and the ''Beneficial Use Compendium: A Collection of Resources and Tools to Support Beneficial Use Evaluations'' to help the beneficial use community evaluate the potential for adverse impacts to human health and the environment associated with the beneficial use of secondary materials, including CCR.

a beneficial use site), based on whether CCR from the pile could fairly be considered to be in the process of being beneficially used. See § 257.53 (definition of CCR pile); 80 FR 21356 (April 17, 2015). While the CCR from the pile on-site *may* someday be beneficially used, it is not currently in the process of being beneficially used, and even when some amount is transported away, a new amount from the utility may replace it. See *Id.* The extended placement of CCR directly on the land in such a manner is a potential source of uncontrolled releases. To address these potential releases, the regulation requires that the pile be containerized (*i.e.,* that the facility adopt measures to control these releases, and any resulting exposures to human health and the environment). Such measures include placement of CCR on an impervious base such as asphalt, concrete or geomembrane; leachate and run off collection; and walls or wind barriers. See *Id.* If CCR is not containerized, the pile is a CCR pile and subject to the same requirements as a CCR landfill. See *Id.*

In contrast, the regulations treat CCR stored off-site at a beneficial use site in a temporary pile to be in the process of being beneficially used (even though a pile is not itself a beneficial use). If the CCR is temporarily placed at a beneficial use site and meets the regulatory definition of a beneficial use, the pile is not a CCR pile and is not subject to disposal requirements. See *Id.* Thus, if the temporary pile contains less than the 12,400-ton threshold amount of CCR identified in criterion 4 of the beneficial use definition, criteria 1–3 must be met. For a temporary pile exceeding the threshold amount in the beneficial use definition, all four criteria must be met, including the environmental demonstration, which generally requires the user to evaluate the potential releases from the pile. One way to meet the environmental demonstration is to control releases from the pile. See 40 CFR 257.53; 80 FR 21347–54 (April 17, 2015). Thus, the regulation seeks to achieve the same end result—controlling releases and potential exposures—through different regulatory mechanisms.

In response to the May 2017 petitions from AES Puerto Rico LP and USWAG, EPA has reconsidered its current approach of distinguishing between on-site and off-site piles; and is proposing to replace it with a single regulatory mechanism applicable to all temporary placement of CCR on the land, whether the CCR is on-site or off-site, and whether the CCR is subsequently destined for disposal or beneficial use. The EPA is not proposing to revise the general standard that already applies to both on-site and off-site piles (''to control releases from the pile''). However, EPA considers that a single regulatory approach would consistently address the potential environmental and human health issues associated with such piles, which are largely unrelated to whether the pile is on the land on-site or off-site and whether the CCR is destined for disposal or beneficial use.

The EPA is, therefore, proposing to establish a single set of requirements applicable to all temporary placement of unencapsulated CCR on the land, whether destined for beneficial use or disposal, that maintains the current standard applicable to both on-site and off-site piles under the current regulation. Rather than characterizing such activities as either disposal or beneficial use, EPA considers that these activities are better characterized as ''storage,'' with criteria established pursuant to the authority in section 1008(a)(3) to control releases. Therefore, EPA is proposing a definition of a CCR storage pile to distinguish between the activities that will be considered storage and those that will be considered disposal. Specifically, EPA is proposing to define a CCR storage pile as a temporary accumulation of unencapsulated CCR on the land, whether on-site or off-site. As a second element, EPA is proposing to include in the definition a requirement to control releases of CCR (*e.g.,* from windblown dust, or from stormwater or run-on and run-off) to the environment. Accumulations of unencapsulated CCR in enclosed structures, would not be required to meet either the definition of a CCR storage pile or the landfill requirements in part 257. The accumulation of unencapsulated CCR that does not meet all elements of the proposed definition of a CCR storage pile, including the requirement to control releases of CCR, would be considered to be disposal when placed on the land, and would be subject to the part 257 landfill regulations.

Accordingly, in this action, EPA is proposing several revisions to § 257.53 and conforming changes in § 257.2.

A. The Definition of a CCR Storage Pile

The EPA is proposing to establish criteria to distinguish activities that constitute the temporary storage of unencapsulated CCR in a pile from those activities that are truly disposal and therefore need to comply with the part 257 requirements. Specifically, EPA is proposing to define a CCR storage pile as ''any temporary accumulation of solid, non-flowing CCR placed on the land that is designed and managed to control releases of CCR to the environment.''

1. Definition of a Temporary Accumulation

As noted in the preamble to the 2015 CCR rule, EPA considered placing a time limit on a pile; as an alternative regulatory strategy, a limit (*e.g.,* 180 days) would have been established on the amount of time that the CCR would have been allowed to be maintained in a pile without regulation as a CCR landfill. See 80 FR 21355 (April 17, 2015). The EPA rejected this option because it would have been difficult to oversee and verify the actual time when CCR had been placed in a pile and when the CCR was subsequently removed. See *Id.* In this action, in place of establishing a time limit, EPA is proposing to define the properties of a temporary accumulation and allow the use of several criteria to identify a temporary pile. Specifically, EPA is proposing to define a temporary accumulation as an accumulation on the land that is neither permanent nor indefinite.

To demonstrate that the accumulation on the land is temporary, at some point, all of the CCR must be removed from the pile at the site. To ensure that a temporary accumulation is identifiable, EPA is proposing that the entity engaged in the activity must have a record, such as a contract, purchase order, facility operation and maintenance plan, or fugitive dust control plan, documenting that all of the CCR in the pile will be completely removed according to a specific timeline.

The criterion requiring possession of a record is designed to be flexible and account for the practical realities of current practices; pile removal is contingent on business activities, which are performed according to agreements and schedules, such as for the sale of CCR, for hauling services for the disposal of CCR, or purchase orders for products made with CCR from the pile. The EPA is not proposing to require any particular type of a record be used to demonstrate that a pile is temporary; however, an appropriate, useful record should contain verifiable information about amounts of CCR to be sold/purchased/removed and the timeline of removal activities.

The EPA solicits comment on whether the criterion requiring possession of a record to show that the CCR will be removed can be feasibly implemented. Namely, EPA requests comment about (i) specific cases where piles are temporary but records are not available; and (ii) an alternative criterion inclusive

of such cases. For example, EPA is considering whether utilities with on-site landfills possess or could develop verifiable records to show that the CCR from piles will be transported for disposal at the utility-owned landfill in a timely manner (*e.g.,* do utilities with on-site landfills, or could utilities with on-site landfills, keep schedules of daily on-site operation, and would such schedules sufficiently provide the needed information). Similarly, EPA is considering whether cement kilns and concrete batch plants can match purchase orders for products made with CCR to piles of CCR, or if alternative records are readily available to demonstrate that the CCR in a pile will be used. The EPA is also seeking comment about whether purchase orders for construction materials are sufficiently forward-looking to allow the piles of CCR that are set up early in a construction season to be matched up with construction projects beginning late in the construction season, or if a grace period should be allowed for cement kilns and concrete batch plants supplying construction materials with CCR, to put applicable agreements in place (*e.g.,* 90–120 days after the start of the construction season). The EPA also requests comment and information on additional or alternative criteria crucial for demonstrating that a pile is temporary and/or effectuating the timely removal of CCR.

2. Proposed Requirement To Control Releases

The EPA is proposing to include in the definition of CCR storage pile a requirement to control releases to be consistent with the definition of disposal in 42 U.S.C. 6903(3). As stated in that definition, disposal includes the ''placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including groundwaters.''

When significant and persistent volumes of unencapsulated CCR are present, similarities exist in the potential risks posed to human health, groundwater resources, or the air between the placement of CCR in piles and placement in CCR landfills, if inappropriately managed. See 80 FR 21356 (April 17, 2015). The same pollution control measures, such as liners, leachate collection systems, and groundwater monitoring, would appropriately control releases and address the potential adverse effects from both the piles of significant and persistent volumes and CCR landfills.

The EPA's proposal is designed to address these potential risks. Under the proposed definition, temporary accumulations are limited to the amount of CCR specified to be used as documented in the relevant record, and all of the CCR will be removed. Therefore, by defining a CCR storage pile as a temporary accumulation, EPA would effectively limit the amount of unencapsulated CCR that will be placed and persist in one location. Due to these factors, EPA considers that it is not necessary to impose on CCR storage piles the same set of technical requirements as for CCR landfills, but that meeting the requirement to control releases of CCR in the definition of a CCR storage pile would result in no reasonable probability of adverse effects on human health and the environment from the management of CCR on-site or off-site.

Moreover, none of these concerns are present when CCR is stored in enclosed structures. The EPA's proposed definition, therefore, would explicitly exclude CCR contained in enclosed structures. In Unit V.B of this preamble (Definition of an Enclosed Structure), EPA is proposing to identify the structural properties and design and operational elements of an enclosed structure, modeled after the requirements in § 264.1100 for units in which hazardous wastes are stored or treated not to be subject to the definition of land disposal.

The definition of disposal in 42 U.S.C. 6903(3) regards all environmental media, and consistent with this definition of disposal, EPA's requirement to control releases of CCR would apply to all environmental media. Releases covered by the requirement to control releases in the proposed definition of the CCR storage pile would at a minimum, include releases through wind-blown dust, surface transport by precipitation runoff and releases to soil and to groundwater.

Meeting the requirement to control releases would mean having to account for normal conditions and operating procedures. The EPA is proposing that one way for the entities engaged in the activity to meet the requirement is by designing and managing piles such that the releases are consistent with the terms of federal, state or local regulations for surface water, groundwater, soil or air protection. Examples of federal, state, or local regulations include stormwater discharge permits for construction sites; nation-wide effluent limits for relevant industry sectors (*e.g.,* cement, concrete and gypsum facilities, and power plants); states' groundwater protection plans; and states' requirements for implementing control measures to prevent releases from storage piles of CCR. Releases that are specifically authorized under federal, state and local regulations for surface water, groundwater, soil or air protection would be allowed under this proposal. Situations in which CCR is being swept away and released to soil, water or air in violation of existing local, state and federal requirements, would be considered to be evidence of disposal.

Examples of measures that might be used to control releases from a CCR storage pile include: Periodic wetting, application of surfactants, tarps or wind barriers to suppress dust; tarps or berms for preventing contact with precipitation and controlling run-on/runoff; and impervious storage pads, geomembrane liners or tarps for soil and groundwater protection. The EPA is not proposing to impose a specific set of control measures in every case, as the amount of CCR stored and the prevailing weather conditions may affect which controls are appropriate. Therefore, EPA intends to provide the entities engaged in the activity with flexibility to determine the control measures most appropriate to meet the requirement to control releases at a given site. This flexibility also ensures that EPA's requirements do not contradict any state or local requirements for the use of prescribed controls. However, if control measures are not used or are inadequate for prevailing conditions, increasing the likelihood of CCR being swept away, then the entity engaged in the activity would not have met the requirement to control releases, and the accumulation of CCR would be considered to be disposal. Visible dust, run-on/runoff and ponding of the water at the bottom of the pile, point to an issue with the choice of control measures.

The EPA's understanding is that for many beneficial uses, beneficial users are implementing measures to protect the mechanical and chemical properties of CCR. These measures frequently match the controls necessary to meet the proposed requirement to control releases. Furthermore, several federal, state and local government regulations for environmental protection require the use of pollution controls that would also meet the requirement. Below is a brief summary of EPA's understanding of current beneficial use handling practices and existing regulations that would apply to control releases.

Fly Ash used in concrete. The EPA's understanding is that the handling of fly ash marketed for beneficial use in concrete production is consistent across

the industry; fly ash is collected in a dry powder form and directed to silos, domes, or buildings at concrete batch plant sites in a self-contained system from start to end. The reason for the containment is that fly ash provides mechanical and chemical benefits when used in concrete, making it a valuable ingredient and fully warranting the protection of its properties through handling and storage.

Flue Gas Desulphurization (FGD) gypsum used in wallboard. The EPA's further understanding is that FGD gypsum may be transferred down a conveyer belt directly from an electric utility or independent power producer to a wallboard plant. Generally, it will either be contained in a building or stored on a pad.[13]

CCR used as raw feed at cement kilns. The EPA's understanding is that the CCR used as a source of silica for production of clinker at cement kilns is generally stored on concrete pads or within partial enclosures composed of a concrete pad, overhead cover and several, but not all four sides. Placement of CCR on concrete pads controls releases to soil and groundwater, and federal, state and local regulations impose further requirements to control releases to air and surface water. For example, at cement kilns, fugitive dust from raw material storage, which includes piles of CCR, must be controlled to an opacity standard in § 60.62(b), and this opacity standard limits the allowed particulate matter (PM) emissions;[14] moreover, federal regulations require National Pollutant Discharge Elimination System (NPDES) permit coverage and compliance with stormwater effluent discharge standards in 40 CFR part 411, subpart C.[15]

CCR used in construction. NPDES permits are also required for construction activities that disturb at least one acre, including sites that are part of a larger common plan of development that will ultimately disturb at least one acre.[16] The EPA has authorized most states to administer the NPDES permitting program; [17] however, where EPA has not authorized states to implement the NPDES program and EPA maintains the NPDES permitting authority, the Agency issues a Construction General Permit (CGP). The CGP requires implementation of pollution prevention controls to minimize the stormwater discharges of pollutants and also requires dust minimization and suppression.[18] [19] States and localities also require dust control during construction.[20] [21]

The EPA requests comment on whether this proposal will appropriately address the risks associated with the potential releases from piles of CCR in all circumstances. The EPA asks if in some cases, it is acceptable to manage releases retroactively. For example, are there situations in which CCR will only enter the topmost layer of soil over the time the CCR is in place at the site, in which retroactive management of these releases combined with an active management of releases to air and water, could avoid all reasonable probability of adverse effects on human health and the environment. For example, commenters may have information to show that the placement of CCR at a construction site, which typically occurs over a brief, one-time period, is precisely one such situation in which releases to soil and groundwater can retroactively be managed by removing the CCR and the contaminated soil beneath it, at the completion of the project. The EPA also seeks comment and data on whether there are additional situations where piles are commonly in place for a short period of time (*e.g.,* 90 days or less), at the end of which the CCR is fully removed and presents no reasonable probability of adverse effects on human health or the environment, thus supporting an exemption from having to meet the requirement to control releases. The EPA also asks for information about key characteristics of such piles that would make them readily identifiable in practice. Further, EPA requests comment on whether requiring that a pile must be temporary is a key element of controlling risks associated with the potential releases from piles of CCR; for example, do commenters have information to show that the size of a pile is sufficiently controlled by the ability to use pollution control measures to control releases of CCR and that the temporary element is not needed. The EPA also solicits comment on the existence of any data documenting instances in which releases from temporary placement of CCR on the land caused adverse effects even though releases had been managed consistently with current regulatory standards. Finally, EPA solicits comment on whether specific state criteria for storage, or any other criteria, would form a more appropriate basis for a national storage standard.

B. The Definition of an Enclosed Structure

The EPA is proposing to define an enclosed structure by identifying structural properties and design and operational elements that would ensure CCR is appropriately contained. Entities containing CCR within such structures would not be subject to the definition of CCR storage pile or CCR landfill requirements in the part 257 regulations. The proposed key properties and elements are modeled after the requirements in § 264.1100 for units in which hazardous wastes are stored or treated not to be subject to the definition of land disposal.

From § 264.1100 requirements, EPA is proposing to omit the requirements that are specifically relevant to the containment of hazardous waste and liquid waste. Examples of such requirements pertain to the control of fumes using pressure gradients, provisions for contact between the structure and hazardous wastes, or the need for a system of containment barriers to contain liquid wastes.

The EPA is also proposing to omit the requirement that the ''no visible fugitive emissions'' standard and Method 22—Visual Determination of Fugitive Emissions from Material Sources and

[13] In order to be subject to RCRA, the material must be a solid waste. When FGD gypsum used for wallboard manufacture is a product rather than a waste or discarded material, and its use meets product specifications, FGD gypsum would not be regulated under the CCR rule. See, 80 FR at 21348. Note that whether the FGD gypsum is being managed as a ''waste'' or a ''product'' is a fact-specific determination, *https://www.epa.gov/coalash/frequent-questions-about-beneficial-use-coal-ash.*

[14] Examples of emission control measures implemented in Portland cement manufacturing facilities for raw materials, such as CCR, can be found at: Bhatty, Javed I., Miller, F. MacGregor, and Kosmatka, Steven H.; editors, *Innovations in Portland Cement Manufacturing,* SP400, Portland Cement Association, Skokie, Illinois, U.S.A, 2004; page 656. This book is available in the docket to this rulemaking.

[15] U.S. EPA, ''Developing your Stormwater Pollution Prevention Plan: A Guide for Industrial Operators.'' EPA 833–B–09–002. June 2015. Available in the docket to this rulemaking.

[16] See, § 122.26(a)(1)(ii), (a)(9)(i)(B), (b)(14)(x), and (b)(15)(i). Exclusions exist if the construction site disturbs less than five acres, and the rainfall erosivity factor (''R'' in the revised universal soil loss equation, or RUSLE) value is less than five during the period of construction activity. For more information, please see EPA's web page on ''Rainfall Erosivity Factor Calculator for Small Construction Sites'' at *https://www.epa.gov/npdes/rainfall-erosivity-factor-calculator-small-construction-sites.*

[17] A copy of EPA's web page titled ''Authorization Status for EPA's Construction and Industrial Stormwater Programs'' is available in the docket to this rulemaking.

[18] A copy of EPA's web page titled ''2017 Construction General Permit (CGP)'' is available in the docket to this rulemaking.

[19] A copy of EPA's 2017 Construction General Permit is available in the docket to this rulemaking.

[20] Examples include: *http://bentoncleanair.org/windblown-dust/urban-fugitive-dust-policy/.*

[21] Examples include: *https://www.michigan.gov/documents/deq/deq-ead-caap-genpub-FugDustMan_313656_7.pdf; https://www.arb.ca.gov/drdb/sb/curhtml/R345.pdf; https://www.tceq.texas.gov/airquality/stationary-rules/pm; https://www.pacode.com/secure/data/025/chapter123/s123.1.html.*

Smoke Emissions from Flares in 40 CFR part 60, appendix A, be met. Rather than requiring a potentially challenging-to-oversee-and-enforce observation and recording procedure, EPA is proposing to include in the design and operational elements of an enclosed structure a performance standard stating that enclosed structures must be designed and operated to prevent the release of fugitive dust emissions through openings, including doors, windows and vents.

The remaining § 264.1100 requirements, which EPA proposes to adopt, pertain to full containment of waste, as well as to the structural stability and integrity of the enclosure. Stability and integrity are marked by the ability to withstand external loads from seismic and climatic conditions, as well as any internal loads from daily operating activities, such as the operating of heavy equipment inside the enclosure.

C. The Definitions of a CCR Pile and CCR Landfill

The EPA is also proposing to revise the definition of a CCR pile to be consistent with the above proposals. In the current definition, EPA distinguishes between piles on-site (which were almost always regulated as landfills) and piles off-site, (which, if temporary, were generally considered to be beneficial use, subject only to the four criteria in the definition). The current regulation also distinguishes between on-site piles that are not containerized and those that are containerized. See 80 FR 21356 (April 17, 2017); § 257.53. In this action, EPA is proposing to maintain the term CCR pile to identify accumulations of CCR that will be subject to the disposal requirements. However, as discussed previously, EPA is proposing to treat all piles on- and off-site the same, such that the only piles of CCR subject to the disposal requirements are those accumulations that do not meet the definition of a CCR storage pile. Consequently, EPA is proposing to delete from the current definition of CCR pile the phrase ''non-containerized'' and the sentence ''CCR that is beneficially used off site is not a CCR pile.'' While EPA is proposing to maintain the term CCR pile, EPA also requests comment whether the term and the definition remain necessary or should instead, be deleted.

In another conforming change, EPA is also proposing to revise the definition of a CCR landfill to include accumulations of CCR on the land that do not meet the definition of a CCR storage pile. This proposed change would apply to the definition of CCR landfill in §§ 257.2 and 257.53.

VI. Proposal To Revise the Annual Groundwater Monitoring and Corrective Action Report Requirements

Section 257.90(e) requires owners and operators of CCR units to prepare an annual groundwater monitoring and corrective action report. This annual report must document the status of the groundwater monitoring and corrective action program for the CCR unit, summarize key actions completed, describe any problems encountered, discuss actions to resolve the problems, and project key activities for the upcoming year. The CCR rule also specifies the minimum information that must be included in the annual report. For example, one of the current requirements is to provide all the monitoring data obtained under the groundwater monitoring and corrective action program for the year covered by the report. The CCR regulations further require the owner or operator to include in the report a summary including the number of groundwater samples that were collected for analysis for each background and downgradient well, the dates the samples were collected, and whether the samples were required by the detection monitoring or assessment monitoring programs. See § 257.90(e)(3). Except for certain inactive CCR surface impoundments, owners and operators were required to prepare the initial annual report no later than January 31, 2018, and post the report to its publicly accessible CCR website within 30 days of preparing the report. See §§ 257.90(e) and 257.107(d). For eligible inactive CCR surface impoundments,[22] the deadline to prepare the initial annual report is August 1, 2019. See § 257.100(e)(5)(ii).

The Agency reviewed the annual reports available on the CCR websites and observed that some facilities provided groundwater monitoring data in formats that were clear and easy for the public to understand, while some did not. Many reports contained a concise summary in the beginning of the report to orient the reader to the stage of groundwater monitoring that the facility was in, whether any constituents have been determined to be present at statistically significant levels above background (for part 257 Appendix III constituents) or a groundwater protection standard (for part 257 Appendix IV constituents), and the groundwater monitoring data in a table format. In other reports, it was difficult to tell whether the analytical results corresponded to background or downgradient wells, whether the CCR unit was operating under the detection or assessment monitoring program, when the assessment monitoring program was initiated for the CCR unit, or whether the facility had initiated corrective action for the unit. In addition, several facilities only provided laboratory printouts of the data, potentially making it difficult for the public and other stakeholders to put the results into context within the overall groundwater monitoring program.

The purpose of requiring posting of the annual reports is to allow the public, states and EPA to easily see and understand the groundwater monitoring data. To accomplish this purpose, the Agency is considering two possible revisions to the annual groundwater monitoring and corrective action reporting requirements.

First, EPA is proposing to amend § 257.90 by adding new paragraph (e)(6). This new provision would establish minimum set of requirements that would need to be addressed in the summary discussion of the status of the groundwater monitoring and corrective action programs for the CCR unit. This summary would be placed at the beginning of the annual report (*e.g.,* as part of the report's executive summary) for readers to readily access the information. The minimum requirements for this summary would include stating whether the CCR unit was operating pursuant to the detection monitoring program under § 257.94 or the assessment monitoring program under § 257.95, identifying those constituents and the corresponding wells, if any, for which the facility had determined that there is a statistically significant increase over background levels for constituents listed in Appendix III (or if operating under the assessment monitoring program, constituents in Appendix IV that were detected at statistically significant levels above the groundwater protection standard), the date when the assessment monitoring program was initiated for the CCR unit, and describing any corrective measures initiated or completed (to include the dates of these actions), including the remedy, during the annual reporting period.

Second, the Agency solicits comment on whether to amend § 257.90 to require that the groundwater monitoring analytical results and related information be presented in a standardized format such as multiple tables and included in the annual

[22] For more information on eligible inactive CCR surface impoundments, see the preamble to the direct final rule published on August 5, 2016 (81 FR 51802).

report. As noted, the purpose of requiring posting of the groundwater reports is to allow members of the public, as well as the states and EPA, to easily see and understand the groundwater monitoring data. The EPA requests comment on whether the regulations need to establish a standardized format for these reports in order to accomplish this purpose. Possible examples of what form these formats could take are available for review in the docket to this rulemaking.[23] The Agency also requests comment on formats that could be used.

Information about the groundwater wells could include the following data elements: Well identification number, sampling date, latitude and longitude in decimal degrees, groundwater elevation including well depth to groundwater and total depth of groundwater, and whether the groundwater well is upgradient or downgradient of the CCR unit. The well information provides context for each sample and therefore helps the members of the public understand the sampling results. This information is already collected and reported in the groundwater sampling and analysis plan under § 257.93 and so the information is readily available to the facility.

Sample information could be provided in a table that contains fields including sampling date, sampling time, sampling phase (*i.e.,* background, detection monitoring, assessment monitoring, corrective action), whether the groundwater well is upgradient or downgradient of the CCR unit, and analytical methods listed separately for every method used to analyze the constituent concentrations. Appendix III to Part 257—Constituents for Detection Monitoring could contain concentrations in milligrams per liter (unless otherwise specified) of the following: Boron, calcium, chloride, fluoride, pH (standard units), sulfate, and total dissolved solids (TDS). Appendix IV to part 257—Constituents for Assessment Monitoring could contain concentrations in milligrams per liter (unless otherwise specified) of the following: Antimony, arsenic, barium, beryllium, cadmium, chromium, cobalt, lead, lithium, mercury, molybdenum, radium 226–228 combined (pCi/L), selenium, and thallium. It is recommended that each constituent concentration identify the detection limit for the analytical method used with data qualifiers specified for non-detect samples.

The EPA solicits comment both on requiring a standardized format and on the elements of the format. The EPA believes that a required standardized format would increase transparency and enable the general public, as well as federal, state, and local officials, to more easily understand the groundwater monitoring data and thus plan for and evaluate the appropriate next steps to protect public health and the environment.

VII. Establishing an Alternative Risk-Based Groundwater Protection Standard for Boron

The 2015 CCR rule required the owner or operator of a CCR unit to set the groundwater protection standard (GWPS) at the Maximum Contaminant Level (MCL) or to background for all constituents in Appendix IV to part 257 that are detected at a statistically significant level above background. MCLs are levels of constituent concentrations promulgated under section 1412 of the Safe Drinking Water Act. If no MCL exists for a detected constituent, then the GWPS was required to be set at background.

On March 15, 2018, EPA proposed to add boron to the list of constituents in Appendix IV of part 257 that trigger corrective action. See 83 FR 11588–89. The EPA is still considering the comments received in response to this and has made no decision on whether to add boron to Appendix IV.

In the July 2018 final rule, EPA established specific GWPS for each of the four constituents now listed in Appendix IV without MCLs, to be used in place of the default background concentrations currently required under § 257.95(h)(2). See 83 FR 36443–45 (July 30, 2018). Consistent with this decision, if EPA does finalize the addition of boron to Appendix IV, an alternative risk-based GWPS should be established since boron does not have an MCL. Accordingly, EPA is proposing to establish an alternate risk-based GWPS for boron, which would be finalized only if boron is ultimately added to Appendix IV.

The EPA is proposing to adopt a standard for boron using the same methods that were used to develop the standards established in the July 30, 2018 final rule. See 83 FR 36443–45. Specifically, the Agency is proposing to adopt 4,000 micrograms per liter (μg/L) as the GWPS for boron, if boron is added to Appendix IV. This level was derived using the same methodology that EPA proposed to require States to use to establish alternative GWPS in the March 15, 2018 proposed rule (see 83 FR 11598–99, 11613), and that EPA ultimately used to develop the revised GWPS in the July 30, 2018 final rule. The methodology follows Agency guidelines for assessment of human health risks of an environmental pollutant. This means that EPA has established this GWPS at the concentration to which the human population could be exposed to on a daily basis without an appreciable risk of deleterious effects over a lifetime.

The EPA used the equations in the Risk Assessment Guidance for Superfund (RAGS) Part B to calculate these revised GWPS.[24] RAGS Part B provides guidance on using drinking water ingestion rates and toxicity values to derive risk-based remediation goals. The use of these methods, consistent with EPA risk assessment guidelines will protect sensitive populations. The EPA relied upon relevant exposure information from the 2008 *Child-Specific Exposure Factors Handbook,*[25] the *Exposure Factors Handbook: 2011 Edition* [26] and the 2014 *Human Health Evaluation Manual, Supplemental Guidance: Update of Standard.*[27] Values based on residential receptors were used to capture the range of current and future potential receptors. The EPA identified toxicity values according to the hierarchy established in the 2003 Office of Solid Waste and Emergency Response Directive 9285.7–53,[28] which encourages prioritization of values from sources that are current, transparent and publicly available, and that have been peer reviewed. Finally, EPA used the same toxicity values (reference doses) that were used in the risk assessment supporting the 2015 CCR Rule. Cancer slope factors (CSF) were not identified for boron. The proposed GWPS for boron was set using a target based on a Hazard Quotient (HQ) equal to 1.

VIII. Revisions to the Publicly Accessible CCR Website Requirements

In the 2015 CCR rule, pursuant to section 7004(b)(2), the Agency

[23] See EPA memorandum titled ''Annual Groundwater Monitoring Report Data Examples''; dated July 1, 2019.

[24] Risk Assessment Guidance for Superfund (RAGS) Part B can be accessed *at https://www.epa.gov/risk/risk-assessment-guidance-superfund-rags-part-b.*

[25] U.S. EPA, ''Child-Specific Exposure Factors Handbook'', EPA/600/R–06/096F, September 2008. This document is available in the docket to this rulemaking.

[26] U.S. EPA, ''Exposure Factors Handbook: 2011 Edition'', EPA/600/R–090/052F, September 2011. This document is available in the docket to this rulemaking.

[27] U.S. EPA, ''2014 Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors.'' This document is available in the docket to this rulemaking.

[28] U.S. EPA, ''Human Health Toxicity Value in Superfund Risk Assessments'', OSWER Directive #9285.7–53, December 5, 2003. This document is available in the docket to this rulemaking.

promulgated a requirement for owners and operators of any CCR unit to establish and maintain a publicly accessible internet site, titled ''CCR Rule Compliance Data and Information.'' Section 7004(b)(3) directs EPA to provide for, encourage, and assist ''[p]ublic participation in the development, revision, implementation, and enforcement of any regulation, guideline, information, or program under this chapter.'' To achieve these ends, internet postings are required for various elements identified in the following sections of the CCR regulations: Location restrictions; design criteria; operating criteria; groundwater monitoring and corrective action; closure and post closure care. Consistent with the statutory directive, the websites are to make the notices and relevant information required by the regulations available to the public in a manner that will encourage and assist public participation in the implementation of the regulations. This necessarily means, for example that the posted documents must be clearly identifiable as documents, reports, demonstrations, etc., to those attempting to access them. The Agency considers the internet the most widely accessible and effective means for gathering and disseminating information to the public and the states.

The EPA has observed that some of the publicly accessible websites that owners and operators of CCR facilities have established in response to the CCR regulations in practice, fail to make the posted documents publicly accessible. For example, a number of CCR websites require either some sort of registration whereby personal information identifying the user must be provided before members of the public are granted ''access'' to the website. The Agency has seen other websites where a user must submit a request for each document individually and the requested document is subsequently emailed to the user. Still other websites have been designed such that the posted ''publicly available'' documents cannot be downloaded or printed from the website. The EPA does not consider these kinds of practices to be consistent with the requirement that the information be made publicly available. The EPA acknowledges that the current regulation does not define the term ''publicly available,'' or contain detailed requirements that such websites must meet; nor are these practices explicitly prohibited. To avoid any further confusion, EPA is proposing to amend the current regulation to clearly specify that facilities must ensure that all information required to be on the websites must be made available to any member of the public, including through printing and downloading, without any requirement that the public wait to be ''approved'', or provide information in order to access the website.

Another issue EPA has noticed is that the internet addresses for many of the publicly accessible CCR websites have changed; for some sites, more than once. It is very difficult for the public, states, and EPA to access the information required to be posted on these websites if the URL's change without notice. The EPA website has a ''contact us'' form whereby anyone can submit a comment or question to EPA that can be accessed at *https://www.epa.gov/coalash/forms/contact-us-about-coal-ash.* It would be very helpful if when a facility decides to change their web address they would submit a comment to that effect so that EPA can update its website that lists the CCR facilities nationwide and includes their web addresses. The Agency is therefore proposing to amend the regulations to require that facilities notify EPA within 14 days of changing their CCR website address, to allow EPA to update the Agency's website with the correct URL address.

Similar to the difficulties that arise when a facility changes its web address for its CCR website, as discussed above, EPA has also noticed that when there is a question or problem with a publicly accessible CCR website, such as a broken link or a document that will not download, it can be difficult to reach the appropriate contact at the facility who has knowledge of the information posted to the CCR website. Therefore, the Agency is requesting comment on whether each CCR website should be required to have a mechanism (*e.g.,* a ''contact us'' electronic form on the CCR website) for the public to bring to the attention of the facility issues of information accessibility.

IX. The Projected Economic Impacts of This Action

A. Introduction

The EPA estimated the costs and benefits of this action in an Economic Analysis (EA) which is available in the docket for this action. The EA estimates the incremental costs and cost savings attributable to the provisions of this action, against the baseline costs and practices in place as a result of the 2015 CCR final rule and, in some cases, existing federal and state regulations governing specific project types. The EA estimates that the net annualized impact of this proposed regulatory action over a 40-year period of analysis will be annual costs of between $0.43 million and $3.8 million. The costs are roughly evenly attributable to the two provisions in the rule. This action is not considered an economically significant action under Executive Order 12866.

B. Affected Universe

The proposed rule affects entities in a number of different sectors who obtain quantities of CCR for use in a range of beneficial use applications and place it in ''piles'' prior to using or disposing it. The universe also includes entities that beneficially use CCR in applications that are (a) unencapsulated, (b) applied to land, and (c) not part of the construction of roadways. The types of facilities and applications potentially affected include: (1) Highway and non-road construction projects that use CCR for flowable fill, structural fill, embankments, soil modifications/stabilization, mineral filler in asphalt, and aggregate; (2) local authorities that use CCR for snow and ice control on roadways; (3) agricultural projects that use FGD gypsum as a soil amendment; and (4) oil/gas field services that use CCR in flowable fill or similar forms to stabilize wells. A number of other potentially affected sectors appear to already have operations consistent with the provisions in the proposed rule and are not expected to change operations or incur any costs. These include cement kilns, concrete batch plants, and mining applications.

While the sectors affected are large, the number of operations and projects using CCR in a manner that would be affected by the rule is limited; the EA estimates that at most, roughly 700 operations across all sectors would be affected by either or both provisions. This number reflects the number of individual projects for construction; the number of companies affected is likely lower. In addition, some or all of these projects and operations may already be operating in a manner consistent with the requirements of the proposed rule, due to existing state and federal regulations.

C. Baseline Costs

The baseline costs for this rule are not explicitly estimated because they represent part of standard operating costs across multiple project types and sectors. The baseline does assume that entities are subject to the relevant (*i.e.,* beneficial use-related) costs of compliance with EPA's 2015 CCR rule, as well as the costs of compliance with other federal and state regulations that address various transportation,

construction, and waste management practices.

D. Costs and Benefits of the Proposed Rule

The costs to comply with this proposed rule for facilities that are not currently operating in compliance includes, for the management of CCR piles, the cost of ensuring that the releases from CCR piles are controlled. For the preparation of a Criteria 4 (of the definition of ''beneficial use of CCR'') investigation two costs are relevant. The first are the costs to determine whether the proposed Criterion 4 location-based standards apply to a specific project and the preparation of a demonstration consistent with Criterion 4. The second are the per-project costs to demonstrate compliance with the proposed rule's location standards.

The EA estimates that number of facilities/operations that will employ new practices to control releases from piles is between 0 (assuming that all existing operations are already compliant due to other federal and state regulations) and 536; the annual costs associated with changing operations are estimated to range from $0 to roughly $3.2 million. These costs are assumed to apply every year to the same number of facilities and construction projects, which may overstate costs to the extent that management changes at permanent facilities may occur only once.

The EA estimates that the number of projects requiring investigation of the applicability of location-based standards under Criterion 4 is between 359 and 585; in most cases these are the same facilities and operations that are affected by the requirement for managing CCR in piles. The annual costs associated with conducting these investigations ranges from roughly $0.26 million to roughly $0.47 million, again assuming a consistent number of projects require assessment every year. Further, the EA estimates that 16 to 43 projects would trigger a location-based standard and therefore require a demonstration consistent with Criterion 4. The annual costs associated with developing these demonstrations are estimated to range from $0.044 million to $0.12 million. Therefore, the total annual costs associated with the location-based standards for Criterion 4 are estimated to range from $0.26 million to $0.47 million, though these costs may be overestimated because they assume that all projects will conduct all six location-based standards investigations (even if a single investigation indicates that a Criterion 4 demonstration must be made), and that new project in new locations occur in the same frequency every year.

The EA also estimates the costs to owners and operators of CCR management units who will have to revise their groundwater monitoring and corrective action reports, as well as the costs to owners and operators of CCR management units who will have to amend their websites to comply with the rule's reporting and documentation requirements. The economic analysis estimates that approximately 700 CCR management units and 5 websites will be affected by these respective provisions, resulting in annualized costs of roughly $0.1 million.

The total costs estimated for this EA across these two provisions are therefore estimated to range roughly between $0.43 million and $3.8 million.

Benefits associated with the rule are not quantified due to the uncertainty about the extent and location of behavior changes. However, improved control of releases from CCR piles and elimination of releases of CCR in areas where location restrictions apply would likely improve ecological and human health by reducing the risk of exposures to arsenic and other toxic metals.

X. Statutory and Executive Orders Reviews

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because this action may raise novel legal or policy issues arising out of legal mandates, the President's priorities or the principles set forth in the Executive Order. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This Economic Analysis (EA), entitled *Economic Analysis; Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals from Electric Utilities; Enhancing Public Access to Information; Reconsideration of Beneficial Use Criteria and Piles,* is summarized in Unit IX of this preamble and the EA is available in the docket for this proposal.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is expected to be an Executive Order 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 1189.31, OMB control number 2050–0053. This is an amendment to the ICR approved by OMB for the Final Rule: Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals from Electric Utilities published April 17, 2015 in the **Federal Register** at 80 FR 21302. You can find a copy of the ICR in the docket for this action, and it is briefly summarized here. This rulemaking, specifically the provision clarifying the type and magnitude of non-groundwater releases that would require a facility to comply with some or all of the corrective action procedures set forth in §§ 257.96–257.98, increases the paperwork burden attributable to provisions of the April 17, 2015 CCR Final Rule.

Respondents/affected entities: Coal-fired electric utility plants that will be affected by the rule.

Respondent's obligation to respond: The recordkeeping, notification, and posting are mandatory as part of the minimum national criteria being promulgated under Sections 1008, 4004, and 4005(a) of RCRA.

Estimated number of respondents: 1,336.

Frequency of response: The frequency of response varies.

Total estimated burden: EPA estimates the total annual burden to respondents to be an increase in burden of approximately 7,829 hours from the currently approved burden. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The total estimated annual cost of this rule is a cost increase of approximately $445,055. This cost is composed of approximately $445,055 in annualized labor costs and $0 in capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities

under the RFA. The small entities subject to the requirements of this action are beneficial users of CCR spread amongst several industries including construction, snow and ice control, the production of gypsum wallboard, agriculture, and oil/gas field services. This action is expected to result in net cost amounting to approximately $0.43 million per year to $3.8 million per year. Costs will accrue to all regulated entities, including small entities. Because fewer than 20% of small entities in any sector will experience impacts, and because impacts will fall below 1% of revenues for small entities in all sectors, this action will not have a significant economic impact on a substantial number of small entities. Further information on the economic effects of this action can be found in Unit IX of this preamble and in the Economic Analysis, which is available in the docket for this action.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments or the private sector. The costs involved in this action are imposed only by participation in a voluntary federal program. UMRA generally excludes from the definition of ''federal intergovernmental mandate'' duties that arise from participation in a voluntary federal program.

F. Executive Order 13132: Federalism

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

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. For the ''Final Rule: Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals from Electric Utilities'' published April 17, 2015 (80 FR 21302), EPA identified three of the 414 coal-fired electric utility plants (in operation as of 2012) as being located on tribal lands; however, they are not owned by tribal governments. These are: (1) Navajo Generating Station in Coconino County, Arizona, owned by the Arizona Salt River Project; (2) Bonanza Power Plant in Uintah County, Utah, owned by the Deseret Generation and Transmission Cooperative; and (3) Four Corners Power Plant in San Juan County, New Mexico owned by the Arizona Public Service Company. The Navajo Generating Station and the Four Corners Power Plant are on lands belonging to the Navajo Nation, while the Bonanza Power Plant is located on the Uintah and Ouray Reservation of the Ute Indian Tribe. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in the document titled ''Human and Ecological Risk Assessment of Coal Combustion Residuals,'' which is available in the docket for the 2015 CCR rule as docket item EPA–HQ–RCRA–2009–0640–11993.

As ordered by E.O. 13045 Section 1–101(a), for the ''Final Rule: Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals from Electric Utilities'' published April 17, 2015 (80 FR 21302), EPA identified and assessed environmental health risks and safety risks that may disproportionately affect children in the revised risk assessment. The results of the screening assessment found that risks fell below the criteria when wetting and run-on/runoff controls required by the rule are considered. Under the full probabilistic analysis, composite liners required by the rule for new waste management units showed the ability to reduce the 90th percentile child cancer and non-cancer risks for the groundwater to drinking water pathway to well below EPA's criteria. Additionally, the groundwater monitoring and corrective action required by the rule reduced risks from current waste management units. This action does not adversely affect these requirements and EPA believes that this rule will be protective of children's health.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. For the 2015 CCR rule, EPA analyzed the potential impact on electricity prices relative to the ''in excess of one percent'' threshold. Using the Integrated Planning Model (IPM), EPA concluded that the 2015 CCR rule may increase the weighted average nationwide wholesale price of electricity between 0.18 percent and 0.19 percent in the years 2020 and 2030, respectively. As the proposed rule represents a cost savings rule relative to the 2015 CCR rule, this analysis concludes that any potential impact on wholesale electricity prices will be lower than the potential impact estimated of the 2015 CCR rule; therefore, this proposed rule is not expected to meet the criteria of a ''significant adverse effect'' on the electricity markets as defined by Executive Order 13211.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in EPA's Regulatory Impact Analysis (RIA) for the CCR rule, which is available in the docket for the 2015 CCR final rule as docket item EPA–HQ–RCRA–2009–0640–12034.

The EPA's risk assessment did not separately evaluate either minority or low-income populations. However, to evaluate the demographic characteristics of communities that may be affected by the CCR rule, the RIA compares the demographic characteristics of populations surrounding coal-fired electric utility plants with broader population data for two geographic areas: (1) One-mile radius from CCR management units (*i.e.,* landfills and impoundments) likely to be affected by groundwater releases from both landfills and impoundments; and (2) watershed catchment areas

downstream of surface impoundments that receive surface water run-off and releases from CCR impoundments and are at risk of being contaminated from CCR impoundment discharges (*e.g.,* unintentional overflows, structural failures, and intentional periodic discharges).

For the population as a whole 24.8 percent belong to a minority group and 11.3 percent falls below the Federal Poverty Level. For the population living within one mile of plants with surface impoundments 16.1 percent belong to a minority group and 13.2 percent live below the Federal Poverty Level. These minority and low-income populations are not disproportionately high compared to the general population. The percentage of minority residents of the entire population living within the catchment areas downstream of surface impoundments is disproportionately high relative to the general population, *i.e.,* 28.7 percent, versus 24.8 percent for the national population. Also, the percentage of the population within the catchment areas of surface impoundments that is below the Federal Poverty Level is disproportionately high compared with the general population, *i.e.,* 18.6 percent versus 11.3 percent nationally.

Comparing the population percentages of minority and low income residents within one mile of landfills to those percentages in the general population, EPA found that minority and low-income residents make up a smaller percentage of the populations near landfills than they do in the general population, *i.e.,* minorities comprised 16.6 percent of the population near landfills versus 24.8 percent nationwide and low-income residents comprised 8.6 percent of the population near landfills versus 11.3 percent nationwide. In summary, although populations within the catchment areas of plants with surface impoundments appear to have disproportionately high percentages of minority and low-income residents relative to the nationwide average, populations surrounding plants with landfills do not. Because landfills are less likely than impoundments to experience surface water run-off and releases, catchment areas were not considered for landfills.

The CCR rule is risk-reducing with reductions in risk occurring largely within the surface water catchment zones around, and groundwater beneath, coal-fired electric utility plants. Since the CCR rule is risk-reducing and this action does not add to risks, this action will not result in new disproportionate risks to minority or low-income populations.

List of Subjects in 40 CFR Part 257

Environmental protection, Waste treatment and disposal.

Dated: July 29, 2019.

Andrew R. Wheeler,

Administrator.

For the reasons set out in the preamble, EPA proposes to amend 40 CFR part 257 as follows:

PART 257—CRITERIA FOR CLASSIFICATION OF SOLID WASTE DISPOSAL FACILITIES AND PRACTICES

■ 1. The authority citation for part 257 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a)(1), 6944(a), 6945(d); 33 U.S.C. 1345(d) and (e).

■ 2. In § 257.2 revise the definition of ''CCR landfill'' to read as follows:

§ 257.2 Definitions.

* * * * *

CCR landfill means an area of land or an excavation that receives CCR and which is not a surface impoundment, an underground injection well, a salt dome formation, a salt bed formation, an underground or surface coal mine, or a cave. For purposes of this subpart, a CCR landfill also includes sand and gravel pits and quarries that receive CCR, CCR piles, any practice that does not meet the definition of a beneficial use of CCR, and any accumulation of CCR on the land that does not meet the definition of a CCR storage pile.

* * * * *

■ 3. Amend § 257.53 by:

■ a. Revising paragraph (4) the definition of ''Beneficial use of CCR'' and the definitions of ''CCR landfill or landfill'' and ''CCR pile''; and

■ b. Adding in alphabetical order the definitions of ''CCR storage pile'', ''Enclosed structure'' and ''Temporary accumulation''.

The revisions and additions read as follows:

§ 257.53 Definitions.

* * * * *

Beneficial use of CCR means the CCR meet all of the following conditions:

(4) When unencapsulated use of CCR involves the placement on the land in the following areas: (a) Within 1.52 meters (five feet) of the upper limit of the uppermost aquifer; (b) in a wetland; (c) in an unstable area (d) within a 100-year flood plain; (e) within 60 meters (200 feet) of a fault area; (f) or within a seismic impact zone in non-roadway applications, the user must demonstrate and keep records, and provide such documentation upon request, that environmental releases to groundwater, surface water, soil and air are comparable to or lower than those from analogous products made without CCR, or that environmental releases to groundwater, surface water, soil and air will be at or below relevant regulatory and health-based benchmarks for human and ecological receptors during use.

* * * * *

CCR landfill or landfill means an area of land or an excavation that receives CCR and which is not a surface impoundment, an underground injection well, a salt dome formation, a salt bed formation, an underground or surface coal mine, or a cave. For purposes of this subpart, a CCR landfill also includes sand and gravel pits and quarries that receive CCR, CCR piles, any practice that does not meet the definition of a beneficial use of CCR, and any accumulation of CCR on the land that does not meet the definition of a CCR storage pile.

CCR pile means any accumulation of solid, non-flowing CCR that is placed on the land and that is not a CCR storage pile.

CCR storage pile means any temporary accumulation of solid, non-flowing CCR placed on the land that is designed and managed to control releases of CCR to the environment. CCR contained in an enclosed structure is not a CCR storage pile. Examples of control measures to control releases from CCR storage piles include: Periodic wetting, application of surfactants, tarps or wind barriers to suppress dust; tarps or berms for preventing contact with precipitation and controlling run-on/runoff; and impervious storage pads or geomembrane liners for soil and groundwater protection.

* * * * *

Enclosed structure means:

(1) A completely enclosed, self-supporting structure that is designed and constructed of manmade materials of sufficient strength and thickness to support themselves, the CCR, and any personnel and heavy equipment that operate within the structure, and to prevent failure due to settlement, compression, or uplift; climatic conditions; and the stresses of daily operation, including the movement of heavy equipment within the structure and contact of such equipment with containment walls;

(2) Has containment walls that are designed to be sufficiently durable to withstand any movement of personnel,

CCR, and handling equipment within the structure;

(3) Is designed and operated to ensure containment and prevent fugitive dust emissions from openings, such as doors, windows and vents, and the tracking of CCR from the structure by personnel or equipment.

* * * * *

Temporary accumulation means an accumulation on the land that is neither permanent nor indefinite. To demonstrate that the accumulation on the land is temporary, all CCR must be removed from the pile at the site. The entity engaged in the activity must have a record in place, such as a contract, purchase order, facility operation and maintenance, or fugitive dust control plan, documenting that all of the CCR in the pile will be completely removed according to a specific timeline.

* * * * *

■ 4. In § 257.90 add paragraph (e)(6) to read as follows:

§ 257.90 Applicability.

* * * * *

(e) * * *

(6) A section at the beginning of the annual report that provides an overview of the current status of groundwater monitoring and corrective action programs for the CCR unit. At a minimum, the summary must specify:

(i) At the start of the current annual reporting period, whether the CCR unit was operating under the detection monitoring program in § 257.94 or the assessment monitoring program in § 257.95;

(ii) At the end of the current annual reporting period, whether the CCR unit was operating under the detection monitoring program in § 257.94 or the assessment monitoring program in § 257.95;

(iii) If it was determined that there was a statistically significant increase over background levels for one or more constituents listed in appendix III to this part pursuant to § 257.94(e):

(A) Identify those constituents listed in appendix III to this part and the names of the monitoring wells associated with such an increase; and

(B) Provide the date when the assessment monitoring program was initiated for the CCR unit.

(iv) If it was determined that there was a statistically significant increase above the groundwater protection standard for one or more constituents listed in appendix IV to this part pursuant to § 257.95(g):

(A) Identify those constituents listed in appendix IV to this part and the names of the monitoring wells associated with such an increase;

(B) Provide the date when the assessment of corrective measures was initiated for the CCR unit; and

(C) Provide the date when the assessment of corrective measures was completed for the CCR unit.

(v) Whether a remedy was selected pursuant to § 257.97 during the current annual reporting period, and if so, the date of remedy selection; and

(vi) Whether remedial activities were initiated or are ongoing pursuant to § 257.98 during the current annual reporting period.

* * * * *

■ 5. In § 257.107 revise paragraph (a) to read as follows:

§ 257.107 Publicly accessible internet site requirements.

(a) Each owner or operator of a CCR unit subject to the requirements of this subpart must maintain a publicly accessible internet site (CCR website) containing the information specified in this section. The owner or operator's website must be titled ''CCR Rule Compliance Data and Information.'' The website must ensure that all information required to be posted is immediately available to anyone visiting the site, without requiring any prerequisite, such as registration or a requirement to submit a document request. All required information must be clearly identifiable and must be able to be printed and downloaded by anyone accessing the site. If the owner/operator changes the URL at any point, they must notify EPA via the ''contact us'' form on EPA's CCR website within 14 days of making the change.

* * * * *

[FR Doc. 2019–16916 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2019–0442; FRL–9997–73]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (19–4.B)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 17 chemical substances which are the subject of premanufacture notices (PMNs). This action would require persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these 17 chemical substances for an activity that is designated as a significant new use by this proposed rule. This action would further require that persons not commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice, and EPA has conducted a review of the notice, made an appropriate determination on the notice under TSCA 5(a)(3), and has taken any risk management actions as are required as a result of that determination.

DATES: Comments must be received on or before September 13, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0442, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import), process, or use the

chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers (including importers) or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these proposed SNURs would need to certify their compliance with the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after September 13, 2019 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What action is the Agency taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for 17 chemical substances which were the subjects of PMNs P–16–92, P–17–346, P–17–347/348/349/350/351/352, P–17–395, P–18–35, P–18–103, P–18–155/156, P–18–286, P–18–392, P–19–29, and P–19–62. These proposed SNURs would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

The record for the proposed SNURs on these chemicals was established as docket EPA–HQ–OPPT–2019–0442. That record includes information considered by the Agency in developing these proposed SNURs.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines through rulemaking that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B)(i) (15 U.S.C. 2604(a)(1)(B)(i)) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. TSCA prohibits such manufacturing or processing from commencing until EPA has conducted a review of the SNUN, made an appropriate determination on the SNUN, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence. As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the conditions of use of the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit. During its review of these chemicals, EPA identified certain conditions of use that are not intended by the submitters, but reasonably foreseen to occur. EPA is

proposing to designate those reasonably foreseen conditions of use as significant new uses.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 17 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR.
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substances if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.

This information may include testing not required to be conducted but which would help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VII. for more information.

- CFR citation assigned in the regulatory text section of these proposed rules.

The regulatory text section of these proposed rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed as CBI.

The chemical substances that are the subject of these proposed SNURs are undergoing premanufacture review. In addition to those conditions of use intended by the submitter, EPA has identified certain other reasonably foreseen conditions of use. EPA has preliminarily determined that the chemicals under their intended conditions of use are not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the reasonably foreseen conditions of use for these chemicals. EPA is proposing to designate these reasonably foreseen and other potential conditions of use as significant new uses. As a result, those conditions of use are no longer reasonably foreseen to occur without first going through a separate, subsequent EPA review and determination process associated with a SNUN.

The substances subject to these proposed rules are as follows:

PMN Number: P–16–92

Chemical name: Polymeric polyamine (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as industrial coatings, open non-dispersive use. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for irritation, corrosion, sensitization and lung effects (based on cationic binding to lung tissues), and toxicity to aquatic organisms at surface water concentrations exceeding 10 ppb, if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

- Use of the PMN substance for other than for the confidential use described in the PMN.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health and environmental toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of sensitization and environmental toxicity testing and pulmonary effects would help characterize the potential health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.11330.

PMN Number: P–17–346

Chemical name: Triarylalkyl phosphonium halide salt (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a destructive use. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for Acute toxicity, irritation/corrosion effects to the skin, eyes, and respiratory tract, systemic toxicity, and environmental toxicity if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

1. Use for other than the confidential uses identified in the PMN.
2. Release of the PMN substance into the waters of the United States resulting in surface water concentrations exceeding 5 ppb.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health and environmental toxicity of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of acute toxicity, specific target organ toxicity, irritation, and environmental toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.11331.

PMN Numbers: P–17–347, P–17–348, P–17–349, P–17–350, P–17–351 and P–17–352

Chemical names: Oxirane, 2-methyl-, polymer with oxirane, mono(2-butyloctyl) ether (P–17–347); Oxirane, 2-methyl-, polymer with oxirane, mono(2-hexyldecyl) ether (P–17–348); Oxirane, 2-methyl-, polymer with oxirane, mono(2-octyldodecyl) ether (P–17–349); Oxirane, 2-methyl-, polymer with oxirane, mono(2-decyltetradecyl) ether (P–17–350); Oxirane, 2-methyl-, polymer with oxirane, mono(2-dodecylhexadecyl) ether (P–17–351); Oxirane, 2-methyl-, polymer with oxirane, mono(2-tetradecyloctadecyl) ether (P–17–352).

CAS numbers: 252756–20–0 (P–17–347); 125005–52–9 (P–17–348); 102640–

44–8 (P–17–349); 72484–69–6 (P–17–350); 102640–42–6 (P–17–351); and 102640–46–0 (P–17–352).

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as an oilfield surfactant. Based on the physical/chemical properties of the PMN substances and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for lung toxicity and toxicity to aquatic organisms, if the chemical substances are used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substances that EPA intends to assess before they occur include the following:

1. Use of the PMN substances other than for the confidential use described in the PMNs.

2. Any manufacture, processing or use of the PMN substances that results in inhalation exposure.

3. Annual production volume exceeding 5,000 kilograms of the PMN substances in aggregate.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health and environmental toxicity of the PMN substances may be potentially useful to characterize the health and environmental effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects and environmental toxicity testing would help characterize the potential health and environmental effects of the PMN substances.

CFR Citations: 40 CFR 721.11332 (P–17–347), 40 CFR 721.11333 (P–17–348), 40 CFR 721.11334 (P–17–349), 40 CFR 721.11335 (P–17–350), 40 CFR 721.11336 (P–17–351), and 40 CFR 721.11337 (P–17–352).

PMN Number: P–17–395

Chemical name: Alkyl tri dithiocarbamate tri salt (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a water treatment additive. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for developmental toxicity, neurotoxicity, carcinogenicity, and skin sensitization, and toxicity to aquatic organisms, if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

1. Use of the PMN substance other than for the confidential uses described in the PMN.

2. Any manufacture, processing or use of the PMN substance that results in inhalation exposure.

3. Release to the PMN substance into the waters of the United States resulting in surface water concentrations exceeding 1 ppb.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health and environmental toxicity of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin sensitization, reproductive/developmental toxicity, specific target organ toxicity, and environmental toxicity testing would help characterize the potential health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.11338.

PMN Number: P–18–35

Chemical name: Methacrylic acid heterocyclic alkyl ester (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a monomer for polymer applications. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for skin and eye irritation and reproductive/developmental toxicity if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

- Uses other than the confidential uses identified in the PMN.

The proposed SNUR would designate as a ''significant new use'' this condition of use.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of genetic toxicology testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11339.

PMN Number: P–18–103

Chemical name: Alkylnitrile imidazole (generic).

CAS number: Not available.

Basis for action: The PMN states that the use of the substance will be as an intermediate for amine manufacture. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for eye irritation, reproductive/developmental toxicity, and specific target organ toxicity if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

1. Use for other than an intermediate for amine manufacture.

2. Any manufacture, processing or use of the PMN substance that results in inhalation exposure.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, reproductive/developmental toxicity, and eye irritation testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.113340.

PMN Numbers: P–18–155 and P–18–156

Chemical names: Crosslinked polymer of alkyl acrylamides, acrylate esters, and alkyl acrylamide sulfonate salt (generic).

CAS number: Not available.

Basis for action: The PMNs state that the generic (non-confidential) use of the substance will be as a component in cement. Based on the physical/chemical properties of the PMN substances and Structure Activity Relationships (SAR) analysis of test data on analogous

substances, EPA has identified concerns for lung effects and carcinogenicity if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substances that EPA intends to assess before they occur include the following:

1. Use of the PMN substances other than for the confidential uses described in the PMNs.

2. Manufacture (including import) of the PMN substances with greater than 10% of particles <10 microns.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substances may be potentially useful to characterize the health effects of the PMN substances if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects testing would help characterize the potential health effects of the PMN substances.

CFR citation: 40 CFR 721.11341 (P–18–155 and P–18–156).

PMN Number: P–18–286

Chemical name: Propane, 1,1,1,3,3,3-hexafluoro-2-methoxy-.

CAS number: 13171–18–1.

Basis for action: The PMN states that the use of the substance will be as solvent in vapor degreasing/vapor cleaning and other confidential uses generically described as heat transfer fluid and additive contained/sealed in low voltage electronics. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for irritation and developmental neurotoxicity effects, if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

1. Use of the PMN substance other than as a solvent in vapor degreasing/vapor cleaning or additional confidential uses described in the PMN.

2. Manufacture (including import), processing or use of the PMN substance without the transport container loading process described in the PMN.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin irritation and developmental neurotoxicity testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11342.

PMN Number: P–18–392

Chemical name: Heteromonocycle, alkenyl alkyl (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate chemical. Based on the physical/chemical properties of and test data on the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for irritation/corrosion and carcinogenicity if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

- No use other than the confidential uses identified in the PMN.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of absorption, skin and eye irritation/corrosion, and carcinogenicity testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11343.

PMN Number: P–19–29

Chemical name: Phosphonium, tributylethyl-, diethyl phosphate (1:1).

CAS number: 20445–94–7.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a catalyst. Based on the physical/chemical properties of and available data on the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for irritation, corrosion, neurotoxicity, reproductive toxicity, liver toxicity, and toxicity to aquatic organisms at surface water concentrations exceeding 51 ppb, if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

1. Use of the PMN substance other than for the confidential uses described in the PMN.

2. Release to the PMN substance into the waters of the United States resulting in surface water concentrations exceeding 51 ppb.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information about the human health and environmental fate of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of irritation, specific target organ toxicity, neurotoxicity, and reproductive toxicity, and environmental fate testing would help characterize the potential health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.11344.

PMN Number: P–19–62

Chemical name: Hydrochlorofluoroolefin (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an industrial solvent. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for neurotoxicity, systemic toxicity, reproductive toxicity, and lung effects if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

- Use other than for the confidential uses identified in the PMN.

The proposed SNUR would designate as a ''significant new use'' this condition of use.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer

or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity and neurotoxicity testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11345.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are the subject of these proposed SNURs and as further discussed in Unit IV, EPA identified certain other reasonably foreseen conditions of use, in addition to those conditions of use intended by the submitter. EPA has preliminarily determined that the chemical under the intended conditions of use is not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the reasonably foreseen conditions of use. EPA is proposing to designate these conditions of use as significant new uses to ensure that they are no longer reasonably foreseen to occur without first going through a separate, subsequent EPA review and determination process associated with a SNUN.

B. Objectives

EPA is proposing SNURs for 17 specific chemical substances which are undergoing premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses that would be designated in this proposed rule:

- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA would be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3) (A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.
- EPA would be able to complete its review and determination on each of the PMN substances, while deferring analysis on the significant new uses proposed in these rules unless and until the Agency receives a SNUN.

Issuance of a proposed SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at *https://www.epa.gov/tsca-inventory.*

VI. Applicability of the Proposed Rules to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule were undergoing premanufacture review at the time of signature of this proposed rule and were not on the TSCA Inventory. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for the chemical substances subject to these proposed SNURs, EPA concludes that the proposed significant new uses are not ongoing.

EPA designates August 1, 2019 (date of web posting) as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified on or after that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under section 5 allowing manufacture or processing to proceed. In developing this proposed rule, EPA has recognized that, given EPA's general practice of posting proposed rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before **Federal Register** publication of the proposed rule.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order or consent agreement under TSCA section 4 (15 U.S.C. 2603), then TSCA section 5(b)(1)(A) (15 U.S.C. 2604(b)(1)(A)) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance, which may assist with EPA's analysis of the SNUN.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

The potentially useful information described in Unit IV. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

• Human exposure and environmental release that may result from the significant new use of the chemical substances.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E–PMN software is available electronically at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.*

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2019–0263.

X. Statutory and Executive Order Reviews

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

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

This proposed rule would establish SNURs for 8 new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to the PRA, 44 U.S.C. 3501 *et seq.,* an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* the Agency hereby certifies that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 12 in FY2016, 13 in FY2017, and 11 in FY2018, only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $16,000 to $2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this proposed rule. As such, EPA has determined that this proposed rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1531–1538 *et seq.*).

E. Executive Order 13132: Federalism

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23,

1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

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

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 31, 2019.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add §§ 721.11330 through 721.11345 to subpart E to read as follows:

Subpart E—Significant New Uses for Specific Chemical Substances

Sec.

§ 721.11330 Polymer of polyethylene polyamine and alkanediol diglycidyl ether (generic).
§ 721.11331 Triarylalkyl phosphonium halide salt (generic).
§ 721.11332 Oxirane, 2-methyl-, polymer with oxirane, mono(2-butyloctyl) ether.
§ 721.11333 Oxirane, 2-methyl-, polymer with oxirane, mono(2-hexyldecyl) ether.
§ 721.11334 Oxirane, 2-methyl-, polymer with oxirane, mono(2-octyldodecyl) ether.
§ 721.11335 Oxirane, 2-methyl-, polymer with oxirane, mono(2-decyltetradecyl) ether.
§ 721.11336 Oxirane, 2-methyl-, polymer with oxirane, mono(2-dodecylhexadecyl) ether.
§ 721.11337 Oxirane, 2-methyl-, polymer with oxirane, mono(2-tetradecyloctadecyl) ether.
§ 721.11338 Alkyl tri dithiocarbamate tri salt (generic).
§ 721.11339 Methacrylic acid heterocyclic alkyl ester (generic).
§ 721.11340 Alkylnitrile imidazole (generic).
§ 721.11341 Crosslinked polymer of alkyl acrylamides, acrylate esters, and alkyl acrylamide sulfonate salt (generic).
§ 721.11342 Propane, 1,1,1,3,3,3-hexafluoro-2-methoxy-.
§ 721.11343 Heteromonocycle, alkenyl alkyl (generic).
§ 721.11344 Phosphonium, tributylethyl-, diethyl phosphate (1:1).
§ 721.11345 Hydrochlorofluoroolefin (generic).

Subpart E—Significant New Uses for Specific Chemical Substances

§ 721.11330 Polymer of polyethylene polyamine and alkanediol diglycidyl ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as polymer of polyethylene polyamine and alkanediol diglycidyl ether (PMN P–16–92) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11331 Triarylalkyl phosphonium halide salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as triarylalkyl phosphonium halide salt (PMN P–17–346) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) where N = 5.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11332 Oxirane, 2-methyl-, polymer with oxirane, mono(2-butyloctyl) ether.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2-methyl-, polymer with oxirane, mono(2-butyloctyl) ether. (P–17–347, CASRN 252756–20–0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (s) (5,000 kilograms, aggregate of PMN substances P–17–347, P–17–348, P–17–349, P–17–350, P–17–351 and P–17–352). It is a significant new use to manufacture, process or use the PMN substances in a manner that results in inhalation exposure.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions

of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11333 Oxirane, 2-methyl-, polymer with oxirane, mono(2-hexyldecyl) ether.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2-methyl-, polymer with oxirane, mono(2-hexyldecyl) ether (P–17–348, CASRN 125005–52–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (s) (5,000 kilograms, aggregate of PMN substances P–17–347, P–17–348, P–17–349, P–17–350, P–17–351 and P–17–352). It is a significant new use to manufacture, process or use the PMN substances in a manner that results in inhalation exposure.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11334 Oxirane, 2-methyl-, polymer with oxirane, mono(2-octyldodecyl) ether.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2-methyl-, polymer with oxirane, mono(2-octyldodecyl) ether (P–17–349, CASRN 102640–44–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (s) (5,000 kilograms, aggregate of PMN substances P–17–347, P–17–348, P–17–349, P–17–350, P–17–351 and P–17–352). It is a significant new use to manufacture, process or use the PMN substances in a manner that results in inhalation exposure.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11335 Oxirane, 2-methyl-, polymer with oxirane, mono(2-decyltetradecyl) ether.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2-methyl-, polymer with oxirane, mono(2-decyltetradecyl) ether (P–17–350, CASRN 72484–69–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (s) (5,000 kilograms, aggregate of PMN substances P–17–347, P–17–348, P–17–349, P–17–350, P–17–351 and P–17–352). It is a significant new use to manufacture, process or use the PMN substances in a manner that results in inhalation exposure.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11336 Oxirane, 2-methyl-, polymer with oxirane, mono(2-dodecylhexadecyl) ether.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as Oxirane, 2-methyl-, polymer with oxirane, mono(2-dodecylhexadecyl) ether (P–17–351, CASRN 102640–42–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (s) (5,000 kilograms, aggregate of PMN substances P–17–347, P–17–348, P–17–349, P–17–350, P–17–351 and P–17–352). It is a significant new use to manufacture, process or use the PMN substances in a manner that results in inhalation exposure.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11337 Oxirane, 2-methyl-, polymer with oxirane, mono(2-tetradecyloctadecyl) ether.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2-methyl-, polymer with oxirane, mono(2-tetradecyloctadecyl) ether (P–17–352, CASRN 102640–46–0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (s) (5,000 kilograms, aggregate of PMN substances P–17–347, P–17–348, P–17–349, P–17–350, P–17–351 and P–17–352). It is a significant new use to manufacture, process or use the PMN substances in a manner that results in inhalation exposure.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions

of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11338 Alkyl tri dithiocarbamate tri salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyl tri dithiocarbamate tri salt (PMN P–17–395) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to manufacture, process, or use the substance in a manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11339 Methacrylic acid heterocyclic alkyl ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as methacrylic acid heterocyclic alkyl ester (PMN P–18–35) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11340 Alkylnitrile imidazole (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkylnitrile imidazole (P–18–103) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* It is a significant new use to manufacture, process or use the PMN substance for use other than as an intermediate for amine manufacture. It is a significant new use to manufacture, process or use the PMN substance in a manner that results in inhalation exposure.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11341 Crosslinked polymer of alkyl acrylamides, acrylate esters, and alkyl acrylamide sulfonate salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances generically identified as crosslinked polymer of alkyl acrylamides, acrylate esters, and alkyl acrylamide sulfonate salt (PMNs P–18–155 and P–18–156) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to manufacture the PMN substances with greater than 10% of the particles less than 10 microns.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11342 Propane, 1,1,1,3,3,3-hexafluoro-2-methoxy-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as propane, 1,1,1,3,3,3-hexafluoro-2-methoxy- (PMN P–18–286, CASRN 13171–18–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to manufacture, process or use the substance without the transport container loading process described in the PMN.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11343 Heteromonocycle, alkenyl alkyl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as heteromonocycle, alkenyl alkyl (PMN P–18–392) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are

applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11344 Phosphonium, tributylethyl-, diethyl phosphate (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as phosphonium, tributylethyl-, diethyl phosphate (1:1) (PMN P–19–29, CASRN 20445–94–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(ii) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) where N = 51.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11345 Hydrochlorofluoroolefin (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as hydrochlorofluoroolefin (P–19–62) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), (j) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

[FR Doc. 2019–17148 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 84, No. 157
Wednesday, August 14, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Document No. AMS–LP–19–0022]

2019 Rates Charged for AMS Services

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice; correction.

SUMMARY: On April 30, 2019, the Agricultural Marketing Service (AMS) published a notice announcing the 2019 rates it will charge for voluntary grading, inspection, certification, auditing, and laboratory services for a variety of agricultural commodities including meat and poultry, fruits and vegetables, eggs, dairy products, and cotton and tobacco. This document makes corrections to the overtime and holiday rates charged to grade specialty crops.

DATES: August 15, 2019.

FOR FURTHER INFORMATION CONTACT: Charles Parrott, AMS, U.S. Department of Agriculture, Room 3070–S, 1400 Independence Ave. SW, Washington, DC 20250; telephone (202) 260–9144, fax (202) 692–0313, email *charles.parrott@usda.gov.*

SUPPLEMENTARY INFORMATION: The Agricultural Marketing Act of 1946, as amended, (AMA) (7 U.S.C. 1621–1627), provides for the collection of fees to cover costs of various inspection, grading, certification or auditing services covering many agricultural commodities and products. On April 30, 2019, AMS published a notice announcing the 2019 rates it will charge for voluntary grading, inspection, certification, auditing, and laboratory services for a variety of agricultural commodities including meat and poultry, fruits and vegetables, eggs, dairy products, and cotton and tobacco. This document makes corrections to the overtime and holiday rates charged to grade specialty crops.

Federal Register Correction

Effective August 15, 2019, 2019, in notice document AMS–LP–19–0022, at Vol. 84, No. 83 in the issue of April 30, 2019, on page 18234, the rates for specialty crops are corrected to read as follows:

	Regular	Overtime	Holiday	Includes travel costs in rate	Start date
Specialty Crops Fees					
7 CFR Part 51—Fresh Fruits, Vegetables and Other Products (Inspection, Certification, and Standards) Subpart A—Regulations; §§ 51.37–51.44 Schedule of Fees and Charges at Destination Markets; § 51.45 Schedule of Fees and Charges at Shipping Point Areas					
Quality and Condition Inspections for Whole Lots	$210.00 per lot			.....	Oct 1, 2019.
Quality and Condition Half Lot or Condition-Only Inspections for Whole Lots	$174.00 per lot			.....	Oct 1, 2019.
Condition—Half Lot	$161.00 per lot			.....	Oct 1, 2019.
Quality and Condition or Condition-Only Inspections for Additional Lots of the Same Product	$96.00 per lot			.....	Oct 1, 2019.
Dockside Inspections—Each package weighing <30 lbs	$0.044 per pkg.			.....	Oct 1, 2019.
Dockside Inspections—Each package weighing >30 lbs	$0.068 per pkg.			.....	Oct 1, 2019.
Charge per Individual Product for Dockside Inspection	$210.00 per lot			.....	Oct 1, 2019.
Charge per Each Additional Lot of the Same Product	$96.00 per lot			.....	Oct 1, 2019.
Inspections for All Hourly Work	$93.00	$125.00	$157.00	.....	Oct 1, 2019
Audit Services—Federal	$115.00			.....	Oct 1, 2019.
Audit Services—State	$115.00			.....	Oct 1, 2019.
GFSI Certification Fee	$250 per audit			.....	Oct 1, 2019.
7 CFR Part 52—Processed Fruits and Vegetables, Processed Products Thereof, and Other Processed Food Products Subpart—Regulations Governing Inspection and Certification; §§ 52.41–52.51 Fees and Charges					
Lot Inspections	$75.00	$104.00	$133.00	.....	Oct 1, 2019.
In-plant Inspections Under Annual Contract (year-round)	$75.00	$103.00	$130.00	.....	Oct 1, 2019.

	Regular	Overtime	Holiday	Includes travel costs in rate	Start date
Additional Graders (in-plant) or Less Than Year-Round	$85.00	$114.00	$142.00		Oct 1, 2019.
Audit Services—Federal	$115.00				Oct 1, 2019.
Audit Services—State	$115.00				Oct 1, 2019.
GFSI Certification Fee	$250 per audit				Oct 1, 2019.

Dated: August 8, 2019.

Bruce Summers,

Administrator.

[FR Doc. 2019–17361 Filed 8–13–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0041]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with regulations for the use of irradiation as a phytosanitary treatment of imported fruits and vegetables.

DATES: We will consider all comments that we receive on or before October 15, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0041.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0041, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0041* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information regarding the regulations for the use of irradiation as a phytosanitary treatment of imported fruits and vegetables, contact Ms. Kara Spofford, Offshore Certification Specialist, PPQ Preclearance and Offshore Programs, PHP, PPQ, APHIS, 4700 River Road, Unit 60, Riverdale, MD 20737–1236; (301) 851–2241. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables.

OMB Control Number: 0579–0155.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture is authorized, among other things, to regulate the importation of plants, plant products (including fruits and vegetables), and other articles to prevent the introduction of plant pests and noxious weeds into the United States.

Regulations governing the importation of fruits and vegetables are set out in ''Subpart L–Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–12). In accordance with these regulations, some fruits and vegetables from certain regions of the world must be treated for pests in order to be eligible for entry into the United States. The regulations in 7 CFR part 305 provide, among other things, for the use of irradiation as a phytosanitary treatment for some fruits and vegetables imported into the United States. Irradiation treatment provides protection against all insect pests, except adults and pupae of the order Lepidoptera. Irradiation treatment may be used as an alternative to other approved treatments for pests in fruits and vegetables, such as fumigation, cold treatment, heat treatment, and other techniques.

The regulations concerning irradiation treatment involve the collection of information such as a compliance agreement, dosimetry agreement at the irradiation facility, request for dosimetry device approval, 30-day notification, labeling and packaging, recordkeeping, request for certification and inspection of facility, irradiation treatment workplan, facility preclearance workplan, trust fund agreement, phytosanitary certificate, denial and withdrawal of certification, and limited permit.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.038 hours per response.

Respondents: National plant protection organizations of exporting countries, irradiation facility operators,

and U.S. importers of fruits and vegetables.

Estimated annual number of respondents: 43.

Estimated annual number of responses per respondent: 483.

Estimated annual number of responses: 20,774.

Estimated total annual burden on respondents: 805 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 8th day of August 2019.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–17467 Filed 8–13–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0026]

Addition of Cambodia to the List of Regions Affected by African Swine Fever

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have added Cambodia to the list of regions that the Animal and Plant Health Inspection Service considers to be affected with African swine fever (ASF). We are taking this action because of the confirmation of ASF in Cambodia.

DATES: Cambodia was added to the APHIS list of regions considered affected with ASF on April 4, 2019.

FOR FURTHER INFORMATION CONTACT: Dr. Ingrid Kotowski, Regionalization Evaluation Services, Veterinary Services, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855–7732; email: *ingrid.kotowski@usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including African swine fever (ASF). ASF is a highly contagious disease of wild and domestic swine that can spread rapidly in swine populations with extremely high rates of morbidity and mortality. A list of regions where ASF exists or is reasonably believed to exist is maintained on the Animal and Plant Health Inspection Service (APHIS) website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions/.* This list is referenced in § 94.8(a)(2) of the regulations.

Section 94.8(a)(3) of the regulations states that APHIS will add a region to that list upon determining ASF exists in the region, based on reports APHIS receives of outbreaks of the disease from veterinary officials of the exporting country, from the World Organization for Animal Health (OIE), or from other sources the Administrator determines to be reliable, or upon determining that there is reason to believe the disease exists in the region.

On April 3, 2019, the veterinary authorities of Cambodia reported to the OIE the occurrence of ASF in that country. In response to this outbreak, on April 4, 2019, APHIS added Cambodia to the list of regions where ASF exists or is reasonably believed to exist. As a result, pork and pork products from Cambodia, including casings, are subject to APHIS import restrictions designed to mitigate the risk of ASF introduction into the United States.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this action as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 8th day of August 2019.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–17468 Filed 8–13–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0020]

Addition of Vietnam to the List of Regions Affected by African Swine Fever

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have added Vietnam to the list of regions that the Animal and Plant Health Inspection Service considers to be affected with African swine fever (ASF). We are taking this action because of the confirmation of ASF in Vietnam.

DATES: Vietnam was added to the APHIS list of regions considered affected with ASF on February 18, 2019.

FOR FURTHER INFORMATION CONTACT: Dr. Hatim Gubara, Senior Staff Veterinarian, Regionalization Evaluation Services, Strategy and Policy, Veterinary Services, 4700 River Road, Unit 38, Riverdale, MD 220737; phone: (301) 851–3310; email: *hatim.gubara@usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including African swine fever (ASF). ASF is a highly contagious disease of wild and domestic swine that can spread rapidly in swine populations with extremely high rates of morbidity and mortality. A list of regions where ASF exists or is reasonably believed to exist is maintained on the Animal and Plant Health Inspection Service (APHIS) website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions/.* This list is referenced in § 94.8(a)(2) of the regulations.

Section 94.8(a)(3) of the regulations states that APHIS will add a region to that list upon determining ASF exists in the region, based on reports APHIS receives of outbreaks of the disease from veterinary officials of the exporting country, from the World Organization for Animal Health (OIE), or from other sources the Administrator determines to be reliable, or upon determining that there is reason to believe the disease exists in the region.

On February 20, 2019, the veterinary authorities of Vietnam reported to the OIE confirmation of an ASF outbreak on February 18, 2019. In response to this outbreak, APHIS has added Vietnam to the list of regions where ASF exists or is reasonably believed to exist. As a result, pork and pork products from Vietnam, including casings, are subject to APHIS import restrictions designed to mitigate the risk of ASF introduction into the United States.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this action as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 8th day of August 2019.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–17471 Filed 8–13–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0075]

Privacy Act of 1974; System of Records

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of a new system of records.

SUMMARY: The Animal and Plant Health Inspection Service proposes to add a system of records to its inventory of records systems subject to the Privacy Act of 1974, as amended. The system of records being proposed is the Agricultural Quarantine Activity System, USDA/APHIS–20. This notice is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of record systems maintained by the agency. Although the Privacy Act requires only that the portion of the system which describes the ''routine uses'' of the system be published for comment, we invite comment on all portions of this notice.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice will become applicable upon publication, subject to a 30-day notice and comment period in which to comment on the routine uses described below. Please submit any comments by September 13, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0075.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0075, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0075* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact Mr. Emilio Vasquez, Business System Manager, QPAS, PPQ, APHIS, 4700 River Road, Unit 60, Riverdale, MD 20737; (301) 851–2257. For Privacy Act questions concerning this system of records notice, please contact Ms. Tonya Woods, Director, Freedom of Information and Privacy Act Staff, 4700 River Road, Unit 50, Riverdale, MD 20737; (301) 851–4076. For USDA Privacy Act questions, please contact the USDA Chief Privacy Officer, Information Security Center, Office of Chief Information Officer, USDA, Jamie L. Whitten Building, 1400 Independence Ave. SW, Washington, DC 20250; email: *USDAPrivacy@ocio.usda.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), notice is given that the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is proposing to add a new system of records, entitled the Agricultural Quarantine Activity System (AQAS), USDA/APHIS–20, which would be used to maintain a record of activities conducted by the agency pursuant to its mission and responsibilities authorized by the Plant Protection Act (7 U.S.C. 7701 *et seq.* and 7 U.S.C. 7781 *et seq.*); the Honey Bee Act (7 U.S.C. 281 *et seq.*); and the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*).

APHIS' Plant Protection and Quarantine (PPQ) program and Department of Homeland Security's U.S. Customs and Border Protection (CBP) will use AQAS to record trade-related activities conducted inside the United States. The data associated with trade events includes shipment arrivals, quarantine activities, invasive pest interceptions, and other commodity inspection and pest exclusion actions. This system aids the free flow of agricultural goods into the country by collecting agricultural risk data that ultimately helps to minimize the impact of quarantine activities on trade. Additionally, it records activities conducted by APHIS within the U.S. borders pertaining to detecting the unlawful entry and distribution of prohibited and/or non-compliant products that may harbor exotic plant and animal pests, diseases, or invasive species. These activities are captured in AQAS via subsystems that are interrelated, web-based systems, and share a common platform. A complete listing of the subsystems is included in the purposes section of the document published with this notice.

APHIS will share information from the system pursuant to the requirements of the Privacy Act and, in the case of its routine uses, when the disclosure is compatible with the purpose for which the information was compiled. A full list of routine uses is included in the routine uses section of the document published with this notice.

A report on the new system of records, required by 5 U.S.C. 552a(r), as implemented by Office of Management and Budget Circular A–108, was sent to the Chairman, Committee on Homeland Security and Governmental Affairs, United States Senate; the Chairman, Committee on Oversight and Reform, House of Representatives; and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget.

Done in Washington, DC, this 8th day of August 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

USDA/APHIS–20

SYSTEM NAME AND NUMBER

Agricultural Quarantine Activity System (AQAS), USDA/APHIS–20.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

AQAS servers, files, data, and software are hosted at the National Information Technology Center (NITC), 8930 Ward Parkway, Kansas City, MO. The AQAS backup system is located at NITC enterprise data centers at 4300 Goodfellow Blvd., St. Louis, MO.

SYSTEM MANAGER:

Director, Quarantine, Policy, Analysis and Support, Plant Health Programs, PPQ, APHIS, 4700 River Road, Unit 60, Riverdale, MD 20737.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Plant Protection Act, 7 U.S.C. 7701 *et seq.* and 7 U.S.C. 7781 *et seq.;* the Honey Bee Act, 7 U.S.C. 281 *et seq.;* and the Animal Health Protection Act, 7 U.S.C. 8301 *et seq.*

PURPOSES OF THE SYSTEM:

The AQAS records agricultural quarantine activities conducted by U.S.

Customs and Border Protection (CBP) and Animal and Plant Health Inspection Service (APHIS) employees at the U.S. ports of entry. This system also records agricultural quarantine activities conducted inside the United States that are related to trade. This system aids the free flow of agricultural goods into the country by collecting agricultural risk data that ultimately helps to minimize the impact of quarantine activities on trade. Additionally, it records activities conducted by APHIS within the U.S. borders pertaining to detecting the unlawful entry and distribution of prohibited and/or noncompliant products that may harbor exotic plant and animal pests, diseases, or invasive species.

AQAS consists of subsystems that are interrelated, web-based systems and share a common platform.

The AQAS subsystems include:

- AQIM—Agricultural Quarantine Inspection Monitoring System
- EAN—Emergency Action Notification Database
- Pest ID—Pest Interception Database
- PPQ280—Regulated Commodities Database
- PPQ264—Propagative Imports Notification Database
- Mail287—Mail Interception Notification Database
- WADS—Work Accomplishment Data System

The AQIM system provides a systematic approach to determining the risks of cargo approaching ports of entry into the United States by collecting specific pieces of data about randomly sampled shipments and analyzing the data to identify the high risk criteria and to target inspections accordingly. The EAN system tracks the issuance of Emergency Action Notifications. CBP and Plant Protection and Quarantine (PPQ) officers at U.S. ports of entry and throughout the country generate an EAN form when an actionable violation is detected related to prohibited pests and/or agricultural products found in foreign cargo or in U.S. marketplaces and domestic sites. The Pest ID system was developed to replace the PIN309 system and records pest interceptions in agricultural commodities at the U.S. ports of entry and throughout the country. The PIN309 system captured all of the data in the current Pest ID system and all data in the PIN309 system was migrated over to the Pest ID system. The PPQ280 system tracks fruits, vegetables, flowers, propagative material, logs, lumber, cotton products, and certain miscellaneous products imported or transiting through a port. It tracks the final disposition of the commodity, the number of shipments, the weight or volume, the type, and the country of origin of the commodity. The PPQ264 portion of the PPQ280 system is used by the PPQ Plant Inspection Stations to track imported propagative material and permitted organisms. The Mail287 system maintains records of Mail Interception Notices. This form documents noncompliant actions of persons who mail United States Department of Agriculture (USDA) regulated articles through postal mail processing facilities. Articles that are prohibited or restricted are often confiscated and the intended recipient is notified via this form. The WADS system records work activities related to agricultural quarantine inspections at U.S. ports of entry. WADS codes are designed to report on activities such as the number of foreign arriving passengers or cargo and number of inspections conducted. The purpose of the WADS system is to enable APHIS to set risk management priorities and to make staffing recommendations. WADS data are analyzed in conjunction with other AQAS data for risk analysis.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system contains records associated with agricultural quarantine inspection activities conducted by CBP and PPQ at U.S. ports of entry. The records include the following categories of individuals: Foreign arrival passengers, senders and recipients listed on intercepted mail, agricultural commodity importers, shippers, carriers, owners, consignees, delivery contact persons, permit holders, and other individuals involved in the relevant programs or activities.

CATEGORIES OF RECORDS IN THE SYSTEM:

For foreign arrival passengers, agricultural commodity importers, shippers, carriers, owners, consignees, delivery contact persons, permit holders, and other individuals involved in the relevant programs or activities, the records include, but are not limited to, some or all of the following: Names, addresses, telephone and fax numbers, permit numbers, and/or emergency action notification form serial numbers. AQAS contains the names and addresses of the senders and recipients recorded on intercepted mail. This system may also contain targeting information used to categorize inspection activities associated with vehicles including name or type of carrier, voyage or flight data, and destination State. AQAS also contains the contact information of the CBP and APHIS inspection officials, including names, telephone numbers, and fax numbers.

RECORD SOURCE CATEGORIES:

Information within this system is obtained from the general public, import documents, CBP data systems, and from Federal and State regulatory officials, including APHIS and CBP employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, records maintained in the system may be disclosed outside USDA, as follows, to the extent that such disclosures are compatible with the purposes for which the information was collected:

(1) To DHS CBP and other cooperating Federal or State government employees, or contractors performing or working on a contract, service, grant, cooperative agreement, or other assignment for USDA, when necessary, to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are USDA officials and employees. Specific applications include, but are not limited to, issuing notifications for noncompliance to importers, shippers, property owners, mail recipients or addressees; informing State entities about upcoming plant shipments; using AQIM data to track and analyze various pathways and the commodities entering those pathways into the United States for purposes of pest risk management; and generating reports to evaluate quality control and effectiveness of the program;

(2) To appropriate law enforcement agencies, entities, and persons, whether Federal, foreign, State, Tribal, local, or other public authority responsible for enforcing, investigating, or prosecuting an alleged violation or a violation of law or charged with enforcing, implementing, or complying with a statute, rule, regulation, or order issued pursuant thereto, when a record in this system on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or court order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutive responsibility of the receiving entity;

(3) To the Department of Justice when the agency, or any component thereof, or any employee of the agency in his or her official capacity, or any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or the United States, in litigation, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

(4) To a court or adjudicative body in administrative, civil, or criminal proceedings when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records;

(5) To appropriate agencies, entities, and persons when: (a) USDA suspects or has confirmed that there has been a breach of the system of records; (b) USDA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, USDA (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with USDA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;

(6) To another Federal agency or Federal entity, when the USDA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

(7) To a Congressional office from the record of an individual in response to any inquiry from that Congressional office made at the written request of the individual to whom the record pertains;

(8) To USDA contractors and other parties engaged to assist in administering the program, analyzing data, and conducting audits. Such contractors and other parties will be bound by the nondisclosure provisions of the Privacy Act;

(9) To USDA contractors, partner agency employees or contractors, or private industry employed to identify patterns, trends, or anomalies indicative of fraud, waste, or abuse; and

(10) To the National Archives and Records Administration or to the General Services Administration for records management activities conducted under 44 U.S.C. 2904 and 2906.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The system includes a database and paper records. Records are maintained on magnetic hard-disk. Paper records, such as Emergency Action Notifications, are maintained in offices that are locked during non-business hours and require the presentation of employee identification for admittance at all times. Onsite storage includes the system and a daily backup of media. Backup media is transferred to an offsite storage facility after 30 days.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by an individual's name, business name, address, telephone number, fax number, email address, permit number, and/or emergency action notification form serial number associated with an importer, shipper, carrier, owner, consignee, delivery contact person, permit holder, and/or a sender and recipient on intercepted mail.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records will be retained indefinitely until appropriate disposition authority is obtained, and records will then be disposed of in accordance with the authority granted.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records, both paper and electronic, are only accessible to authorized personnel. The following physical security measures are in place to prevent outsiders from entering the system:

Electronic records are stored on secure file servers. For electronic records, all AQAS users are required to complete a registration process. AQAS enables users to obtain user-identification accounts that allow password-protected access through the internet. The secure web-based service identifies and validates users before they can access this system.

Paper files are kept in a safeguarded environment with controlled access only by authorized personnel. All APHIS and CBP personnel are required to go through background and security checks. APHIS and CBP employees are also required to complete appropriate training to learn requirements for safeguarding records maintained under the Privacy Act. Access to the system is role-based. Therefore, CBP employees are limited to accessing records created by CBP or associated with a CBP work unit location.

RECORD ACCESS PROCEDURES:

An individual who is the subject of a record in this system may seek access to those records that are not exempt from the access provisions. Exemptions apply only to the extent that the information in the system is subject to exemption pursuant to 5 U.S.C. 552a(k)(2), if applicable. A determination whether a record may be accessed will be made at the time a request is received. All inquiries should be addressed under ''Notification procedures.''

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend information maintained in the system should direct their requests to the address indicated in the ''Notification procedures'' section, below. Some information may be exempt from the amendment provisions, as described in the section entitled ''Exemptions promulgated for the system.'' An individual who is the subject of a record in this system may seek amendment of those records that are not exempt. A determination whether a record may be amended will be made at the time a request is received.

NOTIFICATION PROCEDURES:

Individuals seeking notification of and access to any non-exempt general information contained in this system of records, or seeking to contest its content, may submit a request in writing to the APHIS Freedom of Information Act (FOIA) Officer, whose contact information can be found at *https://www.aphis.usda.gov/aphis/resources/foia.* If an individual believes more than one component maintains Privacy Act

records concerning him or her the individual may submit the request to the Chief FOIA Officer, Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty or perjury as a substitute for notarization. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created;
- Provide any other information that will help the FOIA staff determine which USDA component agency may have responsive records; and
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his or her agreement for you to access his or her records.

Without this bulleted information and the component(s), we will not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

N/A.

[FR Doc. 2019–17461 Filed 8–13–19; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Michigan Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Michigan Advisory Committee (Committee) will hold a meeting on Friday, August 30, 2019, at 12:00 p.m. EST the purpose of the meeting will be to review the first draft of their voting rights report.

DATES: The meeting will be held on Friday, August 30, 2019, at 12:00 p.m. EST.

ADDRESSES: *Public Call Information:* Dial: 800–367–2403; Conference ID: 3685638.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, DFO, at *afortes@usccr.gov* or 213–894–3437.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the above toll-free call-in number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit Office, U.S. Commission on Civil Rights, 230 S Dearborn St., Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324 or emailed to Carolyn Allen at *callen@usccr.gov*. Persons who desire additional information may contact the Regional Programs Office at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Michigan Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Office at the above email or street address.

Agenda

I. Welcome and Roll Call

II. Approval of July 24, 2019 Minutes

III. Review Report Draft

IV. Public Comment

V. Next Steps

VI. Adjournment

Dated: August 8, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–17401 Filed 8–13–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–26–2019]

Foreign-Trade Zone (FTZ) 167—Green Bay, Wisconsin; Authorization of Production Activity; ProAmpac Holdings, Inc. (Flexible Packaging Applications); Neenah and Appleton, Wisconsin

On April 5, 2019, ProAmpac Holdings, Inc. submitted a notification of proposed production activity to the FTZ Board for its facilities within FTZ 167, in Neenah and Appleton, Wisconsin.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (84 FR 16244–16245, April 18, 2019). On August 8, 2019, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: August 8, 2019.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2019–17431 Filed 8–13–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 190215128–9128–01]

RIN 0694–XC053

Impact of Proposed Additions to the ''Annex on Chemicals'' to the Chemical Weapons Convention (CWC) on Legitimate Commercial Chemical, Biotechnology, and Pharmaceutical Activities Involving ''Schedule 1'' Chemicals (Including Schedule 1 Chemicals Produced as Intermediates)

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security (BIS) is seeking public comments on the impact on commercial activities of proposed additions to ''Schedule 1'' in the ''Annex on Chemicals'' to the Chemical Weapons Convention (CWC), as implemented through the Chemical Weapons Convention Implementation Act (CWCIA) and the Chemical Weapons Convention Regulations (CWCR). The purpose of this notice of inquiry is to collect information to assist BIS in assessing the likely impact on United States industry of the proposed addition of five chemical families to ''Schedule 1'' in the ''Annex on Chemicals.''

DATES: Comments must be received by September 13, 2019.

ADDRESSES: You may submit comments by any of the following methods (please refer to RIN 0694–XC053 in all comments and in the subject line of email comments):

- Federal rulemaking portal (*http://www.regulations.gov*)—you can find this notice by searching on its *regulations.gov* docket number, which is BIS–2019–0002;
- *Email: willard.fisher@bis.doc.gov*—include the phrase ''Schedule 1 Notice of Inquiry'' in the subject line;
- *Fax:* (202) 482–3355 (Attn: Willard Fisher);
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: For questions on the Chemical Weapons Convention requirements for ''Schedule 1'' chemicals, contact Douglas Brown, Treaty Compliance Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482–2163. For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

In providing its advice and consent to the ratification of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and Their Destruction, commonly called the Chemical Weapons Convention (CWC or ''the Convention''), the Senate included, in Senate Resolution 75 (S. Res. 75, April 24, 1997), several conditions to its ratification. Condition 23, titled ''Additions to the Annex on Chemicals,'' calls for the President to submit a report to the Committee on Foreign Relations of the Senate, detailing the likely impact of the proposed addition of a chemical or biological substance to a schedule in the ''Annex on Chemicals.'' This report shall include, inter alia, an assessment of the likely impact on United States industry of the proposed addition. President Trump, in his Memorandum of November 5, 2018 (83 FR 62679, December 4, 2018), delegated the authority to carry out this function to the Secretary of State, in coordination with other U.S. Government departments and agencies (including the Department of Commerce), consistent with the process described in National Security Presidential Memorandum-4 of April 4, 2017 (82 FR 16881, April 6, 2017).

The CWC is an international arms control treaty that contains certain verification provisions. In order to implement these verification provisions, the CWC established the Organization for the Prohibition of Chemical Weapons (OPCW). The CWC imposes certain obligations on countries that have ratified the Convention (*i.e.,* States Parties), among which are the enactment of legislation to prohibit the production, storage, and use of chemical weapons, and the establishment of a National Authority to serve as the national focal point for effective liaison with the OPCW and other States Parties in order to achieve the object and purpose of the Convention and the implementation of its provisions. The CWC also requires each State Party to implement a comprehensive data declaration and inspection regime to provide transparency and to verify that both the public and private sectors of the State Party are not engaged in activities prohibited under the CWC.

''Schedule 1'' chemicals consist of those toxic chemicals and precursors set forth in the CWC ''Annex on Chemicals'' and in Supplement No. 1 to Part 712—Schedule 1 Chemicals of the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710–722). The CWC identified these toxic chemicals and precursors as posing a high risk to the object and purpose of the Convention.

The CWC (Part VI of the ''Verification Annex'') restricts the production of ''Schedule 1'' chemicals for protective purposes to two facilities per State Party: A single small-scale facility (SSSF) and a facility for production in quantities not exceeding 10 kg per year. The CWC Article-by-Article Analysis submitted to the Senate in Treaty Doc. 103–21 defined the term ''protective purposes'' to mean ''used for determining the adequacy of defense equipment and measures.'' Consistent with this definition and as authorized by Presidential Decision Directive (PDD)/NSC–70 (December 17, 1999), which specifies agency and departmental responsibilities as part of the U.S. implementation of the CWC, the Department of Defense (DOD) was assigned the responsibility to operate these two facilities. Although this assignment of responsibility to DOD per PDD/NSC–70 effectively precluded the commercial production of ''Schedule 1'' chemicals for protective purposes in the United States, it did not otherwise establish any limitations on ''Schedule 1'' chemical activities that are not prohibited by the CWC.

The provisions of the CWC that affect commercial activities involving ''Schedule 1'' chemicals are implemented in the CWCR (see 15 CFR 712) and in the Export Administration Regulations (EAR) (see 15 CFR 742.18 and 15 CFR 745), both of which are administered by the Bureau of Industry and Security (BIS). Pursuant to CWC requirements, the CWCR restrict commercial production of ''Schedule 1'' chemicals to research, medical, or pharmaceutical purposes only. The CWCR prohibit commercial production of ''Schedule 1'' chemicals for ''protective purposes'' because such production is effectively precluded per PDD/NSC–70, as described above—see 15 CFR 712.2(a). The CWCR also contain other requirements and prohibitions that apply to ''Schedule 1'' chemicals and/or ''Schedule 1'' facilities. Specifically, the CWCR:

(1) Prohibit the import of ''Schedule 1'' chemicals from States not Party to the Convention (15 CFR 712.2(b));

(2) Require annual declarations by facilities engaged in the production of ''Schedule 1'' chemicals in excess of 100 grams aggregate per calendar year (*i.e.,* declared ''Schedule 1'' facilities) for purposes not prohibited by the Convention (15 CFR 712.5(a)(1) and (a)(2));

(3) Provide for government approval of ''declared Schedule 1'' facilities (15 CFR 712.5(f));

(4) Provide that ''declared Schedule 1'' facilities are subject to initial and routine inspection by the OPCW (15 CFR 712.5(e) and 716.1(b)(1));

(5) Require 200 days advance notification of establishment of new ''Schedule 1'' production facilities producing greater than 100 grams aggregate of ''Schedule 1'' chemicals per calendar year (15 CFR 712.4);

(6) Require advance notification and annual reporting of all imports and exports of ''Schedule 1'' chemicals to, or from, other States Parties to the Convention (15 CFR 712.6, 742.18(a)(1) and 745.1); and

(7) Prohibit the export of ''Schedule 1'' chemicals to States not Party to the Convention (15 CFR 742.18(a)(1) and (b)(1)(ii)).

For purposes of the CWCR (see 15 CFR 710.1), ''production of a Schedule 1 chemical'' means the formation of ''Schedule 1'' chemicals through chemical synthesis, as well as processing to extract and isolate ''Schedule 1'' chemicals produced by a biochemical or biologically mediated reaction. Such production is understood, for CWCR declaration purposes, to include intermediates, by-products, or waste products that are produced and consumed within a defined chemical manufacturing sequence, where such intermediates, by-products, or waste products are chemically stable and therefore exist for a sufficient time to make isolation from the manufacturing stream possible, but where, under normal or design operating conditions, isolation does not occur.

Proposed Addition of Five Families of Chemicals to ''Schedule 1'' in the CWC ''Annex on Chemicals''

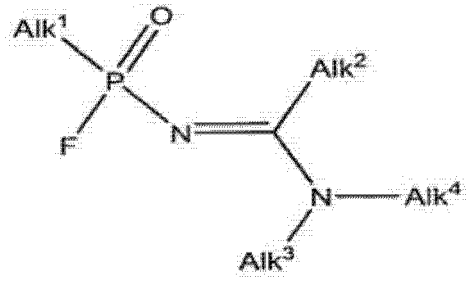
On October 16, 2018 the United States, Canada, and the Netherlands submitted a proposal to the OPCW Director General to add two families of chemicals to ''Schedule 1'' in the CWC ''Annex on Chemicals.'' On December 7, 2018, Russia submitted additional proposals to the Director General, which included adding three additional families to ''Schedule 1.'' However, the CWC States Parties have yet to reach agreement on adding the five chemical families to ''Schedule 1'' in the CWC ''Annex on Chemicals.''

The following five ''Schedule 1'' chemical families are under consideration for being listed as toxic chemicals in ''Schedule 1'' (the addition of the first two chemical families to ''Schedule 1'' was proposed by the United States, Canada, and the Netherlands; the addition of the other three chemical families was proposed by Russia):

(1) P-alkyl-N-fluorophosphonyl amidines

Generic name: P-Alkyl (H or ≤ C10, incl. cycloalkyl) *N*-(1-(dialkyl(≤ C10, incl. cycloalkyl)amino))alkylidene(H or ≤ C10, incl. cycloalkyl) phosphoramidic flourides and corresponding alkylated or protonated salts

Generic structure:

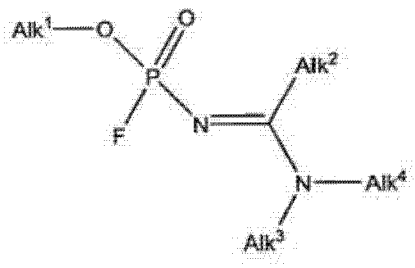


Example: *N*-(1-(di-n-decylamino)-n-decylidene)-*P*-decylphosphonamidic fluoride (No CAS Number)

(2) O-Alkyl-N-fluorophosphorylamidines

Generic name: O-alkyl (H or ≤ C10, incl. cycloalkyl) *N*-(1-(dialkyl(≤ C10, incl. cycloalkyl)amino))alkylidene(H or ≤ C10, incl. cycloalkyl) phosphoramidofluoridates and corresponding alkylated or protonated salts

Generic structure:

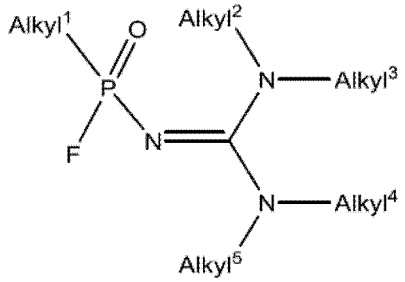


Example: *O*-n-decyl *N*-(1-(di-n-decylamino)-n-decylidene) phosphoramidofluoridate (No CAS Number)

(3) P-alkyl-N-fluorophosphonyl guanidines

Generic name: P-Alkyl (H or ≤ C10, incl. cycloalkyl)-(bis((alkyl (H or ≤ C10, incl. cycloalkyl)alkyl(H or ≤ C10, incl. cycloalkyl)amino))methylene) phosphonamidofluoridates and corresponding alkylated or protonated salts

Generic structure:

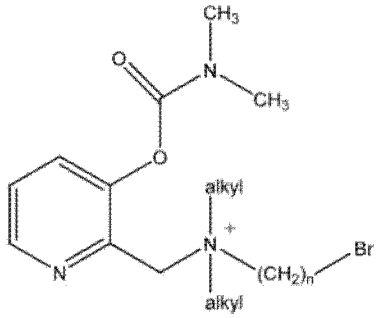


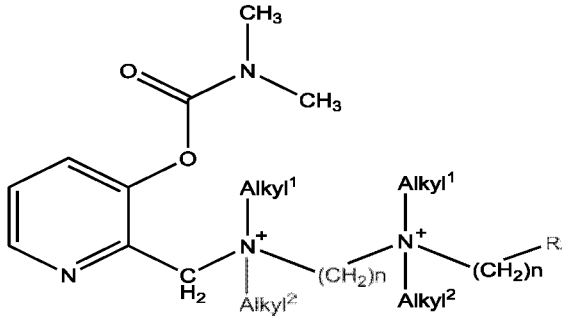
Example: Methyl-(bis(diethylamino)methylene) phosphonamidofluoridate (No CAS Number)

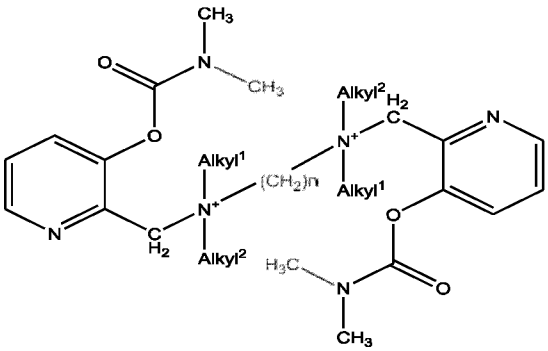
(4) Carbamates (quaternaries and bisquaternaries of dimethylcarbamoyloxypyridines)

Generic names: N-(n-Bromo (Alkyl)-N-(3-dimethylcarbamoxy-α-picolinyl)-N,N-(CnH2n-1, n=1,2,3) ammonium bromide (n=1-10); 1-[N,N-Dialkyl(C≤10)-N-(n-(hydroxyl, cyano, acetoxy)alkyl(C≤10)ammonio]-n-[N-(3-methyl-carbamoxy-α-picolinyl)-N,N-dialkyl(C≤10)ammonio]decane dibromide (n=1-8); 1,n-Bis[N-(3-dimethylcarbamoxy-α-picolyl)-N,N-dialkyl(C≤10)ammonio]-alkane-(2,(n-l)-dione) dibromide (n=2-12)

Generic structures:





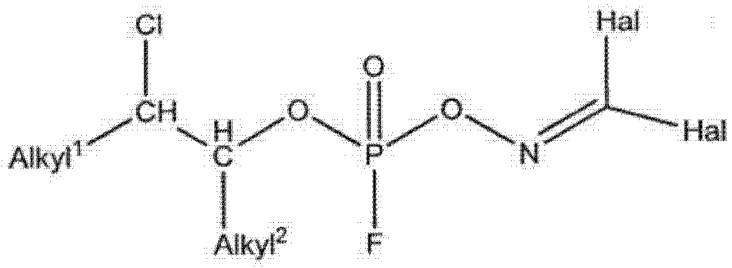


Examples: N-(10-Bromodecyl)-N-(3-dimethylcarbamoxy-α-picolinyl)-N,N-dimethylammonium bromide; 1-[N,N-Dimethyl-*N*-(2-hydroxy)ethylammonio]-10-[*N*-(3-dimethyl-carbamoxy-α-picolinyl)-*N*,*N*-dimethylammonio]decane dibromide (CAS number: 77104-62-2); 1,10-Bis[*N*-(3-dimethylcarbamoxy-*a*-picolyl)-*N*-ethyl-*N*-methylammonio]-decane-2,9-dione dibromide (CAS number: 77104-00-8)

(5) Fluorophosphoryl dihaloformaldoximes (also referred to as substituted ((alkyliden)amino)oxy-phosphates and phosphonates)

Generic name: O-(1-Alkyl(H, Me)-2-alkyl(H, Me)-2-chloroethyl)-(((dihalo(F, Cl)methylene)amino)-oxy)phosphorofluoridates

Generic structure:



Examples: 2-Chloroethyl(((chlorofluoro-methylene)amino)oxy)phosphoro-fluoridate (CAS number: 26102-97-6); 1-Chloropropan-2-yl(((chlorofluoro-methylene)amino)oxy)phosphoro-fluoridate (CAS number: 26102-98-7); 3-Chlorobutan-2-yl(((chlorofluoro-methylene)amino)oxy)phosphoro-fluoridate (CAS number: 26102-99-8)

Request for Comments

BIS is seeking public comments to assist in determining whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States would be significantly harmed by the limitations that would be imposed on access to, and production of, the compounds included in the five chemical families identified above, if the CWC States Parties were to agree to add these chemical families to ''Schedule 1'' in the CWC ''Annex on Chemicals.'' To allow BIS to properly evaluate the significance of any harm to commercial activities involving the proposed ''Schedule 1'' chemical families, public comments submitted in response to this notice of inquiry should include both a quantitative and qualitative assessment of the impact of the CWC on such activities.

Submission of Comments

All comments must be submitted to one of the addresses indicated in this notice. The Department requires that all comments be submitted in written form. BIS will consider all comments received on or before September 13, 2019. All comments (including any personally identifying information or information for which a claim of confidentially is asserted either in those comments or their transmittal emails) will be made available for public inspection and copying. Parties who wish to comment anonymously may do so by submitting their comments via *Regulations.gov*, leaving the fields that would identify the commenter blank and including no identifying information in the comment itself.

Dated: August 6, 2019.

Richard E. Ashooh,

Assistant Secretary for Export Administration.

[FR Doc. 2019–17256 Filed 8–13–19; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–868]

Large Residential Washers From the Republic of Korea: Rescission of Antidumping Duty Administrative Review; 2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding its administrative review of the antidumping duty (AD) order on large residential washers (washers) from the Republic of Korea (Korea) for the period of review (POR) February 1, 2018, through February 14, 2018.

DATES: Applicable August 14, 2019.

FOR FURTHER INFORMATION CONTACT: David Goldberger or Ian Hamilton, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4136 or (202) 482–4798, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 8, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on washers from Korea for the POR.[1] Commerce received timely requests from Whirlpool Corporation (the petitioner) and LG Electronics, Inc. (LGE), in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), to conduct an administrative review of this AD order for LGE.[2]

On April 30, 2019, the International Trade Commission determined that revocation of the AD order on washers from Korea would not be likely to lead to a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time, pursuant to section 751(c) of the Act.[3] Therefore, on May 6, 2019, Commerce revoked the AD order on washers from Korea effective February 15, 2018.[4]

On May 2, 2019, Commerce published in the **Federal Register** a notice of

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 84 FR 2816 (February 8, 2019).

[2] *See* Petitioner's Letter, ''Large Residential Washers from Korea: Request for Administrative Review of Antidumping Order,'' dated February 26, 2019; *see also* LGE Letter, ''LG Electronics' Request for Antidumping Administrative Review Large Residential Washers from Korea,'' dated February 28, 2019.

[3] *See Certain Large Residential Washers from Korea and Mexico,* 84 FR 18319 (April 30, 2019). *See also Certain Large Residential Washers from Korea and Mexico (Inv. Nos. 701–TA–488 and 731–TA–1199–1200 (Review)),* USITC Publication 4882 (April 2019).

[4] *See Large Residential Washers from Mexico and the Republic of Korea: Continuation of Antidumping Duty Order (Mexico) and Revocation of Antidumping and Countervailing Duty Orders (Korea),* 84 FR 19763 (May 6, 2019).

initiation of administrative review with respect to LGE.[5] As a result of the revocation of the AD order, the POR of this administrative review is February 1, 2018, through February 14, 2018.

On July 26, 2019, both the petitioner and LGE timely withdrew their requests for an administrative review of LGE.[6]

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation of the requested review. The petitioner and LGE withdrew their requests for review before the 90-day deadline, and no other party requested an administrative review of this order. Therefore, we are rescinding the administrative review of the AD order on washers from Korea covering the period February 1, 2018, through February 14, 2018.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Because Commerce is rescinding this administrative review in its entirety, the entries to which this administrative review pertained shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of this notice in the **Federal Register.**

Notification to Importers

This notice serves as the only reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement may result in the presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: August 7, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–17429 Filed 8–13–19; 8:45 am]

BILLING CODE 3510–DS–P

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 18777, 18782 (May 2, 2019).

[6] *See* Petitioner's Letter, ''Large Residential Washers from Korea: Withdrawal of Request for Administrative Review of Antidumping Order,'' dated July 26, 2019; *see also* LGE Letter, ''LG Electronics' Withdrawal of Request for Antidumping Administrative Review Large Residential Washers from Korea,'' dated July 26, 2019.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–978]

High Pressure Steel Cylinders From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review; 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that producers and/or exporters subject to this administrative review received countervailable subsidies. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable August 14, 2019.

FOR FURTHER INFORMATION CONTACT: Nicholas Czajkowski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1395.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2018, Commerce published a notice of opportunity to request an administrative review of the countervailing duty order on high pressure steel cylinders from the People's Republic of China (China) for the period of review January 1, 2017 through December 31, 2017.[1] On June 28, 2018 and June 29, 2018, we received review requests from Norris Cylinder Company (the petitioner) and Beijing Tianhai Industry Co., Ltd. (BTIC).[2] We published a notice of initiation for this administrative review on August 10, 2018.[3] We exercised our discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 29, 2019.[4] The revised deadline for the preliminary results of this administrative review thus became April 11, 2019. On March 14, 2019, we postponed the deadline for issuing the preliminary results of this administrative review until August 9, 2019.[5] For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[6]

A list of topics discussed in the Preliminary Decision Memorandum is provided in the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 83 FR 25429 (June 1, 2018).

[2] *See* Petitioner's Letter, ''High Pressure Steel Cylinders from the People's Republic of China: Request for Administrative Review and Entry of Appearance,'' dated June 28, 2018; *see also* BTIC's Letter, ''Request for the Sixth Administrative Review of the Countervailing Duty Order on High Pressure Steel Cylinders from the People's Republic of China, C–570–978 (POR: 01/01/17–12/31/17),'' dated June 29, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 39688 (August 10, 2018).

[4] *See* Memorandum, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[5] *See* Memorandum, ''High Pressure Steel Cylinders from the People's Republic of China: Extension of Time Limit for Preliminary Results of the Countervailing Duty Administrative Review; 2017,'' dated March 14, 2019.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of 2017 Countervailing Duty Administrative Review of High Pressure Steel Cylinders from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

complete version of the Preliminary Decision Memorandum can be accessed directly at *https://enforcement.trade.gov/frn/*. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The merchandise subject to the order is seamless steel cylinders designed for storage or transport of compressed or liquefied gas (high pressure steel cylinders). The high pressure steel cylinders subject to the order are currently classifiable under subheadings 7311.00.00.30 of the Harmonized Tariff Schedule of the United States (HTSUS) and may also enter under HTSUS subheadings 7311.00.00.60 or 7311.00.00.90. While the HTSUS subheadings are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.

Methodology

We are conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily find that there is a subsidy, *i.e.,* a financial contribution by an authority that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.[8]

In making these findings, we relied, in part, on facts available, and because we find that the Government of China (GOC) did not act to the best of its ability to respond to our requests for information, we drew an adverse inference where appropriate in selecting from among the facts otherwise available.[9] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

Preliminary Results of the Review

We preliminarily find that the following net countervailable subsidy rate exists for the mandatory respondent, BTIC, for the period of review January 1, 2017 through December 31, 2017:

Company	Subsidy rate *Ad Valorem* (percent)
Beijing Tianhai Industry Co., Ltd.[10]	30.62

Assessment Rates

Upon issuance of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue assessment instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

Pursuant to section 751(a)(2)(C) of the Act, we also intend, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amount indicated above for BTIC, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We will disclose to parties in this review the calculations performed in reaching the preliminary results within five days of publication in the **Federal Register** of these preliminary results.[11] Unless Commerce instructs otherwise, interested parties may submit written comments (case briefs) on the preliminary results no later than 30 days from the date of publication of this notice in the **Federal Register**, and rebuttal comments (rebuttal briefs) within five days after the time limit for filing case briefs.[12] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[13]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to the issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.[14] Hearing requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a date and time to be determined.[15] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, we intend to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, no later than 120 days after the date of publication of this notice. These preliminary results and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: August 7, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Diversification of China's Economy
V. Subsidies Valuation Information
VI. Benchmarks and Discount Rates
VII. Use of Facts Otherwise Available and Adverse Inferences
VIII. Analysis of Programs
IX. Disclosure and Public Comment
X. Conclusion

[FR Doc. 2019–17432 Filed 8–13–19; 8:45 am]

BILLING CODE 3510–DS–P

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5)(A) of the Act regarding specificity.

[8] A list of topics discussed in the Preliminary Decision Memorandum can be found in the appendix to this notice.

[9] *See* sections 776(a) and (b) of the Act.

[10] As discussed in the Preliminary Decision Memorandum, we have found the following companies to be cross-owned with BTIC: Tianjin Tianhai High Pressure Container Co., Ltd.; Langfang Tianhai High Pressure Container Co., Ltd.; Beijing Jingcheng Machinery Electric Holding Co., Ltd.; and Beijing Jingcheng Machinery Electric Co., Ltd.

[11] *See* 19 CFR 351.224(b).

[12] *See* 19 CFR 351.309(c)(1)(ii) and (d)(1); and 19 CFR 351.303 (for general filing requirements).

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

[14] *See* 19 CFR 351.310(c).

[15] *See* 19 CFR 351.310(d).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–806]

Silicon Metal From the People's Republic of China: Preliminary Rescission of the Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Yunnan Fuyang Trade Co., Ltd. (Fuyang), the sole company under review, did not make a *bona fide* sale for antidumping purposes during the period of review (POR) June 1, 2017 through May 31, 2018. Thus, Commerce is preliminarily rescinding this review. We invite interested parties to comment on these preliminary results.

DATES: Applicable August 14, 2019.

FOR FURTHER INFORMATION CONTACT: Eli Lovely, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1593.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the notice of initiation of this review on August 10, 2018.[1] On January 28, 2019, Commerce exercised its discretion to toll all deadlines affected by the closure of the federal government from December 22, 2018 through January 28, 2019.[2] Pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended these preliminary results by 120 days, until August 9, 2019.[3] For a complete discussion of the background of this review, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The product covered by the order is silicon metal containing at least 96.00 but less than 99.99 percent of silicon by weight, and silicon metal with a higher aluminum content containing between 89 and 96 percent silicon by weight. The subject merchandise is currently classifiable under item numbers 2804.69.10 and 2804.69.50 of the Harmonized Tariff Schedule of the United States (HTSUS) as a chemical product, but is commonly referred to as a metal. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.[5]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act and (2) of the Act. For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum, which is hereby adopted by this notice. The topics discussed in the Preliminary Decision Memorandum are listed in the Attachment to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Bona Fides Analysis

As discussed in the *Bona Fide* Sales Analysis Memorandum,[6] Commerce preliminarily finds that the sale made by Fuyang serving as the basis for this review is not a *bona fide* sale for antidumping purposes. Commerce reached this conclusion based on the totality of the following circumstances regarding Fuyang's reported sale: The price and quantity of the U.S. sale; concerns regarding the resale's profitability and the arm's-length nature of the transaction; the limited number of sales (*i.e.,* one sale) that Fuyang reported during the POR; and other factors relevant as to whether the sale under review is likely to typical of future sales.

Preliminary Rescission of Review

Because the non-*bona fide* sale was the only reported sale of subject merchandise during the POR, we find that Fuyang had no reviewable transactions during this POR. Accordingly, we are preliminarily rescinding this administrative review.[7] Given that the factual information used in our *bona fides* analysis of Fuyang's sale involves business proprietary information, see the *Bona Fide* Sales Analysis Memorandum for a full discussion of the basis for our preliminary determination.

Public Comment

Interested parties may submit case briefs no later than 30 days after the date of publication of the preliminary results of review.[8] Rebuttals to case briefs may be filed no later than five days after the briefs are filed.[9] All rebuttal comments must be limited to comments raised in the case briefs.[10]

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement & Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice.[11] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. Oral argument presentations will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a date and time to be determined.[12] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

All submissions, with limited exceptions, must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time (ET) on the due date. Documents excepted from the electronic

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 39688 (August 10, 2018) (*Initiation Notice*).

[2] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[3] *See* Memorandum, ''Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated March 12, 2019.

[4] *See* Decision Memorandum for the Preliminary Rescission of the Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China; 2017–2018 (Preliminary Decision Memorandum), dated concurrently with, and hereby adopted by, this notice.

[5] For a complete description of the scope of the order, *see* Preliminary Decision Memorandum.

[6] *See* Memorandum, ''2017–2018 Antidumping Duty Administrative Review of Silicon Metal from the People's Republic of China: Preliminary *Bona Fide* Sales Analysis for Yunnan Fuyang Trade Co., Ltd.,'' dated concurrently with this notice (*Bona Fide* Sale Analysis Memorandum).

[7] *See* 19 CFR 351.213(d)(3).

[8] *See* 19 CFR 351.309(c)(ii).

[9] *See* 19 CFR 351.309(d)(1).

[10] *See* 19 CFR 351.309(d)(2).

[11] *See* 19 CFR 351.310(c).

[12] *See* 19 CFR 351.310(d).

submission requirements must be filed manually (*i.e.,* in paper form) with the APO/Dockets Unit in Room 18022, and stamped with the date and time of receipt by 5 p.m. ET on the due date.[13]

Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any briefs received, no later than 120 days after the date these preliminary results of review are published, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

If Commerce proceeds to a final rescission of this administrative review, the assessment rate to which Fuyang's shipments will be subject will not be affected by this review. If Commerce does not proceed to a final rescission of this administrative review, pursuant to 19 CFR 351.212(b)(1), we will calculate importer-specific (or customer-specific) assessment rates based on the final results of this review.

Cash Deposit Requirements

If Commerce proceeds to a final rescission of this administrative review, Fuyang's cash deposit rate will continue to be the China-wide entity rate of 139.49 percent. If Commerce does not proceed to a final rescission of this administrative review, but calculates a dumping margin for Fuyang, we will instruct CBP to collect a cash deposit, effective upon the publication of the final results, at the dumping rate calculated for Fuyang.

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(l) and 777(i)(l) of the Act and 19 CFR 351.213.

Dated: August 6, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Recommendation

[FR Doc. 2019–17430 Filed 8–13–19; 8:45 am]

BILLING CODE 3510–DS–P

[13] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XT009

Atlantic Highly Migratory Species; Meeting of the Atlantic Highly Migratory Species Advisory Panel

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

ACTION: Notice of public meeting and webinar/conference call.

SUMMARY: NMFS will hold a 2-day Atlantic Highly Migratory Species (HMS) Advisory Panel (AP) meeting in September 2019. The intent of the meeting is to consider options for the conservation and management of Atlantic HMS. The meeting is open to the public.

DATES: The AP meeting and webinar will be held from 8:30 a.m. to 6 p.m. on Wednesday, September 4 and 8:30 a.m. to 12:00 p.m. on Thursday, September 5.

ADDRESSES: The meeting will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Avenue, Silver Spring, MD 20910. The meeting presentations will also be available via WebEx webinar/conference call.

The meeting on Wednesday, September 4, and Thursday, September 5, will also be accessible via conference call and webinar. Conference call and webinar access information are available at: *https://www.fisheries.noaa.gov/event/september-2019-hms-advisory-panel-meeting.*

Participants are strongly encouraged to log/dial in 15 minutes prior to the meeting. NMFS will show the presentations via webinar and allow public comment during identified times on the agenda.

FOR FURTHER INFORMATION CONTACT: Craig Cockrell or Peter Cooper at (301) 427–8503.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.,* as amended by the Sustainable Fisheries Act, Public Law 104–297, provided for the establishment of an AP to assist in the collection and evaluation of information relevant to the development of any FMP or FMP amendment for Atlantic HMS. NMFS consults with and considers the comments and views of AP members when preparing and implementing FMPs or FMP amendments for Atlantic tunas, swordfish, billfish, and sharks.

The AP has previously consulted with NMFS on: Amendment 1 to the Billfish FMP (April 1999); the HMS FMP (April 1999); Amendment 1 to the HMS FMP (December 2003); the Consolidated HMS FMP (October 2006); and Amendments 1, 2, 3, 4, 5a, 5b, 6, 7, 8, 9, 10, 11, 12, 13, and 14 to the 2006 Consolidated HMS FMP (April and October 2008, February and September 2009, May and September 2010, April and September 2011, March and September 2012, January and September 2013, April and September 2014, March and September 2015, March, September, and December 2016, May and September 2017, March and September 2018, and May 2019), among other things.

The intent of this meeting is to consider alternatives for the conservation and management of all Atlantic tunas, swordfish, billfish, and shark fisheries. We anticipate discussing:

- Presentation on the Amendment 12 Issues and Options document;
- Summary of comments from Amendment 13, Amendment 14, and Research and Data Collection in Support of Spatial Fisheries Management scoping;
- A summary of the Atlantic Tunas General category cost earnings survey;
- Recreational fishery issues;
- An overview on shark interactions with commercial and recreational fisheries.

We also anticipate inviting other NMFS offices and the United States Coast Guard to provide updates, if available, on their activities relevant to HMS fisheries.

Additional information on the meeting and a copy of the draft agenda will be posted prior to the meeting at: *https://www.fisheries.noaa.gov/event/may-2019-hms-advisory-panel-meeting.*

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Craig Cockrell at (301) 427–8503 at least 7 days prior to the meeting.

Dated: August 8, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–17365 Filed 8–13–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Termination of the Chief of Engineers Environmental Advisory Board

AGENCY: Department of Defense.

ACTION: Termination of Federal Advisory Committee.

SUMMARY: The Department of Defense is publishing this notice to announce that it is terminating the Chief of Engineers Environmental Advisory Board (''the Board''), effective August 31, 2019.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Board is being terminated under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix) and 41 CFR 102–3.55, and the Government in the Sunshine Act of 1976 (5 U.S.C. 552b), effective August 31, 2019.

Dated: August 8, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–17381 Filed 8–13–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of the Record of Decision for the Final Supplemental Environmental Impact Statement/Supplemental Overseas Environmental Impact Statement (SEIS/SOEIS) for Surveillance Towed Array Sensor System (SURTASS) Low Frequency Active (LFA) Sonar

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The United States Department of the Navy (DoN), announces its decision to continue utilizing SURTASS LFA and Compact LFA sonar systems (LFA hereafter inclusive of both systems) onboard United States Navy surveillance ships for training and testing activities conducted under the authority of the Secretary of the Navy in the western and central North Pacific and eastern Indian Oceans, including certain geographical restrictions, as described in Alternative 2 of the June 2019 Final SEIS/SOEIS for SURTASS LFA Sonar. Under Alternative 2, the DoN will be able to meet current and future DoN training and testing requirements.

SUPPLEMENTARY INFORMATION: Alternative 2 is the DoN's preferred alternative, and provides for additional training and testing capacity for vessels to participate in at-sea exercises, to conduct acoustic research testing, and to conduct new SURTASS LFA sonar system testing. The complete text of the Record of Decision (ROD) for the June 2019 Final SEIS/SOEIS for SURTASS LFA Sonar is available on the project website at *http://www.surtass-lfa-eis.com/,* along with the June 2019 Final SEIS/SOEIS for SURTASS LFA Sonar and supporting documents. Single copies of the ROD are available upon request by contacting: Chief of Naval Operations Energy and Environmental Readiness Division, Attn: SURTASS LFA SONAR SEIS/SOEIS Project Manager, 2000 Navy Pentagon Rm. 2D253, Washington DC, 20350–2000.

Dated: August 9, 2019.

D.J. Antenucci,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2019–17427 Filed 8–13–19; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2019–ICCD–0098]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; DC School Choice/DC Opportunity Scholarship Program Application

AGENCY: Office of Elementary and Secondary (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 13, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0098. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9089, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Norris Dickard, 202–453–6723.

SUPPLEMENTARY INFORMATION: ED, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps ED assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand ED's information

collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. ED is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of ED; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might ED enhance the quality, utility, and clarity of the information to be collected; and (5) how might ED minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: DC School Choice Application.

OMB Control Number: 1855–0015.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 3,000.

Total Estimated Number of Annual Burden Hours: 1,000.

Abstract: The DC Opportunity Scholarship Program, authorized by the Consolidated Appropriations Act of 2004, and reauthorized in 2017 by the *Scholarships for Opportunity and Results (SOAR) Reauthorization Act,* awarded a grant to Serving Our Children in order to administer scholarships to students who reside in the District of Columbia and come from households whose incomes do not exceed 185% of the poverty line. To assist in the student selection and assignment process, the information collected is used to determine the eligibility of those students who are interested in the available scholarships. Also, since the authorizing statute requires an evaluation we are proposing to collect certain family demographic information because they are important predictors of school success. Finally, we are asking to collect information about parental participation and satisfaction because these are key topics that the statute requires the evaluation to address. This request adds revised versions of two questions previously approved by OMB.

Dated: August 9, 2019.

Stephanie Valentine,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–17426 Filed 8–13–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0097]

Agency Information Collection Activities; Comment Request; RISE Award

AGENCY: Department of Education (ED), Office of Communications and Outreach (OCO)

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before October 15, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0097. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9089, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Andrea Falken, 202–503–8985.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: RISE Award.

OMB Control Number: 1860–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 120.

Total Estimated Number of Annual Burden Hours: 4,920.

Abstract: The purpose of the Recognizing Inspirational School Employees (RISE) Award is to recognize and promote the commitment and excellence exhibited by classified school employees who provide exemplary service to students in pre-kindergarten through high school and to inspire innovation and excellence among all classified school employees. A classified school employee is an employee of a state or any political subdivision of a state, or an employee of a nonprofit entity, who works in any grade from pre-kindergarten through high school in any of the following occupational specialties: Paraprofessional, clerical and administrative services, transportation services, food and nutrition services, custodial and maintenance services, security services, health and student services, technical services, and skilled trades. The terms used have the meaning given the terms in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801). The U.S. Department of Education (Department) invites the governor of each state to nominate up to two classified school employees by November 30, 2020. The Secretary of Education will select a single classified school employee to receive the RISE Award for that school year by spring 2021. The Department will communicate the selectee's story in order to inspire other innovative

practices and excellence among classified school employees.

Dated: August 9, 2019.

Stephanie Valentine,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–17428 Filed 8–13–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Request for Comment on the DOE Cybersecurity Capability Maturity Model Version 2.0

AGENCY: Office of Cybersecurity, Energy Security, and Emergency Response; Department of Energy.

ACTION: Notice of availability; request for comment.

SUMMARY: Through this notice, the Department of Energy (DOE) seeks comments and information from the public on enhancements to the Cybersecurity Capability Maturity Model (C2M2) Version 2.0. C2M2 Version 2.0 incorporates enhancements to align model domains and functional questions with internationally-recognized cyber standards and best practices, including the NIST Cybersecurity Framework Version 1.1 released in April 2018. Since C2M2's last update, new cybersecurity standards have been developed and existing standards have improved. Both technology and threat actors have become more sophisticated, creating new attack vectors and introducing new risks. DOE intends to address these challenges in version 2.0 of C2M2.

DATES: Comments and information are requested by September 13, 2019.

ADDRESSES: Copies of the draft maturity model are available for public inspection at the U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0121. Public inspection can be conducted between 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays. These documents can also be accessed online at *http://www.energy.gov/ceser/downloads/public-comment-draft-c2m2-v2.*

FOR FURTHER INFORMATION CONTACT: Mr. Timothy Kocher, Special Advisor, U.S. Department of Energy, Office of Cybersecurity, Energy Security, and Emergency Response, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0121. Tel.: (202) 586–5281. Email: *timothy.kocher@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: C2M2 Version 2.0 leverages and builds upon existing efforts, models, and cybersecurity best practices to advance the model by adjusting to new technologies, practices, and environmental factors. The initiative also accounts for the strategic guidance of E.O. 13800, *Strengthening the Cybersecurity of Federal Networks and Critical Infrastructure,* and E.O. 13636, *Improving Critical Infrastructure Cybersecurity,* aiming to strengthen and improve the nation's cyber posture and capabilities and to reinforce systematic security and resilience. As industry's use of networked technologies has grown, malicious actors have increasingly targeted the safe and reliable supply of energy. These challenges, along with the evolution of cyber practices, necessitated the C2M2 Version 2.0 update.

A *maturity model* is a set of characteristics, attributes, indicators, or patterns that represent capability and progression in a particular discipline. Model content typically exemplifies best practices and may incorporate standards or other codes of practice of the discipline.

A maturity model thus provides a benchmark against which an organization can evaluate the current level of capability of its practices, processes, and methods and set goals and priorities for improvement. Also, when a model is widely used in a particular industry (and assessment results are shared), organizations can benchmark their performance against other organizations. An industry can determine how well it is performing overall by examining the capability of its member organizations.

The C2M2 is meant to be used by an organization to evaluate its cybersecurity capabilities consistently, to communicate its capability levels in meaningful terms, and to inform the prioritization of its cybersecurity investments. An organization performs an evaluation against the model, uses that evaluation to identify gaps in capability, prioritizes those gaps and develops plans to address them, and finally implements plans to address the gaps. As plans are implemented, business objectives change, and the risk environment evolves, the process is repeated.

To measure progression, maturity models typically have ''levels'' along a scale—C2M2 uses a scale of maturity indicator levels (MILs) 0–3, which are described in Section 4.2. A set of attributes defines each level. If an organization demonstrates these attributes, it has achieved both that level and the capabilities that the level represents. Having measurable transition states between the levels enables an organization to use the scale to:

- Define its current state
- Determine its future, more mature state
- Identify the capabilities it must attain to reach that future state

The model arises from a combination of existing cybersecurity standards, frameworks, programs, and initiatives. The model provides flexible guidance to help organizations develop and improve their cybersecurity capabilities. As a result, the model practices tend to be at a high level of abstraction, so that they can be interpreted for organizations of various structures and sizes.

The model is organized into 10 domains. Each domain is a logical grouping of cybersecurity practices. The practices within a domain are grouped by objective—target achievements that support the domain. Within each objective, the practices are ordered by MIL.

The C2M2 Version 2.0 initiative leverages and builds upon existing efforts, models, and cybersecurity best practices to advance the model by adjusting to new technologies, practices, and environmental factors that have occurred since the Version 1.1 release.

Advances Between C2M2 Versions 1.1 to 2.0

The C2M2 Version 2.0 was necessitated by advancements in technologies, practices, and frameworks to protect critical infrastructure against cyber intrusions. A comprehensive review of all domains and MILs conducted by teams of industry experts ensured C2M2 Version 1.1 user concerns were addressed and revisions to domains and MILs were achieved in accordance with user feedback. C2M2 Version 2.0 builds upon initial development activities and was further developed through the following approach:

Public–private partnership: Numerous government, industry, and academic organizations participated in the development of this model, bringing a broad range of knowledge, skills, and experience to the team. The model was developed collaboratively with an industry advisory group through a series of working sessions, and it was revised based on feedback from more than 60 industry experts with extensive experience using Version 1.1.

Best practices and sector alignment: The model builds upon and ties together a number of existing cybersecurity resources and initiatives and was informed by a review of cyber threats to the energy sector. Leveraging related works shortened the development schedule and helped to ensure that the model would be relevant and beneficial to the sector.

Descriptive, not prescriptive: This model was developed to provide descriptive, not prescriptive, guidance to help organizations develop and improve their cybersecurity capabilities. As a result, the model practices tend to be abstract so that they can be interpreted for entities of various structures, functions, and sizes.

Fast-paced development: The development effort focused on quickly developing a model that would provide value to the energy sector and be available as soon as possible. The sector has widely adopted the model and provided valuable feedback for improvements.

The model has also been enhanced to account for updates made to the NIST Cybersecurity Framework. While aligning with the NIST Framework and accounting for Version 1.1 comments, the development of Version 2.0 updates include the following:

- Establishing a Cybersecurity Architecture domain
- Separating the MILs from the Information Sharing and Communications domain to include sharing practices in the Threat and Vulnerability Management and Situational Awareness domains
- Movement of Continuity of Operations MILs from the Incident and Event Response to the Cybersecurity Program Management domain to account for continuity activities beyond response events
- Increasing the use of common language throughout the model

A mapping of C2M2 Version 1.1 to 2.0 will be included in Appendix B in the final document to ensure existing users can understand variations from historical evaluation scoring to continue the maturation process with the changes to the model.

Signed in Washington, DC, on August 7, 2019.

Timothy Kocher,

Special Advisor, Office of Cybersecurity, Energy Security, & Emergency Response, U.S. Department of Energy.

[FR Doc. 2019–17446 Filed 8–13–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2058–098]

Avista Corporation; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC's) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed Avista Corporation's application for an amendment to the license for the Clark Fork Hydroelectric Project (FERC Project No. 2058), and have prepared an Environmental Assessment (EA) for the proposed amendment. The licensee proposes to construct and operate a permanent upstream fish passage facility at the project's Cabinet Gorge development. The project is located on the Clark Fork River in Bonner County, Idaho and Sanders County, Montana and occupies federal land within the Idaho Panhandle, Lolo, and Kootenai National Forests administered by the U.S. Forest Service.

The EA contains Commission staff's analysis of the potential environmental effects of the proposed amendment to the license, and concludes that the proposed amendment, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, 202–502–8659.

You may also register online at *www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support. For further information, contact Marybeth Gay at (202) 502–6125.

Dated: August 8, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–17396 Filed 8–13–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2126–005.
Applicants: Idaho Power Company.
Description: Supplement to June 21, 2019 Updated Market Power Analysis for the Northwest Region of Idaho Power Company.
Filed Date: 8/6/19.
Accession Number: 20190806–5165.
Comments Due: 5 p.m. ET 8/27/19.

Docket Numbers: ER10–2575–009.
Applicants: Watson Cogeneration Company.
Description: Supplement to June 28, 2019 Updated Market Power Analysis (Exhibits A & B, Watson Screens, Appendix B) of Watson Cogeneration Company.
Filed Date: 7/8/19.
Accession Number: 20190708–5147.
Comments Due: 5 p.m. ET 7/29/19.

Docket Numbers: ER10–2575–010.
Applicants: Watson Cogeneration Company.
Description: Supplement to June 28, 2019 Notification of Change in Status (Watson Screens) of Watson Cogeneration Company.
Filed Date: 7/8/19.
Accession Number: 20190708–5148.
Comments Due: 5 p.m. ET 7/29/19.

Docket Numbers: ER13–1865–003.
Applicants: Tesoro Refining & Marketing Company LLC.
Description: Supplement to June 28, 2019 Updated Market Power Analysis (Exhibits A & B, TRMC Screens) of Tesoro Refining & Marketing Company LLC.
Filed Date: 7/8/19.
Accession Number: 20190708–5153.
Comments Due: 5 p.m. ET 7/29/19.

Docket Numbers: ER13–1865–004.
Applicants: Tesoro Refining & Marketing Company LLC.
Description: Supplement to June 28, 2019 Notification of Change in Status (TRMC Screens) of Tesoro Refining & Marketing Company LLC.
Filed Date: 7/8/19.
Accession Number: 20190708–5146.
Comments Due: 5 p.m. ET 7/29/19.

Docket Numbers: ER19–192–001.
Applicants: Great Plains Windpark Legacy, LLC.
Description: Notice of Non-Material Change in Status of Great Plains Windpark Legacy, LLC.
Filed Date: 8/7/19.

Accession Number: 20190807–5143.
Comments Due: 5 p.m. ET 8/28/19.

Docket Numbers: ER19–2265–000.
Applicants: TransCanada Energy Sales Ltd.
Description: Supplement to June 26, 2019 TransCanada Energy Sales Ltd. tariff filing.
Filed Date: 8/8/19.
Accession Number: 20190808–5092.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2543–000.
Applicants: New York Independent System Operator, Inc., Central Hudson Gas & Electric Corporation, Niagara Mohawk Power Corporation.
Description: § 205(d) Rate Filing: EPC Agreement (SA 2449) re: NYISO, NMPC, Central Hudson, et al to be effective 6/28/2019.
Filed Date: 8/7/19.
Accession Number: 20190807–5088.
Comments Due: 5 p.m. ET 8/28/19.

Docket Numbers: ER19–2544–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: BPA AC Intertie Agreement 15th Revised to be effective 10/27/2019.
Filed Date: 8/7/19.
Accession Number: 20190807–5102.
Comments Due: 5 p.m. ET 8/28/19.

Docket Numbers: ER19–2545–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original ISA, SA No. 5448; Queue No. AD2–070 to be effective 7/9/2019.
Filed Date: 8/7/19.
Accession Number: 20190807–5122.
Comments Due: 5 p.m. ET 8/28/19.

Docket Numbers: ER19–2546–000.
Applicants: Tuscola Wind II, LLC.
Description: Baseline eTariff Filing: Reactive Power Compensation Filing to be effective 9/29/2019.
Filed Date: 8/8/19.
Accession Number: 20190808–5000.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2547–000.
Applicants: Pheasant Run Wind, LLC.
Description: Baseline eTariff Filing: Pheasant Run Reactive Power Compensation Re-Filing to be effective 9/29/2019.
Filed Date: 8/8/19.
Accession Number: 20190808–5002.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2548–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3558 WAPA, MDU & MISO Interconnection Agreement to be effective 12/31/9998.
Filed Date: 8/8/19.
Accession Number: 20190808–5005.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2549–000.
Applicants: NorthWestern Corporation.
Description: NorthWestern Corporation submits Average System Cost Filing for Sales of Electric Power to the Bonneville Power Administration, FY 2020–2021.
Filed Date: 8/8/19.
Accession Number: 20190808–5017.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2550–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–08–08_SA 3313 WAPA–MDU Interconnection Agreement to be effective 12/31/9998.
Filed Date: 8/8/19.
Accession Number: 20190808–5019.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2551–000.
Applicants: Beech Ridge Energy LLC.
Description: § 205(d) Rate Filing: Amended Assignment, Co-Tenancy, and Shared Facilities Agreement to be effective 10/8/2019.
Filed Date: 8/8/19.
Accession Number: 20190808–5055.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2552–000.
Applicants: Beech Ridge Energy II LLC.
Description: § 205(d) Rate Filing: Amended Assignment, Co-Tenancy, and Shared Facilities Agreement to be effective 10/8/2019.
Filed Date: 8/8/19.
Accession Number: 20190808–5056.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2553–000.
Applicants: Beech Ridge Energy Storage LLC.
Description: § 205(d) Rate Filing: Amended Assignment, Co-Tenancy, and Shared Facilities Agreement to be effective 10/8/2019.
Filed Date: 8/8/19.
Accession Number: 20190808–5057.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2554–000.
Applicants: Alabama Power Company.
Description: § 205(d) Rate Filing: Randolph County Solar LGIA Amendment Filing to be effective 5/3/2019.
Filed Date: 8/8/19.
Accession Number: 20190808–5061.
Comments Due: 5 p.m. ET 8/29/19.

Docket Numbers: ER19–2555–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: Implementation Agreement (SA 2474) re: Fuel Oil NYISO & Astoria Generating to be effective 10/8/2019.
Filed Date: 8/8/19.
Accession Number: 20190808–5068.
Comments Due: 5 p.m. ET 8/29/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 8, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–17397 Filed 8–13–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3063–022]

Gelardin Bruner Cott Inc.; Notice of Application for After the Fact Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

On March 29, 2019, Gelardin Bruner Cott Inc. (GBC) (licensee) filed an application for an after-the-fact transfer of license for the Central Falls Hydroelectric Project (project) No. 3063, located on the Blackstone River in Central Falls, Providence County, Rhode Island.

On August 28, 1981, the Commission issued a minor license to GBC, with three principal officers: Robert Gelardin, Simone Bruner, and Leland Cott. Prior to license issuance on June 15, 1981, GBC formed a limited partnership, Blackstone Hydro Associates (BHA), to acquire the necessary real property interests and rights for project construction and maintenance. Subsequent to license issuance, project's construction and maintenance was achieved by BHA. The licensee has recently learned during the relicensing of the project that the license for the project had not been formally changed from GBC to BHA. The licensee seeks an

after-the-fact approval of the transfer of license.

Applicant's Contact: For transferor/transferee: Mr. Robert Leahly, BHA, 130 Prospect Street, Cambridge, MA 02139, Phone: 617–491–2320, Email: *bleahly@theshorelinecorp.com.*

FERC Contact: Kim A. Nguyen, (202) 502–6105, *kim.nguyen@ferc.gov.*

Deadline for filing comments, motions to intervene, and protests: 30 days from the date that the Commission issues this notice. The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–3063–022.

Dated: August 8, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–17395 Filed 8–13–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR19–70–000.

Applicants: Columbia Gas of Ohio, Inc.

Description: Tariff filing per 284.123(b),(e)/: COH Rates effective July 31 2019 to be effective 7/31/2019.

Filed Date: 8/7/19.

Accession Number: 201908075109.

Comments/Protests Due: 5 p.m. ET 8/28/19.

Docket Numbers: CP19–496–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Abbreviated Application for the Abandonment of Service under Rate Schedule X–234 of Transcontinental Gas Pipe Line Company, LLC under CP19–496.

Filed Date: 8/2/19.

Accession Number: 20190802–5187.

Comments Due: 5 p.m. ET 8/23/19.

Docket Numbers: RP19–1060–001.

Applicants: WBI Energy Transmission, Inc.

Description: Compliance filing 2019 Compliance Filing on 7–29–19 Order on Filings in with Order No. 587–Y to be effective 8/1/2019.

Filed Date: 8/6/19.

Accession Number: 20190806–5118.

Comments Due: 5 p.m. ET 8/19/19

Docket Numbers: RP19–1457–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 080619 Negotiated Rates—Spotlight Energy, LLC R–7725–05 to be effective 10/1/2019.

Filed Date: 8/6/19.

Accession Number: 20190806–5033.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–1458–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 080619 Negotiated Rates—Castleton Commodities Merchant Trading L.P. R–4010–18 to be effective 10/1/2019

Filed Date: 8/6/19.

Accession Number: 20190806–5034.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–1459–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 080619 Negotiated Rates—Castleton Commodities Merchant Trading L.P. R–4010–19 to be effective 10/1/2019.

Filed Date: 8/6/19.

Accession Number: 20190806–5035.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–1088–001.

Applicants: Enable Gas Transmission, LLC.

Description: Compliance filing NAESB 3.1 Compliance Filing to be effective 8/1/2019.

Filed Date: 8/7/19.

Accession Number: 20190807–5104.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–1095–001.

Applicants: Enable Mississippi River Transmission, LLC.

Description: Compliance filing MRT—NAESB 3.1 Complianec Filing to be effective 8/1/2019.

Filed Date: 8/7/19.

Accession Number: 20190807–5106.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–1460–000.

Applicants: WBI Energy Transmission, Inc.

Description: § 4(d) Rate Filing: 2019 Non Conforming and Negotiated SA's FT–1517 and IT–838 to be effective 9/13/2019.

Filed Date: 8/7/19.

Accession Number: 20190807–5027.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–1461–000.

Applicants: Anadarko Energy Services Company, Pacific Summit Energy LLC.

Description: Joint Petition for Temporary Waiver of Commission Policies, Capacity Release Regulations and Policies, et al. of Anadarko Energy Services Company, et al. under RP19–1461.

Filed Date: 8/7/19.

Accession Number: 20190807–5030.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–1462–000.

Applicants: Anadarko Energy Services Company,Sequent Energy Management, L.P.

Description: Joint Petition for Temporary Waiver of Commission Policies, Capacity Release Regulations and Policies, et al. of Anadarko Energy Services Company, et al. under RP19–1462.

Filed Date: 8/7/19.

Accession Number: 20190807–5031.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–915–001.

Applicants: SG Resources Mississippi, L.L.C.

Description: Compliance filing SG Resources Mississippi, L.L.C.—Order No. 587–Y Compliance, Directed Changes to be effective 8/1/2019.

Filed Date: 8/7/19.

Accession Number: 20190807–5028.

Comments Due: 5 p.m. ET 8/19/19.

Docket Numbers: RP19–917–001.

Applicants: Pine Prairie Energy Center, LLC.

Description: Compliance filing Pine Prairie Energy Center, LLC—Order No. 587–Y Compliance, Directed Changes to be effective 8/1/2019.

Filed Date: 8/7/19.

Accession Number: 20190807–5026.

Comments Due: 5 p.m. ET 8/19/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings

can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 8, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–17394 Filed 8–13–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9998–14–OAR]

Alternative Methods for Calculating Off-Cycle Credits Under the Light-Duty Vehicle Greenhouse Gas Emissions Program: Applications From Hyundai Motor Company and Kia Motors Corporation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is requesting comment on applications from Hyundai Motor Company (''Hyundai'') and Kia Motors Corporation (''Kia'') for off-cycle carbon dioxide (CO_2) credits under EPA's light-duty vehicle greenhouse gas emissions standards. ''Off-cycle'' emission reductions can be achieved by employing technologies that result in real-world benefits, but where that benefit is not adequately captured on the test procedures used by manufacturers to demonstrate compliance with emission standards. EPA's light-duty vehicle greenhouse gas program acknowledges these benefits by giving automobile manufacturers several options for generating ''off-cycle'' CO_2 credits. Under the regulations, a manufacturer may apply for CO_2 credits for off-cycle technologies that result in off-cycle benefits. In these cases, a manufacturer must provide EPA with a proposed methodology for determining the real-world off-cycle benefit. Hyundai and Kia have submitted applications that describe methodologies for determining off-cycle credits from technologies described in their application. Pursuant to applicable regulations, EPA is making Hyundai's and Kia's off-cycle credit calculation methodologies available for public comment.

DATES: Comments must be received on or before September 13, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2019–0459, to the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Roberts French, Environmental Protection Specialist, Office of Transportation and Air Quality, Compliance Division, U.S. Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105. Telephone: (734) 214–4380. Fax: (734) 214–4869. Email address: *french.roberts@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

EPA's light-duty vehicle greenhouse gas (GHG) program provides three pathways by which a manufacturer may accrue off-cycle carbon dioxide (CO_2) credits for those technologies that achieve CO_2 reductions in the real world but where those reductions are not adequately captured on the test used to determine compliance with the CO_2 standards, and which are not otherwise reflected in the standards' stringency. The first pathway is a predetermined list of credit values for specific off-cycle technologies that may be used beginning in model year 2014.[1] This pathway allows manufacturers to use conservative credit values established by EPA for a wide range of technologies, with minimal data submittal or testing requirements, if the technologies meet EPA regulatory definitions. In cases where the off-cycle technology is not on the menu but additional laboratory testing can demonstrate emission benefits, a second pathway allows manufacturers to use a broader array of emission tests (known as ''5-cycle'' testing because the methodology uses five different testing procedures) to demonstrate and justify off-cycle CO_2 credits.[2] The additional emission tests allow emission benefits to be demonstrated over some elements of real-world driving not adequately captured by the GHG compliance tests, including high speeds, hard accelerations, and cold temperatures. These first two methodologies were completely defined through notice and comment rulemaking and therefore no additional process is necessary for manufacturers to use these methods. The third and last pathway allows manufacturers to seek EPA approval to use an alternative methodology for determining the off-cycle CO_2 credits.[3] This option is only available if the benefit of the technology cannot be adequately demonstrated using the 5-cycle methodology. Manufacturers may also use this option for model years prior to 2014 to demonstrate off-cycle CO_2 reductions for technologies that are on the predetermined list, or to demonstrate reductions that exceed those available via use of the predetermined list.

Under the regulations, a manufacturer seeking to demonstrate off-cycle credits with an alternative methodology (*i.e.,* under the third pathway described above) must describe a methodology that meets the following criteria:

- Use modeling, on-road testing, on-road data collection, or other approved analytical or engineering methods;
- Be robust, verifiable, and capable of demonstrating the real-world emissions benefit with strong statistical significance;
- Result in a demonstration of baseline and controlled emissions over a wide range of driving conditions and number of vehicles such that issues of data uncertainty are minimized;
- Result in data on a model type basis unless the manufacturer demonstrates that another basis is appropriate and adequate.

Further, the regulations specify the following requirements regarding an application for off-cycle CO_2 credits:

- A manufacturer requesting off-cycle credits must develop a methodology for demonstrating and determining the benefit of the off-cycle technology and carry out any necessary testing and analysis required to support that methodology.
- A manufacturer requesting off-cycle credits must conduct testing and/or prepare engineering analyses that demonstrate the in-use durability of the

[1] See 40 CFR 86.1869–12(b).

[2] See 40 CFR 86.1869–12(c).

[3] See 40 CFR 86.1869–12(d).

technology for the full useful life of the vehicle.

- The application must contain a detailed description of the off-cycle technology and how it functions to reduce CO_2 emissions under conditions not represented on the compliance tests.
- The application must contain a list of the vehicle model(s) which will be equipped with the technology.
- The application must contain a detailed description of the test vehicles selected and an engineering analysis that supports the selection of those vehicles for testing.
- The application must contain all testing and/or simulation data required under the regulations, plus any other data the manufacturer has considered in the analysis.

Finally, the alternative methodology must be approved by EPA prior to the manufacturer using it to generate credits. As part of the review process defined by regulation, the alternative methodology submitted to EPA for consideration must be made available for public comment.[4] EPA will consider public comments as part of its final decision to approve or deny the request for off-cycle credits.

II. Off-Cycle Credit Applications

A. High-Efficiency Alternators

Using the alternative methodology approach discussed above, Hyundai and Kia are applying for credits for model years 2010 and later for off-cycle credits using the alternative demonstration methodology pathway for high-efficiency alternators. Automotive alternators convert mechanical energy from a combustion engine into electrical energy that can be used to power a vehicle's electrical systems. Alternators inherently place a load on the engine, which results in increased fuel consumption and CO_2 emissions. High efficiency alternators use new technologies to reduce the overall load on the engine yet continue to meet the electrical demands of the vehicle systems, resulting in lower fuel consumption and lower CO_2 emissions. Some comments on EPA's proposed rule for GHG standards for the 2016–2025 model years suggested that EPA provide a credit for high-efficiency alternators on the pre-defined list in the regulations. While EPA agreed that high-efficiency alternators can reduce electrical load and reduce fuel consumption, and that these impacts are not seen on the emission test procedures because accessories that use electricity are turned off, EPA noted the difficulty in defining a one-size-fits-all credit due to lack of data. Since then, however a methodology has been developed that scales credits based on the efficiency of the alternator; alternators with efficiency (as measured using an accepted industry standard procedure) above a baseline value could get credits. EPA has previously approved credits for high-efficiency alternators using this methodology for Ford Motor Company, General Motors Corporation, Fiat Chrysler Automobiles, and Toyota Motor Company. Details of the testing and analysis can be found in the manufacturer's applications.

B. Hyundai and Kia Stop-Start System

Hyundai and Kia applied for engine idle stop-start credit covering 2012–2016 model year vehicles with stop-start technology, including hybrid electric vehicles and plug-in hybrid electric vehicles. Based on the analysis presented in their application, they are requesting a credit of 3.7 grams/mile for vehicles with stop-start technology that are not hybrids, and 3.8 grams/mile for hybrid electric and plug-in hybrid electric vehicles.

The methodology used by Hyundai and Kia was essentially the same as that used by Mercedes and approved by EPA in September of 2014.[5] This methodology is based on the following analyses:

- Estimate or measure the total idle fraction as a percentage of all vehicle operation in the real-world;
- Estimate or measure the percentage of idle fraction that the stop-start system is enabled out of all the available idle time (*i.e.,* eligible stop-start percentage or stop-start system effectiveness);
- Determine the benefit of the stop-start system in grams per mile based on A–B emissions testing (*i.e.,* technology on and off);
- Multiply the eligible real world stop-start time (relative to the 2-cycle eligible time) by the stop-start system benefit to estimate the idle stop-start credit; and,
- For vehicles that allow the driver to disable the stop-start system, the frequency of disablement by the driver must be determined.

The Mercedes application and EPA's Decision Document are both available on EPA's website; however, for convenience the table below shows a comparison of the key inputs to the methodologies approved by EPA for Mercedes and proposed by Hyundai and Kia.

Input	Mercedes (as approved by EPA)	Hyundai-Kia (proposed in application)
Idle Time Fraction	22.7	22.7
System Effectiveness	52%	59.4%
Driver Disablement	11%	1.6%
Credit (g/mi)	~3.5–4.5	3.7–3.8

III. EPA Decision Process

EPA has reviewed the applications for completeness and is now making the applications available for public review and comment as required by the regulations. The off-cycle credit applications submitted by the manufacturer (with confidential business information redacted) have been placed in the public docket (see **ADDRESSES** section above) and on EPA's website at *https://www.epa.gov/vehicle-and-engine-certification/compliance-information-light-duty-greenhouse-gas-ghg-standards.*

EPA is providing a 30-day comment period on the applications for off-cycle credits described in this notice, as specified by the regulations. The manufacturers may submit a written rebuttal of comments for EPA's consideration, or may revise an application in response to comments. After reviewing any public comments and any rebuttal of comments submitted by manufacturers, EPA will make a final decision regarding the credit requests. EPA will make its decision available to the public by placing a decision document (or multiple decision documents) in the docket and on EPA's website at the same manufacturer-specific pages shown above. While the

[4] See 40 CFR 86.1869–12(d)(2).

[5] ''EPA Decision Document: Mercedes-Benz Off-cycle Credits for MYs 2012–2016.'' U.S. Environmental Protection Agency, EPA–420–R–14–025, September 2014.

broad methodologies used by these manufacturers could potentially be used for other vehicles and by other manufacturers, the vehicle specific data needed to demonstrate the off-cycle emissions reductions would likely be different. In such cases, a new application would be required, including an opportunity for public comment.

Dated: August 5, 2019.

Byron J. Bunker,

Director, Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2019–17473 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0091; FRL–9996–70]

Product Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrants and accepted by the Agency, of the products listed in Table 1 of Unit II, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a May 29, 2019 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 2 of Unit II to voluntarily cancel these product registrations. In the May 29, 2019 notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency received comments on the notice but none merited its further review of the requests. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are applicable August 14, 2019.

FOR FURTHER INFORMATION CONTACT: Christopher Green, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–0367; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0091, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm., 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the Agency taking?

This notice announces the cancellation, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

Registration No.	Company No.	Product name	Active ingredients
100–1222	100	Quadris S	Azoxystrobin.
279–3555	279	Nuance Herbicide	Tribenuron-methyl.
279–3559	279	Harass Herbicide	Thifensulfuron.
279–3561	279	Chisum Herbicide	Chlorsulfuron & Metsulfuron.
279–3562	279	Report Herbicide	Chlorsulfuron.
279–3573	279	Chi-Chlorsul NC–75 Herbicide	Chlorsulfuron.
279–9633	279	Ciramet Herbicide	Metsulfuron.
538–189	538	Turf Builder Plus Halts	Pendimethalin.
538–214	538	Proturf Fertilizer Plus Preemergent Weed Control	Pendimethalin.
1015–82	1015	Sanafoam Diquat	Diquat dibromide.
1043–26	1043	1-Stroke Environ	2-Benzyl-4-chlorophenol; 4-tert-Amylphenol & o-Phenylphenol (NO INERT USE).
1043–87	1043	Vesphene II SE	4-tert-Amylphenol & o-Phenylphenol (NO INERT USE).
1043–91	1043	LPH Master Product	4-tert-Amylphenol & o-Phenylphenol (NO INERT USE).
1043–92	1043	LPH SE	4-tert-Amylphenol & o-Phenylphenol (NO INERT USE).
1043–114	1043	Vesta-Syde Interim Instrument Decontamination Solution.	4-tert-Amylphenol & o-Phenylphenol (NO INERT USE).
2749–582	2749	Novaluron EC Insecticide	Novaluron.
2749–583	2749	Novaluron Technical MUP	Novaluron.
19713–621	19713	Drexel Aquapen	Pendimethalin.
42750–66	42750	Gly Star Ready-To-Use Grass and Weed Killer	Glyphosate-isopropylammonium.

TABLE 1—PRODUCT CANCELLATIONS—Continued

Registration No.	Company No.	Product name	Active ingredients
61282–59	61282	DC & R Disinfectant	Formaldehyde; Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18) & 2-(Hydroxymethyl)-2-nitro-1,3-propanediol.
62719–12	62719	Telone C–17	Chloropicrin & Telone.
62719–457	62719	Asulam 400	Asulam, sodium salt.
71655–3	71655	Sodium Hypochlorite 12.5%	Sodium hypochlorite.
71655–4	71655	Sodium Hypochlorite	Sodium hypochlorite.
89442–44	89442	Prodiazone Select	Prodiamine & Sulfentrazone.
OR–080014	400	Comite	Propargite.
OR–080016	400	Comite	Propargite.
OR–080017	400	Comite	Propargite.
OR–080018	400	Comite	Propargite.
OR–080019	400	Comite	Propargite.
OR–080026	62719	Starane Ultra	Fluroxypyr 1-methylheptyl ester.
OR–080031	400	Acramite-4SC	Bifenazate.
OR–080033	400	Dimilin 2L	Diflubenzuron.
TN–130004	100	Boundary(R) 6.5EC Herbicide	Metribuzin & S-Metolachlor.
WA–130011	5481	Parazone 3SL Herbicide	Paraquat dichloride.
WA–140003	5481	Abba Ultra Miticide/Insecticide	Abamectin.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 of this unit.

TABLE 2—REGISTRANTS OF CANCELLED PRODUCTS

EPA company No.	Company name and address
100	Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300.
279	FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104.
400	Macdermid Agricultural Solutions, Inc., C/O Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, NC 27513.
538	The Scotts Company, 14111 Scottslawn Road, Marysville, OH 43041.
1015	Douglas Products and Packaging Company, LLC, D/B/A Douglas Products and Packaging, Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct., NW, Gig Harbor, WA 98332.
1043	Steris Corporation, P.O. Box 147, St. Louis, MO 63166–0147.
2749	Aceto Agricultural Chemicals Corp., 4 Tri Harbor Court, Port Washington, NY 11050–4661.
5481	Amvac Chemical Corporation, 4695 Macarthur Court, Suite 1200, Newport Beach, CA 92660–1706.
19713	Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–0327.
42750	Albaugh, LLC, P.O. Box 2127, Valdosta, GA 31604–2127.
61282	Hacco, Inc., 620 Lesher Place, Lansing, MI 48912.
62719	Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268–1054.
71655	BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932.
89442	Prime Source, LLC, Agent Name: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707.

III. Summary of Public Comments Received and Agency Response to Comments

The Agency received three public anonymous comments on the notice. For this reason, the Agency does not believe that the comments submitted during the comment period merit further review or a denial of the requests for voluntary cancellation

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)), EPA hereby approves the requested cancellations of the registrations identified in Table 1 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 of Unit II are canceled. The effective date of the cancellations that are the subject of this notice is August 14, 2019. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI will be a violation of FIFRA.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of May 29, 2019 (84 FR 24779) (FRL–9994–18). The comment period closed on June 28, 2019.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The existing stocks provisions for the products subject to this order are as follows.

The registrants may continue to sell and distribute existing stocks of products listed in Table 1 of Unit II until August 14, 2019, which is 1 year after the publication of the Cancellation Order in the **Federal Register**. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1, except for export in accordance with FIFRA section 17 (7 U.S.C. 136o), or proper disposal. Persons other than the registrants may sell, distribute, or use existing stocks of products listed in Table 1 of Unit II until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 29, 2019.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2019–17404 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9997–51–OMS]

Privacy Act of 1974; System of Records

AGENCY: Office of Mission Support, Environmental Protection Agency (EPA).

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Docket Management System (FDMS), is a regulatory, multi-agency use system that contains **Federal Register** notices, materials supporting regulatory actions such as scientific and economic analyses, and public comments.

The system of records is being amended to remove all information and data elements related to the Environmental Protection Agency's (EPA) Freedom of Information Act (FOIA) tracking system, FOIAonline, and to change the number assigned to the FDMS system of records. The status and storage of FOIAonline records should henceforth be detailed in a separate SORN for that system. The number previously assigned to FDMS identified the system as a government wide system of records. FDMS is a multi-agency use system and should be identified as such. The original system of records notice for FDMS was published in the **Federal Register** on March 24, 2005, was amended on October 2, 2013 and February 18, 2014, to add records collected and categories of records in a Freedom of Information Act (FOIA) system.

DATES: Persons wishing to comment on this system of records notice must do so by September 13, 2019. New or Modified routine uses for this modified system of records will be effective September 13, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OEI–2015–0757, by one of the following methods:

Regulations.gov: www.regulations.gov Follow the online instructions for submitting comments.

Email: oei.docket@epa.gov.

Fax: 202–566–1752.

Mail: OMS Docket, Environmental Protection Agency, Mail code: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery: OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OEI–2015–0757. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Controlled Unclassified Information (CUI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CUI or otherwise protected through *www.regulations.gov.* The *www.regulations.gov* website is an ''anonymous access'' system for EPA, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. However, over 180 federal partner and participating agencies use *www.regulations.gov* and some may require Personally Identifiable Information (PII) and some may not. Each agency determines submission requirements within their own internal processes and standards. EPA has no requirement of personal information. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CUI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington. DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OMS Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Tobias Schroeder, (202) 250–8603, or *Schroeder.tobias@epa.gov,* eRulemaking Program Management Office, U.S. EPA, Office of Mission Support, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION: The Federal Docket Management System (FDMS), is a regulatory, multi-agency use system that contains **Federal Register** notices, materials supporting regulatory actions such as scientific and economic analyses, and public comments. The repository also contains dockets that are non-rulemaking. The system is used by over 180 federal partner and participating agencies that conduct rulemaking activities. Each agency is responsible for managing its own docket and rulemaking documents. An agency may share documents with other agencies or persons in addition to making them available to the public on the *regulations.gov* website. Each agency has sole responsibility for documents submitted in support of its rulemakings. These documents will be processed by the responsible agencies. Some agencies require individuals to provide personally identifiable

information when submitting a comment (*e.g.,* name and contact information) that the agency can use if it experiences a problem receiving the comment or requires additional information to process the comment. A comment that meets all requirements of the recipient agency will be posted at *www.regulations.gov.* Once the comment is posted, the public may access those regulatory records. All the contents of posted comments will be searchable. Information in FDMS is accessed via the FDMS website by FDMS agency administrators, docket managers, rule writers, agency viewers (this is a view only access) and records managers. Each agency manages, accesses, and controls the information in the regulatory system that is submitted to it and maintains the sole ability to disclose the information it receives. Records in FDMS are maintained in a secure, password protected electronic system that utilizes security hardware and software to include multiple firewalls, active intrusion detection, and role-based access controls. Additional safeguards will vary by agency. FDMS is located at the U.S. EPA, Research Triangle Park, N.C. The system is maintained by the Office of Mission Support, eRulemaking Program Management Office.

SYSTEM NAME AND NUMBER

Federal Docket Management System (FDMS), EPA–71.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

U.S. EPA, 109 T.W. Alexander Drive, Durham, NC 27709.

SYSTEM MANAGER(S):

Tobias Schroeder, (202) 250–8603, or *Schroeder.tobias@epa.gov,* eRulemaking Program Management Office, U.S. EPA, Office of Mission Support, MC 2282T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 206(d) of the E-Government Act of 2002 (Public Law 107–347, 44 U.S.C. Ch 36); Clinger-Cohen Act of 1986, 40 U.S.C. 11318; and 5 U.S.C. 301.

PURPOSE(S) OF THE SYSTEM:

To provide the public a central online location to search, view, download and comment on Federal rulemaking documents.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM

Any individual commenting on a Federal agency's rulemaking activities or submitting supporting materials.

CATEGORIES OF RECORDS IN THE SYSTEM:

Agency rulemaking materials including **Federal Register** publications, supporting rulemaking documentation, scientific and financial studies and public comments.

RECORD SOURCE CATEGORIES:

Agencies and other individuals who create records derived from individuals commenting on Federal rulemaking activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The following new routine uses apply to this system because the use of the record is necessary for the efficient conduct of government operations. The routine uses are related to and compatible with the original purpose for which the information was collected. EPA general routine uses A (Disclosure for Law Enforcement Purposes), B (Disclosure Incident to Requesting Information), C (Disclosure to Requesting Agency), D (Disclosure to Office of Management and Budget), E (Disclosure to Congressional Offices), F (Disclosure to Department of Justice), G (Disclosure to National Archives), H (Disclosure to Contractors, Grantees and Others), K (Disclosure in Connection with Litigation), apply to this system (73 FR 2245). (*https://www.federalregister.gov/documents/2008/01/14/E8-445.pdf*) The following new routine uses are in accordance with M–17–12.

To appropriate agencies, entities, and persons when (1) the Agency suspects or has confirmed that there has been a breach of the system of records, (2) the Agency has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Agency's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

To another Federal agency or Federal entity, when the Agency determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in file folders in lockable file cabinets as maintained by the agency from where the record was initiated. Records are also stored in a secure, password protected electronic system that utilizes security hardware and software to include firewalls, encryption, active intrusion detection and role-based access controls. Additional safeguards vary by participating agencies.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The system retrieves records by numerous data elements and key word searches, including agency, dates, subject, docket type, docket sub-type, agency docket ID, docket title, docket category, document type, CFR Part, date received and **Federal Register** publication date, and name of the commenter, document, and docket.

The unique identifiers within the system are the docket ID, comment tracking number, and document ID.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Each Federal agency handles its records in accordance with its records schedule as approved by the National Archives and Records Administration (NARA).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

FDMS security protocols meet multiple security standards from authentication to certification and accreditation, as identified by the National Institute of Standards and Technology (NIST). Records in the system are maintained in a secure, password protected electronic system that utilizes security hardware and software to include multiple firewalls, active intrusion detection, and role-based access controls. Additional safeguards vary by agency for the regulatory records. Security controls are commensurate with those required for an information system rated moderate for confidentiality, integrity and availability as prescribed by NIST.

RECORD ACCESS PROCEDURES:

Uncontrolled access to information is restricted to publically available information. Partner agencies determine the specific unrestricted information that may be accessed by the public. That information is posted on an open publically accessible website, *Regulations.gov*. Information

maintained on FDMS is only available to the particular partner agency that posts the particular information. User access is controlled by password access. Passwords are maintained in accordance with the government security guidelines. Individuals seeking access to their own personal information in this system of records are required to provide adequate identification (*e.g.,* driver's license, military identification card, employee badge or identification card). Additional identity verification procedures may be required as warranted. Requests must meet the requirements of EPA regulations at 40 CFR part 16.

CONTESTING RECORD PROCEDURES:

Record content is controlled by individual partner agencies. The system collects public comment. All comments are assigned a tracking number. Comments are publically viewable. The system does not accept requests for correction or amendment only initial input. Requests for correction or amendment must identify the record to be changed and the corrective action sought. Requests must be submitted to the agency contact indicated on the initial document for which the related contested record was submitted. Complete EPA Privacy Act procedures are described in EPA's Privacy Act regulations at 40 CFR part 16.

NOTIFICATION PROCEDURE:

Any individual who wants to know whether this system of records contains a record about him or her should contact the agency responsible for the rulemaking activity that the individual believes may contain this information. Agency contact information is provided in the corresponding **Federal Register** notice. If an individual wants to contact EPA regarding an EPA rulemaking activity, they should send a written request to OMS Docket, Environmental Protection Agency, Mail code: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

81 FR 81096—Posted on December 27, 2016—The Environmental Protection Agency (EPA) provided notice that it was amending the FOIA Request and Appeal File system of records. All information and data elements collected by the Environmental Protection Agency (EPA) and participating agencies as it relates to FOIA requests, appeals and responses was removed from the Federal Docket Management System (FDMS) system of records and being added to the FOIA Request and Appeal File (EPA–9) system of records.

79 FR 9201—Posted on February 18, 2014—The Environmental Protection Agency (EPA) provided notice that it had amended the Federal Docket Management System (FDMS) system of records to include additional categories of records. The amendment was required to address additional categories of information collected from Freedom of Information Act (FOIA) requesters by some participating agencies and information voluntarily provided, even when not required.

78 FR 60868—Posted on October 2, 2013—The Environmental Protection Agency (EPA) provided notice that it had amended the Federal Docket Management System (FDMS) system of records to add information collected in a Freedom of Information Act (FOIA) system.

73 FR 2245—Posted on January 14, 2008—The Environmental Protection Agency provided notice that it proposed to amend its current list of General Routine Uses to add a new routine use. The new general routine use will allow the Agency to disclose information in its systems covered under the Privacy Act to persons and entities that may be needed by the Agency to respond, prevent, minimize or remedy harm resulting from an actual or suspected breach or compromise of personally identifiable information.

70 FR 15086—Posted on March 24, 2005—The EPA, as managing partner of the Federal-wide eRulemaking, eGovernment Initiative, provided notice that it proposed to establish a government-wide system of records, the Federal Docket Management System (FDMS).

Dated: August 1, 2019.

Vaughn Noga,

Senior Agency Official for Privacy.

[FR Doc. 2019–17459 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R05–OAR–2019–0239; FRL–9998–02–Region 5]

Adequacy Status of the Columbus, Ohio Area for the Submitted 2015 Ozone Standard Maintenance Plan for Transportation Conformity Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of finding of adequacy.

SUMMARY: In this notice, the EPA is notifying the public that we have found the motor vehicle emissions budgets (MVEBs) for volatile organic compounds (VOCs) and oxides of nitrogen (NO_X) in the 2015 ozone National Ambient Air Quality Standard (NAAQS) maintenance plan for the Columbus, Ohio area (Delaware, Fairfield, Franklin, and Licking Counties) adequate for use in transportation conformity determinations under the Clean Air Act. On April 23, 2019, the Ohio Environmental Protection Agency (OEPA) submitted a 2015 ozone NAAQS maintenance plan for the Columbus area, which included VOC and NO_X MVEBs for 2023 and 2030. As a result of our finding of adequacy, the MVEBs from the submitted maintenance plan must be used by state and Federal agencies in determining whether proposed transportation projects conform to the State Implementation Plan (SIP) as required by the Clean Air Act.

DATES: This finding is applicable August 29, 2019.

FOR FURTHER INFORMATION CONTACT: Anthony Maietta, Environmental Protection Specialist, Control Strategies Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8777, *maietta.anthony@epa.gov.*

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

Background

Today's notice is an announcement of a finding that we have already made. On April 23, 2019, OEPA submitted to EPA a plan for maintaining the 2015 ozone NAAQS in the Columbus area. This plan included MVEBs for VOC and NO_X for the years 2023 and 2030. On April 23, 2019, EPA sent a letter to OEPA transmitting our finding that the 2023 and 2030 MVEBs contained in the 2015 ozone NAAQS maintenance plan for the Columbus area are adequate for transportation conformity purposes. Receipt of these MVEBs was announced on EPA's transportation conformity website: *https://www.epa.gov/state-and-local-transportation/adequacy-review-state-implementation-plan-sip-submissions-conformity.* The finding and other relevant information are also available on EPA's transportation conformity website.

The 2023 MVEBs for the Columbus area are 29.28 tons per day (tpd) of NO_X

and 28.67 tpd of VOCs. The 2030 MVEBs for the Columbus area are 20.98 tpd of NO_X and 22.03 tpd of VOCs.

Transportation conformity is required by section 176(c) of the Clean Air Act. EPA's conformity rule requires that transportation plans, programs, and projects conform to state air quality implementation plans and establishes the criteria and procedures for determining whether they conform. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS.

The criteria by which we determine whether a SIP's MVEBs are adequate for transportation conformity purposes are outlined in 40 CFR 93.118(e)(4). Please note that an adequacy review is separate from EPA's completeness review, and is also a separate action from EPA's evaluation of and decision whether to approve a proposed SIP revision.

Authority: 42 U.S.C. 7401–7671q.

Dated: July 30, 2019.

Cheryl L. Newton,

Acting Regional Administrator, Region 5.

[FR Doc. 2019–17348 Filed 8–13–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0960]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before October 15, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0960.

Title: 47 CFR 76.122, Satellite Network Non-duplication Protection Rules; 47 CFR 76.123, Satellite Syndicated Program Exclusivity Rules and 47 CFR 76.124, Requirements for Invocation of Non-duplication and Syndicated Exclusivity Protection.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 1,428 respondents and 9,806 responses.

Estimated Time per Response: 0.5–1 hour.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 9,352 hours.

Total Annual Costs: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 4(i), 4(j), 303(r), 339 and 340 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 76.122, 76.123 and 76.124 are used to protect exclusive contract rights negotiated between broadcasters, distributors, and rights holders for the transmission of network syndicated in the broadcasters' recognized market areas. Rule sections 76.122 and 76.123 implement statutory requirements to provide rights for in-market stations to assert non-duplication and exclusivity rights.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2019–17411 Filed 8–13–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012380–007.

Agreement Name: Wallenius Wilhelmsen Ocean AS/Liberty Global Logistics LLC Space Charter Agreement.

Parties: Wallenius Wilhelmsen Ocean AS and Liberty Global Logistics LLC.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment changes the name of the Wallenius Wilhelmsen entity that is party to the Agreement, corrects its address, and restates the Agreement.

Proposed Effective Date: 9/22/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/79.

Agreement No.: 010050–022.

Agreement Name: U.S. Flag Discussion Agreement.

Parties: American President Lines, LLC; APL Co. Pte. Ltd.; Hapag-Lloyd AG; and Hapag-Lloyd USA, LLC.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment deletes Maersk Line A/S as a party to the Agreement.

Proposed Effective Date: 8/8/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/99.

Dated: August 9, 2019.

Rachel Dickon,

Secretary.

[FR Doc. 2019–17464 Filed 8–13–19; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 29, 2019.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Julia L. Koellner, Fort Madison, Iowa, individually, and acting in concert with Kathleen K. Bentler, Le Claire, Iowa; the Paula M. Friedman Declaration of Trust-II with Paula M. Friedman as trustee, both of Dubuque, Iowa; the Terrance J. Friedman Declaration of Trust-II with Terrance J. Friedman as trustee, both of Dubuque, Iowa; the Revocable Trust Agreement of Agnes L. Koellner, with Agnes L. Koellner as trustee, both of Fort Madison, Iowa; the Revocable Trust Agreement of Steven M. Koellner, with Steven M. Koellner as trustee, both of Fort Madison, Iowa; Kevin P. Koellner, Bettendorf, Iowa; Nicole M. Koellner, Bettendorf, Iowa; the J. Patrick Koellner Irrevocable Trust Agreement, Burlington, Iowa, with Kevin P. Koellner as voting proxy; Kimberly E. Mendez, Fort Madison, Iowa; and Christine A. Smith, Le Claire, Iowa;* to retain voting shares of Lee Capital Corp, and thereby retain shares of Lee County Bank, both of Fort Madison, Iowa.

Board of Governors of the Federal Reserve System, August 9, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–17447 Filed 8–13–19; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 12, 2019.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Ames National Corporation, Ames, Iowa;* to acquire 100 percent of Iowa State Savings Bank, Creston, Iowa.

Board of Governors of the Federal Reserve System, August 9, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–17448 Filed 8–13–19; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. 191 0039]

Boston Scientific Corporation; Analysis of Agreement Containing Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement; Request for Comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis of Agreement Containing Consent Orders to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before September 13, 2019.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: ''Boston Scientific Corporation; File No. 191 0039'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jonathan Ripa (202–326–2230), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC

Home Page (for August 7, 2019), on the World Wide Web, at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before September 13, 2019. Write ''Boston Scientific Corporation; File No. 191 0039'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Boston Scientific Corporation; File No. 191 0039'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before September 13, 2019. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Agreement Containing Consent Orders to Aid Public Comment

I. Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Boston Scientific Corporation (''BSC'') designed to remedy the anticompetitive effects resulting from BSC's proposed acquisition of BTG plc (''BTG''). The proposed Decision and Order (''Order'') contained in the Consent Agreement requires BSC to divest all rights and assets related to its drug eluting bead (''DEB'') business, as well as its closely related bland bead business, to Varian Medical Systems (''Varian'').

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Under the terms of the Co-Operation Agreement dated November 20, 2018, BSC will acquire BTG in exchange for cash consideration of $4.2 billion (the ''Acquisition''). The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by substantially lessening competition in the U.S. market for DEBs. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in this market as a result of the proposed Acquisition.

II. The Parties

BSC, headquartered in Marlborough, Massachusetts, is a global supplier of medical devices that are used in a broad range of interventional medical specialties. BSC currently offers its products through seven core business segments: Interventional Cardiology, Cardiac Rhythm Management, Endoscopy, Peripheral Interventions, Urology and Pelvic Health, Neuromodulation, and Electrophysiology. The Peripheral Interventions segment—which includes BSCs DEB business—focuses on products that treat an array of diseases, including arterial diseases, vascular diseases, as well as various cancers.

BTG is headquartered in London, England, with operational headquarters in Conshohocken, Pennsylvania. The company develops, manufacturers, and sells products used in various interventional medicine applications, and it also has a portfolio of specialty pharmaceutical products.

III. The Relevant Product and Structure of the Market

DEBs are microscopic beads used in transarterial chemoembolization (''TACE'') procedures for treating primary and secondary liver cancers. TACE involves the use of embolic agents (typically microscopic beads) mixed with chemotherapy drugs (often doxorubicin) that are delivered to the targeted tumor in the liver via a catheter inserted into the patient's artery that leads to the tumor. When used in TACE procedures, DEBs work by blocking the flow of blood to the liver tumor, causing it to shrink over time, while simultaneously slowly releasing a chemotherapy agent that also attacks the tumor.

BTG and BSC are the two leading suppliers of DEBs in the United States and are each other's closest competitors. The only other participant in the U.S. DEB market is Merit Medical (''Merit''), which is substantially smaller than either BSC or BTG.

IV. The Relevant Geographic Market

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. DEBs are medical devices that are regulated by the U.S. Food and Drug Administration (''FDA''). As such, DEBs sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

V. Competitive Effects of the Acquisition

The proposed Acquisition would likely result in substantial competitive harm to consumers in the market for DEBs. The parties are two of only three significant suppliers of DEBs in the United States. Eliminating the head-to-head competition between BSC and BTG in this highly concentrated market would allow the combined firm to exercise market power unilaterally, resulting in higher prices, reduced innovation, and less choice for consumers.

VI. Entry Conditions

Entry in the relevant market would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, developing clinical history supporting the long-term efficacy of the product, and establishing a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

VII. The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring BSC to divest its DEB business and closely related bland bead business to Varian. A sale of BSC's DEB business without its bland business could undermine the divestiture's effectiveness. The two products share key intellectual property, and BSC manufactures bland beads on the same production line as DEBs. Thus, including the bland bead business in the divestiture package will ensure that Varian has outright ownership of all necessary intellectual property and allow it to manufacture DEBs at a cost and output level comparable to that of BSC. BSC must divest all assets and rights to research, develop, manufacture, market, and sell the BSC DEB and bland bead products, including all related intellectual property and other confidential business information, manufacturing technology, existing inventory, and all related agreements to manufacture and distribute the products. Additionally, to ensure that the divestiture is successful and maintain continuity of supply, the proposed Order requires BSC to supply Varian with DEBs and bland beads for a limited time while Varian establishes its own manufacturing capability. The provisions of the Consent Agreement ensure that Varian becomes an independent, viable, and effective competitor in the U.S. market in order to maintain the competition that currently exists.

Headquartered in Palo Alto, California, Varian operates globally and develops, manufactures, and markets a variety of medical devices and software for treating cancer and other medical conditions. Varian's existing interventional oncology business includes products that are highly complementary to the divestiture assets. Varian has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.

BSC must accomplish the divestitures no later than ten days after consummating the proposed Acquisition. If the Commission determines that Varian is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires BSC to unwind the sale of rights and assets to Varian and then divest the affected products to a Commission-approved acquirer within six months of the date the Order becomes final. To ensure compliance with the Order, the Commission has agreed to appoint a Monitor to ensure that BSC complies with all of its obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the DEB and bland bead rights and assets to Varian. The proposed Order further allows the Commission to appoint a trustee in the event that BSC fails to divest the products as required.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2019–17460 Filed 8–13–19; 8:45 am]

BILLING CODE 6750–01–P

GENERAL SERVICES ADMINISTRATION

[Notice-MA–2019–07; Docket No. 2019–0002; Sequence No. 19]

Maximum Per Diem Reimbursement Rates for the Continental United States (CONUS)

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of GSA Per Diem Bulletin FTR 20–01, Fiscal Year (FY) 2020 CONUS per diem reimbursement rates.

SUMMARY: The GSA Fiscal Year FY 2020 per diem reimbursement rates review has resulted in lodging and meal allowance changes for certain locations within CONUS to provide for reimbursement of Federal employees' subsistence expenses while on official travel.

DATES: *Applicability Date:* This notice applies to travel performed on or after October 1, 2019, through September 30, 2020.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Jill Denning, Program Analyst, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–208–7642, or by email at *travelpolicy@gsa.gov.* Please cite Notice of GSA Per Diem Bulletin FTR 20–01.

SUPPLEMENTARY INFORMATION:

Background

The CONUS per diem reimbursement rates prescribed in Bulletin 20–01 may be found at *www.gsa.gov/perdiem.* GSA bases the maximum lodging allowance rates on the average daily rate that the lodging industry reports to an independent organization. If a maximum lodging allowance rate and/or a meals and incidental expenses (M&IE) per diem reimbursement rate is insufficient to meet necessary expenses in any given location, Federal executive agencies can request that GSA review that location. Please review questions six and seven of GSA's per diem Frequently Asked Questions page at *www.gsa.gov/perdiem* for more information on the special review

process. In addition, the Federal Travel Regulation (FTR) allows for actual expense reimbursement as provided in §§ 301–11.300 through 301–11.306.

For FY 2020, one new non-standard area (NSA) location was added for Boise, Idaho (Ada County). In addition, Park County, Montana was added to the Big Sky, Montana NSA area. In Montana, Missoula and Flathead Counties were separated into their own NSAs instead of a combined NSA. The standard CONUS lodging rate will increase from $94 to $96. The M&IE reimbursement rate tiers were unchanged for FY 2020. The standard CONUS M&IE rate remains at $55, and the M&IE NSA tiers remain at $56–$76.

GSA issues and publishes the CONUS per diem rates, formerly published in Appendix A to 41 CFR Chapter 301, solely on the internet at *www.gsa.gov/perdiem.* GSA also has removed and now solely publishes the M&IE deduction table from Appendix B to 41 CFR Chapter 301, which is used when employees are required to deduct meals from their M&IE reimbursement pursuant to FTR § 301–11.18, at *www.gsa.gov/mie.* This process, implemented in 2003, for per diem reimbursement rates and in 2015 (internet publication) and 2018 (removal from the FTR) for the M&IE deduction table, ensures more timely changes in per diem reimbursement rates established by GSA for Federal employees on official travel within CONUS.

Notices published periodically in the **Federal Register** now constitute the only notification of revisions in CONUS per diem reimbursement rates to agencies other than the changes posted on the GSA website.

Jessica Salmoiraghi,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2019–17416 Filed 8–13–19; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*Safety Program in Perinatal Care (SPPC)—II Demonstration Project.*''

This proposed information collection was previously published in the **Federal Register** on May 1, 2019, and allowed 60 days for public comment. AHRQ received no substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by date 30 days after date of publication.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Safety Program in Perinatal Care (SPPC)—II Demonstration Project

Maternal mortality and severe maternal morbidity (SMM) increased significantly and continuously in the United States (US) over the past 30 years. A considerable proportion of these adverse events are attributable to preventable harm and unintended consequences arising from clinical practice and the system of delivering perinatal care. To address these alarming trends, AHRQ has developed the Safety Program in Perinatal Care (SPPC). During its initial phase (SPPC–I), the program was comprised of three pillars: Teamwork and communication, patient safety bundles, and in situ simulations. Despite several promising results, the evaluation of SPPC–I revealed considerable hospital attrition due to heavy data burden and competing safety initiatives. Also, differences in the local adaptation of the SPPC–I patient safety bundles selected by implementation sites thwarted a meaningful cross-site comparison of programmatic impact.

The current, second phase of the program (SPPC–II), focuses on integrating the teamwork and communication pillar into patient safety bundles developed by key professional organizations and implemented in 20+ US states with technical assistance by the Alliance for Innovation on Maternal Health (AIM) program and funding from the Health Resources and Services Administration (HRSA). Of note, the model used by AIM to implement these bundles is through statewide perinatal quality collaboratives (PQC) aiming to enroll all birthing hospitals in the state in the PQC.

During the *Planning Phase* of SPPC–II, the contractor, Johns Hopkins University (JHU), developed SPPC–II Training Toolkits for two AIM patient safety bundles: Obstetric hemorrhage and severe hypertension in pregnancy. The aim of the SPPC–II *Demonstration Project* is to implement and evaluate an integrated AIM–SPPC II program that overlays the SPPC–II Training Toolkits and the AIM patient safety bundles and program infrastructure in two states—Oklahoma (OK), currently implementing the severe hypertension bundle; and Texas (TX), currently implementing the hemorrhage bundle.

Over the next five years, the AIM program is expected to cover about two thirds of US states. Therefore, there is need to determine the feasibility and impact of the proposed integrated AIM–SPPC II program, and inform future government funding decisions regarding these two programs.

To this end, the SPPC–II *Demonstration Project* has the following goals:

(1) To implement the integrated AIM–SPPC II program in birthing hospitals in OK and TX in coordination with AIM and the respective state PQC;

(2) To assess the implementation of the integrated AIM–SPPC II program in these hospitals; and

(3) To ascertain the short- and medium-term impact of the integrated AIM–SPPC II program on hospital (*i.e.,* perinatal unit) teamwork and communication, patient safety, and key maternal health outcomes.

This study is being conducted by AHRQ through its contractor, Johns Hopkins University (JHU) and the AIM program, JHU's subcontractor, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a (a)(1) and (2).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

(a) *Training of AIM Team Leads* from 48 birthing hospitals in OK and 210 birthing hospitals in TX (*i.e.,* all birthing hospitals enrolled in the respective state

PQC) on using teamwork and communication tools and strategies in clinical obstetric practice. The training will be conducted in-person, through a full-day workshop organized in collaboration and coordination with the AIM program and state PQCs, and led by JHU. Only one such training workshop will be conducted in OK using the SPPC–II Toolkit for severe hypertension in pregnancy. Given the size of the state, potential long distances to be traveled by trainees, and the cost-efficiency of coordinating with back-to-back regional PQC meetings planned in TX this fall, five training workshops will be conducted in this state using the SPPC–II Toolkit for obstetric hemorrhage. We expect about half of the birthing hospitals in both states to send 2 hospital champions, of which one to be designated as AIM Team Lead, for training. JHU will keep and bi-annually update a roster of AIM Team Leads in each hospital to assess the need for training of new AIM Team Leads if turnover occurs. Training workshop evaluation forms will be distributed for completion by trainees on a voluntary basis to assess the perceived utility of training workshops.

(b) *Training of all frontline clinical staff* in 48 birthing hospitals in OK and 210 birthing hospitals in TX on teamwork and communication tools and strategies will be coordinated by AIM Team Leads in each hospital by: (a) Providing unique trainee IDs and information for them to access 8 training e-modules online (with option to leave voluntary comments/suggestions), and (b) using the JHU-developed facilitator guide included in the SPPC–II Toolkits to facilitate brief, in-person demonstration sessions on how to use the information from the training e-modules in clinical practice. Each of the eight training e-modules will take about 15 minutes to complete online, for a total of about 120 minutes. Because these training e-modules will be accessed and completed online, tracking of e-module completion and re-take, needed to assess overall staff exposure to training, is possible through the online training platform.

(c) *Coaching calls* will be organized monthly and led by JHU to address program implementation questions and assist with potential challenges. AIM Team Leads in all *Demonstration Project* hospitals will be invited to join these calls and ask questions. A list of coaching call participants and topics addressed will be maintained by JHU.

(d) *AIM Team Lead self-administered baseline surveys* will be made available 2–3 weeks before the AIM Team Leads training workshop, together with a corresponding consent form. The purpose of this survey is to assess key characteristics of project hospitals, including human resources, processes in place for AIM bundle implementation, and use of teamwork and communication tools in clinical practice. Respondents will have the option to complete the survey online or on paper, in line with the current administration of the Hospital Survey on Patient Safety Culture. The expected response rate for this survey is 95% in both states.

(e) *Clinical staff self-administered baseline surveys* will be made available before the first training workshop with AIM Team Leads, together with a corresponding consent form. The purpose of this survey is to assess baseline levels of previous teamwork and communication training, overall use of teamwork and communication tools and strategies, teamwork and communication perceptions, experience with AIM bundle implementation. Three respondents will be randomly selected in each hospital using comprehensive lists of clinical staff developed by the AIM Team Leads. These lists will be updated by AIM Team Leads on a quarterly basis to capture new hires and staff turnover. Respondents will be given the option to complete the survey online or on paper, in line with the administration of the national Hospital Survey on Patient Safety Culture. The expected response rate for this survey is 85% in both states.

(f) *Qualitative, semi-structured interviews with AIM Team Leads* will be conducted by phone about 3–4 months after their training workshop to assess the perceived utility of the training and assistance needed with the rollout of training to all frontline clinical staff using the e-modules and facilitation sessions to consolidate the information. An interview guide developed based on the Consolidated Framework for Implementation Research framework will be used to conduct the interviews, together with a corresponding consent form.

(g) *Clinical staff self-administered implementation surveys* will be made available at about 6, 18, and 30 months after the first AIM Team Leads training, together with a corresponding consent forms, to assess training knowledge, transfer, and results such as use of teamwork and communication tools and strategies, teamwork and communication perceptions, experience with AIM bundle implementation overlaid with the teamwork and communication tools. The time points were chosen to assess: *Early* adoption and results of the training (6-month survey); adoption and results of the training at the *time when unit culture changes are expected* per available implementation research (18-month survey); and medium-term program sustainability (30-month survey). For each survey, three respondents will be randomly selected in each hospital using the most up to date comprehensive lists of clinical staff developed by the AIM Team Leads. Respondents will have the option to complete these surveys online or on paper, in line with the administration of the national Hospital Survey on Patient Safety Culture. The expected response rates are 80%, 77.5% and 75% for surveys completed at 6, 18 and 30 months after AIM Team Leads training workshops, respectively.

(h) AIM program data will be obtained from the AIM program, a subcontractor of JHU's, under data use agreements with coordinating bodies of state PQCs in the fall of 2019. These data are needed for the evaluation of the SPPC–II *Demonstration Project* to assess changes in key AIM program processes and maternal health outcomes, such as severe maternal morbidity, throughout the project.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden ours for the respondents' time to participate in the SPPC–II Demonstration Project.

An estimated 387 AIM Team Leads from the 258 Demonstration Project sites will be trained during 8-hour workshops using the SPPC–II Toolkit. An evaluation form, which will take approximately 5 minutes to complete, will be distributed to them at the end of the workshop, and about 75% of them (290 AIM Team Leads) are expected to complete the evaluation. They will also be asked to extract from an available human resources computerized database and update bi-annually rosters of frontline clinical staff in their units—first extraction and each update is expected to take about 5 minutes.

An estimated 15,480 frontline clinical staff are expected to be trained using the training e-modules in the SPPC–II Toolkit. Completion of the 8 e-modules will take about 2 hours. These trainings will be complemented by four 15-min facilitation sessions led by AIM Team Leads in their respective units. The AIM Team Leads will track attendance of the facilitation session, work estimated to take about 15 minutes after each session.

Monthly 1-hour coaching calls will be organized during the first 18 months of the project and at least one

representative from about half of the sites is expected to participate at each coaching call.

Several surveys will be administered throughout the Demonstration Project, specifically: Baseline, 20-minute surveys with AIM Team Leads at each of 258 sites; baseline, 25-minute surveys with 3 randomly selected frontline clinical staff at each of 258 sites; 30-minute implementation surveys with 3 randomly selected frontline clinical staff at each of 258 sites will be conducted at 6, 18, and 30 months after the initial training workshops in both states. In addition, one-hour qualitative interviews will be conducted with 25 AIM Team Leads in the 2 states about 3–4 months after the initial training workshops in their respective state.

We will inform AIM Team Leads of the DUAs put in place to access AIM data—this will take about 5 minutes.

The total annual burden hours are estimated to be 54,654 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Training of AIM Team Leads	387	1	8	3,096
Frontline staff rosters developed by AIM Team Leads	258	6	0.08	124
Evaluation form for training of AIM Team Leads	290	1	0.08	23
Training of frontline clinical staff	15,480	1	2.00	30,960
Facilitation sessions	15,480	4	0.25	15,480
Tracking attendance of facilitation sessions	258	4	1.00	1,032
Coaching calls	129	18	1.00	2,322
Self-administered baseline surveys with AIM Team Leads	258	1	0.33	85
Self-administered baseline surveys with clinical staff	774	1	0.42	325
Qualitative semi-structured interviews with AIM Team Leads	25	1	1.00	25
Self-administered implementation surveys with clinical staff at 6 months	774	1	0.50	387
Self-administered implementation surveys with clinical staff at 18 months	774	1	0.50	387
Self-administered implementation surveys with clinical staff at 30 months	774	1	0.50	387
DUA for AIM data	258	1	0.08	21
Total	36,048	NA	NA	54,654

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $1,489,998.34 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Training of AIM Team Leads	387	3,096	$49.83	$154,273.68
Frontline staff rosters developed by AIM Team Leads	258	124	49.83	6,178.92
Evaluation form for training of AIM Team Leads	290	23	49.83	1,146.09
Training of frontline clinical staff	15,480	30,960	66.32	2,053,267.20
Facilitation sessions	15,480	15,480	66.32	1,026,633.60
Tracking attendance of facilitation sessions	258	1,032	49.83	51,424.56
Coaching calls	129	2,322	66.32	153,995.04
Self-administered baseline surveys with AIM Team Leads	258	85	49.83	4,235.55
Self-administered baseline surveys with clinical staff	774	325	66.32	21,554
Qualitative semi-structured interviews with AIM Team Leads	25	25	49.83	1,245.75
Self-administered implementation surveys with clinical staff at 6 months	774	387	66.32	25,665.84
Self-administered implementation surveys with clinical staff at 18 months	774	387	66.32	25,665.84
Self-administered implementation surveys with clinical staff at 30 months	774	387	66.32	25,665.84
DUA for AIM data	258	21	49.83	1,046.43
Total	36,048	54,716		1,489,998.34

* National Compensation Survey: Occupational wages in the United States May 2017 "U.S. Department of Labor, Bureau of Labor Statistics."

[a] Hourly wage for nurse-midwives ($48.36; occupation code 29–1161).

[b] Weighted mean hourly wage for obstetrician-gynecologists ($113.10; occupation code 29–1064; 30%); nurse-midwives ($49.83; occupation code 29–1161; 30%); registered nurses ($35.36; occupation code 29–1161; 20%); and nurse practitioners ($51.86; occupation code 29–1171; 20%).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the

collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 8, 2019.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–17398 Filed 8–13–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2374]

Drugs Intended for Human Use That Are Improperly Listed Due to Lack of Annual Certification or Identification of a Manufacturing Establishment Not Duly Registered With the Food and Drug Administration; Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intention to begin inactivating drug listing records that are improperly listed in accordance with FDA requirements because these drug listings are not certified as being active and up to date or are associated with a manufacturing establishment that is not currently registered with FDA. FDA's regulations governing drug establishment registration and drug listing require registrants to notify FDA if commercial distribution of a listed drug is discontinued. They also require firms to submit drug listing updates if any material changes are made to information previously submitted, including a change in manufacturing establishment(s). FDA has found that listings for many drug products do not comply with these regulations because they have not been updated in over a year, they have not been certified as being up to date, or they identify within the listing information at least one manufacturing establishment that is not currently registered with FDA. Many of the drugs that are the subject of these listings appear to no longer be in commercial distribution. The purpose of this notice is to remind registrants of their legal obligations and announce that, if drug listings are not appropriately updated, certified, or associated with a registered establishment, they will be marked by FDA as ''inactive,'' and the date of inactivation will be added to the listing record. This process will result in the closure of drug records in all public drug listing databases maintained by FDA, including the National Drug Code (NDC) Directory and the NDC SPL Data Elements (NSDE) file, until corrections to the relevant listings are made.

DATES: This notice is applicable September 13, 2019.

FOR FURTHER INFORMATION CONTACT: Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2262, Silver Spring, MD 20993–0002, 301–796–2173, *Paul.loebach@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and part 207 (21 CFR part 207) of FDA's regulations have long required owners or operators of drug manufacturing establishments to register their establishments with FDA. In this notice, the term ''manufacture'' refers to all activities that trigger the drug establishment registration obligation under part 207, including repacking, relabeling, and salvaging as defined in part 207. Registrants are also required by section 510 and part 207 to ''list'' each drug manufactured at their establishments for commercial distribution and submit updated drug listing information to FDA twice yearly, in June and December, notifying FDA if this information has changed. Specifically, section 510(i)(2) and (j) of the FD&C Act require registered establishments to report and periodically update, among other information, listing information for each drug manufactured, prepared, propagated, compounded, or processed by them for commercial distribution in the United States. Under 21 CFR 207.49, 207.53, and 207.54, registrants must provide listing information that corresponds to the activity or activities they engage in for that drug.

As part of the drug listing information they submit to FDA, registrants must identify all establishments where a ''listed drug'' (as the term used in the context of section 510 of the FD&C Act and part 207) is manufactured or provide a source NDC that enables FDA to identify such establishments. Registered establishments must also report to FDA the discontinuation of commercial distribution of a listed drug (section 510(j)(2)(B) of the FD&C Act) and any material change in drug listing information previously submitted, which includes any changes in the establishment(s) where the drug is manufactured (section 510(j)(2)(D) of the FD&C Act and 21 CFR 207.1). On August 31, 2016, FDA amended part 207 to require drug manufacturers and other registrants, at the time of registration renewal, to certify that no changes have occurred to their listings that were not submitted or updated during the current calendar year (81 FR 60170 and § 207.57 (21 CFR 207.57)). The first certifications under this new requirement were due during the registration renewal period from October 1 to December 31, 2017 (81 FR 60170 at 60201 and § 207.57). Establishments and labeler code holders are also required to update contact information (name, telephone number, and email) submitted to FDA within 30 calendar days of any changes (21 CFR 207.25(g), 207.29(a)(3), and 207.33(c)(2)).

Complete, accurate, and up-to-date establishment registration and drug listing information is essential to FDA's mission. FDA relies on establishment registration and drug listing information in administering several key programs, including drug establishment inspections, postmarketing surveillance, counterterrorism, recalls, drug quality reports, adverse event reports, monitoring of drug shortages and availability, supply chain security, and identification of products that are marketed without an approved application. If registration and listing information is outdated or otherwise unreliable (such as inaccurate, superfluous, incomplete, or missing), the integrity of the drug establishment registration and listing database—and FDA's ability to rely on the reported information for these programs—is compromised. Drug registration and listing information is also widely used outside FDA for several purposes, including electronic drug prescribing, prescription drug reimbursement, and patient education. A review of our data shows that the types of errors discussed in this notice affect tens of thousands of records. Therefore, the inclusion of such incorrect or outdated information in FDA's NDC Directory, the NSDE file, or other public drug listing databases can negatively affect public health.

II. Circumstances Under Which Certain Drug Listing Information Becomes Inaccurate

Each registrant must list all drugs it manufactures for commercial distribution within 3 days of initial

registration (21 CFR 207.45). Establishment registration must be renewed annually between October 1 and December 31 (21 CFR 207.29). Each registrant must in June and December each year: (1) Update its drug listing information to provide FDA with information about any drugs introduced for U.S. commercial distribution not previously listed, (2) report the discontinuation of any listed drug, and (3) report any material changes in drug listing information submitted previously (including any updates in the manufacturing establishments) (§ 207.57). If there are no changes to listing information to report in June or December, then the registrant must certify that there have been no changes to the listing information previously submitted, during the October 1 and December 31 registration renewal and listing certification period (§ 207.57). By December 31 of each calendar year, registrants should review their current files of listed human drugs to determine whether any data elements in their drug listing records are no longer accurate and submit updated listing files or listing certifications.

While a new drug listing submission transmitted to FDA electronically will not be accepted if the listing information identifies a manufacturing establishment that is not registered in accordance with FDA's requirements, previously submitted establishment and listing information may become outdated for a variety of reasons. In some cases, establishments that have discontinued manufacturing let their registration expire by not renewing their annual establishment registration at the end of the year but fail to update their drug listing information to report discontinuation of their listed drug(s). The result is that listing information for certain drugs may be certified to be current but potentially identifies one or more establishments that are not currently registered with FDA in accordance with FDA's requirements.

In other cases, registrants may incorrectly include additional establishments in their drug listing submissions (for example, in anticipation of a future business relationship with a contract manufacturer). Consistent with the applicable regulatory requirements in part 207, FDA expects all establishments identified in a drug listing submission to reflect current manufacturing facilities for the listed drug at the time of the listing submission or at the time of the update so that the Agency can rely on the information when submitted as an accurate picture of the supply chain. There are also cases in which a registrant fails to review and update its previously reported drug listing information as required in June and December of each year. Similarly, a registrant may neglect to certify to FDA that its listings are still up to date and accurate. (See section IV of this document for links to FDA's NDC Directory and other resources that may help registrants determine whether any data elements in their drug listing records are no longer accurate and correct inaccurate drug listings.)

III. FDA's Intended Response

To address the above registration and listing problems, FDA is encouraging firms that are required to register drug establishments and list human drugs under part 207 to review their currently listed human drugs and determine whether any information in their drug listings, including drug establishments identified, is no longer accurate. Any active drug listing submissions that are inaccurate should be updated as soon as possible.

Thirty days after publication of this notice, and every January thereafter, FDA will begin to inactivate human drug listings that remain uncertified from the previous renewal period of October 1 to December 31. In addition, every July thereafter, FDA will begin to inactivate human drug listings that remain active and certified after the June listing update, but still contain at least one establishment that is not currently registered in accordance with FDA's requirements. This action taken by FDA will include listings for finished drug products, as well as for active pharmaceutical ingredients and other unfinished drugs. These listing records, including their NDCs, will be inactivated and subject to immediate removal from FDA's NDC Directory and notification of each NDC's inactivation date will be included in FDA's NSDE file. NDCs that are inactivated by FDA may be reactivated with an updated and compliant drug listing submission as soon as the next business day. If activated again, the listing will again be included in the NDC Directory and the reactivation date will be included in the NSDE file. If a drug remains in commercial distribution after it has been inactivated and removed from the NDC Directory, the drug may be deemed misbranded for failure to fulfill registration or listing obligations under section 502(o) of the FD&C Act (21 U.S.C. 352(o)), and persons marketing the drug in the United States or offering it for import into the United States may be subject to enforcement.

Manufacturers and repackagers of products subject to the new product identification requirement (see section 582(b)(2) and (e)(2) of the FD&C Act, respectively (21 U.S.C. 360eee–1(b)(2) and (e)(2))), and who have incorporated the new product identifier (serialization) into their labeling, must submit such updated labeling with listing updates (§ 207.57) and not merely certify that affected listings are up to date via ''no changes'' certifications during the registration renewal period. Such a change requires that a new and representative sample of labeling incorporating the new product identifier requirements be submitted as an update to listing (§ 207.57). Note that such an update would satisfy the annual certification requirement for the drug listing and not require an additional ''blanket no changes'' submission to maintain the listing's active status.

Firms are required by law to update their drug listings when they discontinue marketing their listed drugs (§ 207.57). To properly discontinue a listed drug, the listing record must be updated to include an accurate marketing end date that corresponds with the last lot expiration date of the drug (§ 207.57(b)(ii)). If the listing record expires without an update, certification, or discontinuance submitted, the process described above will assign an inactivation date that is different from the actual date of discontinuance and may have unintended consequences for dispensing and reimbursement. Rather than explicitly discontinuing certain listings, some firms have notified FDA that they do not intend to certify or update those listings. However, listing certification is a separate requirement and should not be treated as a mechanism to discontinue the drug listing record.

IV. Resources Available To Assist With Updating or Certifying Drug Listings

The NDC Directory (available at: *https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm*) currently identifies all active, but uncertified, listings. The online search marks uncertified listings with a ''(U)'' in red font. The online search also marks active but otherwise deficient or erroneous listing records with an ''(E)''. Listing records marked with an ''(E)'' have been identified by FDA as having an error or deficiency associated with the submission. These include, but are not limited to, records with at least one establishment that is not registered in accordance with FDA's requirements. All listing records should be reviewed for accuracy at least biannually,

regardless of whether they have been marked as deficient or not. Within the download files for the NDC Directory, uncertified listings may be identified using the LISTING CERTIFIED THROUGH DATE column. Any value that appears in this date field occurring in the past identifies a product listing that has not been certified. Erroneous or deficient listings are identified by a value of ''E'' in the EXCLUDE FLAG column.

Updates and certifications to listing information must be provided electronically in Structured Product Labeling (SPL) format. Anyone seeking information on how to update listing information may visit *www.fda.gov/edrls* or contact *edrls@fda.hhs.gov.* Additionally, FDA offers two SPL authoring tools for use in the creation and submission of SPL: Xforms and CDER Direct. Xforms is available from FDA's SPL web page at: *https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.* CDER Direct is available at: *https://direct.fda.gov.*

Dated: August 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17436 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0520]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 13, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0339. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR 589.2000(e)(1)(iv)

OMB Control Number 0910–0339—Extension

Section 701(a) (21 U.S.C. 371(a)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. Our regulation at 21 CFR 589.2000 provides that animal protein derived from mammalian tissue (with some exclusions) is not generally recognized as safe (GRAS) for use in ruminant feed and is a food additive subject to certain provisions of the act (62 FR 30936, June 5, 1997).

This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain, or may contain, protein derived from mammalian tissue, and feeds made from such products.

Specifically, this regulation requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution to maintain written procedures specifying the cleanout procedures or other means and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize their processes, and then to help inspection personnel confirm that the firm is operating in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being followed when they are conducting an inspection.

These written procedures must be maintained as long as the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process the record must be updated. Written procedures required by this section shall be made available for inspection and copying by FDA.

Description of Respondents: Respondents include renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution.

In the **Federal Register** of December 21, 2018 (83 FR 65681), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received in support of the collection of information.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
589.2000(e)(1)(iv); written procedures	320	1	320	14	4,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on our experience with similar requirements to maintain written procedures. We base our estimate of the number of recordkeepers on inspectional data. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17478 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0375]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Agreement for Shipment of Devices for Sterilization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 13, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0131. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150

OMB Control Number 0910–0131—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations at § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms.

Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Contact information of the firms involved and the identification of the signature authority of the shipper and receiver, (2) instructions for maintaining accountability of the number of units in each shipment, (3) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (4) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (see § 801.150(a)(2)).

The respondents to this collection of information are device manufacturers and contract sterilizers. FDA's estimate of the reporting burden is based on data obtained from industry over the past several years. It is estimated that each of the firms subject to this requirement prepares an average of 20 written agreements each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part-time basis for only one customer, while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a usual and customary business practice. The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the records required under the third-party disclosure section of this collection.

In the **Federal Register** of April 26, 2019 (84 FR 17837), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Record retention, 801.150(a)(2)	100	20	2,000	0.5	1,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Agreement and labeling requirements, 801.150(e)	100	20	2,000	4	8,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 900 total hours and a corresponding increase of 400 records/disclosures. We attribute this increase to an increase in the number of agreements that we have seen in inspection data received over the last few years.

Dated: August 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17477 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects; Informed Consent; and Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions found in Agency regulations pertaining to the protection of human subjects and responsibilities of institutional review boards (IRBs).

DATES: Submit either electronic or written comments on the collection of information by October 15, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 15, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 15, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0403 for ''Protection of Human Subjects; Informed Consent; and Institutional Review Boards.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Protection of Human Subjects; Informed Consent; and Institutional Review Boards—21 CFR Parts 50 and 56

OMB Control Numbers 0910–0755 and 0910–0130—Revision

This information collection supports Agency regulations pertaining to the protection of human subjects, informed consent, and responsibilities of IRBs as set forth in parts 50 and 56 (21 CFR parts 50 and 56). Parts 50 and 56 apply to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA. The regulations in parts 50 and 56 are intended to protect the rights and safety of subjects involved in investigations filed under sections 403, 406, 409, 412, 413, 503, 505, 510, 513–515, 520, 531–539, 541, 542, 701, and 721 of the FD&C Act (21 U.S.C. 343, 346, 348, 350a, 350b, 353, 355, 360, 360c, 360c–1, 360d, 360e, 360j, 360hh–360pp, 360rr, 360ss, 371, and 379e) and section 351 of the Public Health Service Act (42 U.S.C. 262). The regulations also contain the standards for composition, operation, and responsibilities of IRBs that review clinical investigations regulated by FDA.

I. Part 50—Protection of Human Subjects

With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. Basic elements of informed consent are set forth in § 50.25 (21 CFR 50.25) and include a statement of the purpose and duration of a subject's participation in the research, as well as a description of the procedures to be followed, risks, benefits, experimental nature, contact information, that participation is voluntary, and additional elements as may be appropriate. Exceptions to these requirements are governed by § 50.23 (21 CFR 50.23), which requires both investigator and physician to certify in writing that necessary elements for exception from general requirements have been satisfied, and § 50.24 (21 CFR 50.24), which covers exception from informed consent requirements for emergency research. In accordance with § 50.27 (21 CFR 50.27), informed consent must be documented.

II. Part 56—Institutional Review Boards

The general standards for the composition, operation, and responsibility of an IRB are set forth in part 56. Administrative activities are also covered and documentation that must be prepared and maintained is identified. Required recordkeeping includes documentation pertaining to written procedures, committee membership, meeting minutes, correspondence, as well as other functional and operational aspects of the IRB. Finally, the regulations describe administrative actions for non-compliance, including both disqualification of IRBs or IRB parent institutions, as well as reinstatement and alternative and additional actions.

On our own initiative, we are revising the information collection by consolidating the information collection currently approved under OMB control number 0910–0130 with the information collection currently approved under OMB control number 0910–0755 pertaining to human subject protection and IRB responsibilities. Because of the related nature of the information collections and the applicable regulations in parts 50 and 56, we believe taking this action will improve our operational efficiency.

We estimate the annual burden for the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
50.24; exceptions from informed consent for emergency research.	8	3	24	1	24
50.25; elements of informed consent—required statements.	2,520	40	100,800	0.5 (30 minutes)	50,400
50.27; documentation of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400
56.109(d); written statement about minimal risk research when documentation of informed consent is waived.	2,520	2	5,040	0.5 (30 minutes)	2,520
56.109(e); written notification to approve or disapprove research.	2,520	40	100,800	0.5 (30 minutes)	50,400

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
56.113; suspension of research	2,520	1	2,520	0.5 (30 minutes)	1,260
56.120(a); IRB response to lesser administration actions for noncompliance.	7	1	7	10	70
56.123; reinstatement of an IRB or an institution.	1	1	1	5	5
Total					155,079

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of data, there are currently 2,520 IRBs overseeing FDA-regulated clinical research. We have revised the table to list only one requirement per row, rather than estimating the combination of several requirements. The estimated burden resulted in an increase from 1 hour to 1.5 hours when these combined requirements were estimated separately. We believe this is a more accurate measure of the cumulative time necessary for these activities. We invite comment on this estimate.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
56.115; IRB records	2,520	14.6	36,792	40	1,471,680

[1] There are no capital or operating and maintenance costs associated with the information collection.

We assume each of the 2,520 IRBs meets an average of 14.6 times annually and that approximately 40 hours of person-time per meeting are required to meet the requirements of the regulation. We have reduced the average burden per record from 100 hours to 40 hours because we believe the original estimate of 100 hours has decreased with the use of electronic recordkeeping and new technologies available to maintain records. We request comments on this revision.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
56.109(g) IRB written statement about public disclosures to sponsor of emergency research under 50.24	8	2	16	1	16

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For the third-party disclosure burden, we estimate that eight IRBs per year will receive a request to review emergency research under § 50.24. We estimate that it will take an IRB approximately 1 hour to prepare each written statement, for a total of 2 hours per study. The total annual third-party disclosure burden for IRBs to fulfill this requirement is estimated at 16 hours.

Dated: August 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17462 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2479]

Gastroparesis: Clinical Evaluation of Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Gastroparesis: Clinical Evaluation of Drugs for Treatment.'' This draft guidance is intended to provide the FDA's current thinking regarding clinical trial design and clinical endpoint assessments to support development of drugs for the treatment of diabetic and idiopathic gastroparesis. This draft guidance replaces the draft guidance for industry of the same name issued July 23, 2015.

DATES: Submit either electronic or written comments on the draft guidance by October 15, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–2479 for ''Gastroparesis: Clinical Evaluation of Drugs for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Juli Tomaino, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5373, Silver Spring, MD 20993–0002, 301–796–8812.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Gastroparesis: Clinical Evaluation of Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of diabetic and idiopathic gastroparesis. This draft guidance replaces the draft guidance for industry of the same name issued July 23, 2015 (80 FR 43781). This draft was updated to address public comments received in 2015 and to reflect FDA's current thinking on the development of clinical outcome assessment tools and statistical considerations for use of those tools as a measure of the primary and secondary efficacy endpoints.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the FDA's current thinking of FDA on ''Gastroparesis: Clinical Evaluation of Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: August 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17463 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2163]

Child-Resistant Packaging Statements in Drug Product Labeling; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Child-Resistant Packaging Statements in Drug Product Labeling.'' This guidance is intended to assist applicants,

manufacturers, packagers, and distributors who choose to include child-resistant packaging (CRP) statements in prescription and over-the-counter human drug product labeling. The guidance discusses what information should be included to support CRP statements and to help ensure that such labeling is clear, useful, informative, and, to the extent possible, consistent in content and format.

DATES: The announcement of the guidance is published in the **Federal Register** on August 14, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–2163 for ''Child-Resistant Packaging Statements in Drug Product Labeling.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4132, Silver Spring, MD 20993, 301–796–1697; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Child-Resistant Packaging Statements in Drug Product Labeling.'' In 1970, the Poison Prevention Packaging Act (PPPA) was enacted to protect children (under 5 years of age) from unintentional exposure to household substances including food, drugs, and cosmetics. Under the Federal Food, Drug, and Cosmetic Act, a drug that has packaging or labeling that is in violation of a regulation issued pursuant to section 3 or 4 of the PPPA is deemed to be misbranded. FDA was responsible for enforcing the PPPA until 1973, when jurisdiction was transferred to the U.S. Consumer Product Safety Commission (CPSC). Because of FDA's authority to regulate labeling for prescription and nonprescription drug products, if firms choose to make statements in their labeling for such products about child-resistant packaging, such statements must comply with FDA's statutory and regulatory requirements. The guidance explains that to ensure that CRP statements on labeling are not false or misleading, such statements should only be used when the drug product packaging has been shown to comply with CPSC regulatory standards and test procedures for CRP, as applicable. This guidance is intended to apply to FDA-regulated drug products that bear CRP statements, regardless of whether CRP is required for such products under 16 CFR 1700. For example, bulk packages of prescription drugs that are shipped to pharmacies for repackaging by a pharmacist are not required to utilize CRP, but a firm may nevertheless choose to use CRP (and a CRP statement) for such drugs.

CPSC's regulations list ''special packaging standards'' for a wide range of household products, including most oral prescription drugs and many nonprescription drug products (see 16 CFR 1700 for substances requiring special packaging and the relevant packaging standards and testing procedures). It should be noted that ''child-resistant'' should not be equated with ''child-proof,'' because CRP is not designed to completely eliminate the possibility of an accidental pediatric ingestion. It can only impede access to harmful products and is recognized by public health experts as only one component of preventing these events. There are different ways to make packaging child-resistant, with the most common forms being a child-resistant closure (*e.g.,* a ''safety cap'') and certain unit-dose blister packaging (*e.g.,* puncture-resistant and peel-push blisters). FDA advocates that all drugs, irrespective of the type of packaging, be stored safely out of reach and sight of children to further the overall public health efforts to address this safety issue.

Because health care professionals and consumers may not be able to determine on visual inspection whether the packaging is child-resistant, a labeling statement may help to identify this attribute. Therefore, in this guidance, we recommend text that may be appropriate to consider when including CRP statements in labeling. All of the stakeholder comments on the draft guidance were carefully reviewed and, where appropriate, clarifying edits were made in the final guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Child-Resistant Packaging Statements in Drug Product Labeling.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information for submitting labeling in original and supplemental new drug applications (NDAs), and abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) in 21 CFR 314.50(e) and (l), 314.94(a)(8), 314.70, and 314.97, and 21 CFR 601.2 and 601.12 has been approved under OMB control number 0910–0001 and 0910–0338, respectively. The collection of information for preparing prescription drug product labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collection of information for Drug Facts labeling under 21 CFR 201.66 has been approved under OMB control number 0910–0340. The collection of information for Medication Guides has been approved under OMB control number 0910–0393. The collection of information for submitting chemistry, manufacturing, and controls information in original and supplemental NDAs, ANDAs, and BLAs in 21 CFR 314.50(d)(1), 314.94(a)(9), 314.70, and 314.97, and 21 CFR 601.2 and 601.12 has been approved under OMB control number 0910–0001 and 0910–0338, respectively.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov*.

Dated: August 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17433 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Requests for NIH Certificates of Confidentiality

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), in the Office of the Director, the National Institutes of Health (NIH) is streamlining the electronic system for the submission and processing of requests for NIH to issue Certificates of Confidentiality (CoCs).

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Pamela Reed Kearney, Division of Human Subjects Research, OER, NIH, 6705 Rockledge Dr., Building Rockledge 1, Room 812–C, Bethesda, MD 20817, or call non-toll-free number (301) 402–2512, or email your request, including your address to: *NIH-CoC-Coordinator@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925–0689, exp., date 12/31/2019 REVISION. Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This request system provides one electronic form to be used by all research organizations that request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the agencies of Department of Health and Human Services (DHHS), including NIH, to authorize researchers to protect the privacy of human research subjects by prohibiting them from releasing names and identifying characteristics of

research participants to anyone not connected with the research, except in limited circumstances specified in the statute. At NIH, the issuance of CoCs has been delegated to the NIH OER in the NIH Office of the Director. NIH received 529 requests for CoCs from April 2017 through March 2018 and expects to receive approximately the same number of requests in subsequent years. The NIH has been using an online CoC system to review requests and issue CoCs since 2015. The current CoC request form includes 15 sections of information collected from research organizations. The streamlined NIH CoC electronic system will have seven sections of structured or short text fields. The information provided will be used to determine eligibility for a CoC and to issue the CoC to the requesting organization. Eligible requesting organizations that provide legally binding affirmations that they will abide by the terms of the CoC would be issued a Certificate of Confidentiality. This system is expected to increase efficiency and reduce burden for both requestors and NIH staff who currently process these requests.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 177.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
CoC Applicants—Private	372	1	20/60	124
CoC Applicants—State/local	26	1	20/60	9
CoC Applicants—Small business	53	1	20/60	18
CoC Applicants—Federal	78	1	20/60	26
Total	529			177

Dated: August 7, 2019.

Lawrence Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–17358 Filed 8–13–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 26, 2019, 10:00 a.m. to 5:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on July 03, 2019, 84 FR 31878.

The meeting will be held on August 20, 2019 at 9:00 a.m. to 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: August 8, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17400 Filed 8–13–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, September 4, 2019, 8:30 a.m. to September 5, 2019, 12:00 p.m., National Institutes of Health, National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room TE406 & 408, Rockville, MD 20817 which was published in the **Federal Register** on February 11, 2019, 84 FR 3203.

This meeting notice is amended to change the meeting from a face-to-face meeting on September 4, 2019, 8:30 a.m. to September 5, 2019, 12:00 p.m. to a virtual meeting on September 4, 2019 from 1:00 p.m. to 4:30 p.m. The open session will be held from 1:00 p.m. to 3:15 p.m. and the closed session will be held from 3:30 p.m. to 4:30 p.m. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). The meeting is partially closed to the public.

Dated: August 8, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17399 Filed 8–13–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning; Software Products

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

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (''CBP'') has issued a final determination concerning the country of origin of CIS Secure Computing, Inc.'s software products for use on mobile devices and on servers and other similar network devices. Based upon the facts presented, CBP has concluded that the software products are substantially transformed in the United States for purposes of U.S. Government procurement.

DATES: The final determination was issued on August 7, 2019. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than September 13, 2019.

FOR FURTHER INFORMATION CONTACT: James Kim, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202) 325–0158.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on August 7, 2019, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart

B), CBP issued a final determination concerning the country of origin of CIS Secure Computing, Inc.'s software products, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H301776, was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that CIS Secure Computing, Inc.'s software products are substantially transformed in the United States for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: August 7, 2019.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

HQ H301776

August 7, 2019

OT:RR:CTF:VS H301776 JK

CATEGORY: Origin

John Turner, CTO

CIS Secure Computing, Inc.

21050 Ashburn Crossing Drive, Suite 145

Ashburn, VA 20147

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Substantial Transformation

Dear Mr. Turner:

This is in response to your letter, dated September 19, 2018, requesting a final determination on behalf of CIS Secure Computing, Inc. (''CIS Secure Computing'' or ''Company''), pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (CBP) Regulations (19 C.F.R. Part 177). As a U.S. importer, CIS Secure Computing is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

FACTS:

CIS Secure Computing requests a final determination on two software products that it intends to produce for government procurement purposes: software for use on mobile devices (''Mobile Device Software''), and software for use on servers and other similar network devices (''Server Software''). The Mobile Device Software includes a customized version of the Android operating system and mobile configuration management software, which provide advanced security features and functions to a mobile device. The Server Software includes configuration management software for remotely controlling certain functions and operations of a mobile device configured with the Mobile Device Software.

Both software products are produced in a four-step process that involves: (1) writing original source code, or modifying open source software code in the United States; (2) writing or modifying source code in Canada; (3) compiling the source code into executable object code in the United States; and (4) delivering the finished software to the purchaser. The source code will be written by the Company's employees at its offices located in Ashburn, Virginia and in Canada.[1]

In a submission dated May 21, 2019, CIS Secure Computing provided additional information on the processes involved in writing source code and compiling it into executable object code in steps (1) through (3).

Writing the source code for the Mobile Device Software will involve the following steps:

1. The Company's software developers in Ashburn, Virginia will download certain open source software code for the Android operating system, also known as Operating System code (''OS code''). The Company will modify the OS code and write original source code in Ashburn, Virginia. Modifying the OS code includes deleting or modifying one or more portions of the original source code to produce modified OS code.

2. The Company's software developers in Canada will access the modified OS code and the original source code stored in a collaborative software development environment and may further modify the OS code and write original source code.

3. In performing steps 1 and 2, software programmers write computer code using tools such as Android Studio, Eclipse and Text Editors. The software programmers may also write the computer code in C++, C, Java, Kotlin, Python and Perl programming languages. User interface designers design and write computer code for a graphical layout using tools such as Android Studio and Eclipse. Software developers modify Android Open Source Code Project (AOSP) build scripts using tools such as GNU Make and Blueprint.

4. Once the modified OS code and the original source code are completed, the Company will download all of the modified OS code and the original source code to computers located at its offices in Ashburn, Virginia. Completed code is checked into the Company's software repository for storage. The result of the combination will be the source code for the Mobile Device Software; however, it will not be executable software code.

Writing the source code for the Server Software will involve the following steps:

1. The Company's software developers in Ashburn, Virginia will write original source code. The original source code will be stored in a collaborative software development environment.

2. The Company's software developers in Canada will also write original source code. The original source code written by the Company's software developers in Canada will also be stored in the same collaborative software development environment.

3. In performing steps 1 and 2, software programmers write computer code using tools such as IntelliJ, Eclipse and Text Editors. The software programmers may also write the computer code in Scala, Java and JavaScript languages. User interface designers design and write computer code for a graphical layout using Angular JS and related tools such as Node, NPM, Bower and Grunt.

4. When the source code is complete, the Company will download all of the original source code to one or more computers in Ashburn, Virginia. Completed code is checked into the Company's software repository for storage. The downloaded original source code will comprise the source code for the Server Software; however, it will not be executable software code.

CIS Secure Computing will then perform a software build on computers located in its offices in Ashburn, Virginia. During this step, the source code for the Mobile Device Software and

[1] In your original submission dated September 18, 2018, you stated that the writing of source code in Canada was performed by a contract Canadian software development company. In your submission dated May 21, 2019, you stated that CIS Secure Computing had completed acquisition of this contract Canadian software development company, and that any software writing, software compilation, or other operations that were originally described as performed by the Canadian software development company are now performed by employees of CIS Secure Computing.

the Server Software will each be compiled into executable object code.

Compiling the source code into executable object code for the Mobile Device Software involves the following steps:

1. The Company's software developers in Ashburn, Virginia sign into a Jenkins build server and schedule a build action to perform the compilation process. The Jenkins build server also performs a nightly build action.

2. The Jenkins build server retrieves the latest version of the source code from the Company's software repository and, if needed, from a source code repository for AOSP.

3. The build server performs a compilation process using AOSP compilation tools such as gcc, Jack, Proguard and Python to compile the source code into object code for each relevant platform on Android ARM 32-bit CPU and ARM 64-bit CPU.

4. The Company's software developers perform work to address any incompatibilities or errors that emerge during compilation. If needed, they verify or rectify the source code, and may re-perform steps 1 through 3.

Compiling the source code into executable object code for the Server Software involves the following steps:

1. The Company's software developers in Ashburn, Virginia sign into the Jenkins build server and schedule a build action to perform the compilation process. The Jenkins build server also performs a nightly build action.

2. The Jenkins build server retrieves the latest version of the source code from the Company's software repository.

3. The build server performs a compilation process using a Scala build tool or Java compiler for the Linux platform to compile the source code into object code.

4. The build server transcodes and minifies [2] Javascript using a Grunt compiler.

5. The Company's software developers perform work to address any incompatibilities or errors that emerge during compilation. If needed, they verify or rectify the source code, and may re-perform steps 1 through 4.

As a final step, CIS Secure Computing will deliver the finished software to the purchaser. For the Mobile Device Software, the Company will load the object code onto mobile devices at its offices in Ashburn, Virginia. Then the Company will provide the mobile devices with the object code to the purchaser.

For the Server Software, CIS Secure Computing will deliver the object code to the purchaser in one of the following ways, depending on the purchaser's requirements: (1) the Company will load the object code onto a server device at its offices in Ashburn, Virginia and may provide the server device to a purchaser; (2) the Company will transmit the object code electronically to a purchaser server; and/or (3) the Company will load the object code to a storage medium, such as a CD or a disk drive, and may deliver the CD or disk drive containing the object code to the purchaser.

ISSUE:

Whether the Mobile Device Software and Server Software are substantially transformed in the United States for government procurement purposes.

LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*) (TAA).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

> An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define ''U.S.-made end product'' as:

> . . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

The issue in this case is whether the source code written for the Mobile Device Software and Server Software is substantially transformed in the United States when the Company performs a ''software build'' in the United States, *i.e.*, compiles the source code written in Canada (along with source code written in the United States) into executable object code. At the outset, we note that ''source code'' and ''object code'' differ in several important ways. Source code is a ''computer program written in a high level human readable language.'' *See, e.g.*, Daniel S. Lin, Matthew Sag, and Ronald S. Laurie, *Source Code versus Object Code: Patent Implications for the Open Source Community*, 18 Santa Clara High Tech. L.J. 235, 238 (2001). While it is easier for humans to read and write programs in ''high level human readable languages,'' computers cannot execute these programs. *See* Note, *Copyright Protection of Computer Program Object Code*, 96 Harv. L. Rev. 1723, 1724 (1983). Computers can execute only ''object code,'' which is a program consisting of clusters of ''0'' and ''1'' symbols. *Id.* Programmers create object code from source code by feeding it into a program known as a ''compiler.'' *Id.* In this case, the writing of source code in Canada (and the United States) involves the creation of computer instructions in a high level human readable language, whereas the software build performed in the United States involves the compilation of those instructions into a format that computers can execute.

CBP has consistently held that conducting a software build—compiling source code into object code—results in substantial transformation. For example, in HQ H268858, dated Feb. 12, 2016, four software products were produced using the same three-step process: (1) writing the source code in Malaysia; (2) compiling the source code into usable object code in the United States; and (3) installing the finished software on U.S.-origin discs in the United States. CBP held that all four software products were substantially transformed in the United States, finding that the software build conducted in the United States was sufficient to create a new and different article with a new name,

[2] Minification refers to the process of removing unnecessary or redundant data without affecting how the resource is processed by the browser - *e.g.*, code comments and formatting, removing unused code, using shorter variable and function names, and so on. *See https://developers.google.com/speed/docs/insights/MinifyResources* (last accessed August 6, 2019).

character, and use. *See also* HQ H243606, dated Dec. 4, 2013 (source code programmed in China and then compiled into object code in the United States was substantial transformation).

Consistent with the rulings cited above, we find that the Mobile Device Software and Server Software are substantially transformed in the United States as a result of the software build: the name of the product changes from source code to object code, the character changes from computer code to finished software, and the use changes from instructions to an executable program.

HOLDING:

Based on the information provided, the Mobile Device Software and Server Software are substantially transformed in the United States for U.S. government procurement purposes.

Notice of this final determination will be given in the **Federal Register**, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the **Federal Register** notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

[FR Doc. 2019–17377 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Modification of the National Customs Automation Program Test Regarding Post-Summary Corrections for Extensions of Liquidation

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

ACTION: General notice.

SUMMARY: This document announces U.S. Customs and Border Protection's (CBP's) modification to the National Customs Automation Program (NCAP) test pertaining to the processing of post-summary corrections (PSCs). The modification in this notice expands the time period in which a PSC must be filed by allowing a PSC to be transmitted up to 15 days prior to the scheduled date of liquidation when liquidation has been extended. Except to the extent expressly announced or modified by this document, all aspects, rules, terms and conditions announced in previous notices regarding the PSC test remain in effect.

DATES: The modifications announced in this test will become operational on August 14, 2019.

ADDRESSES: Comments concerning this notice and any aspect of this test may be submitted at any time during the test via email to Randy Mitchell, Director, Commercial Operations, Revenue and Entry Division, Trade Policy and Programs, Office of Trade, via email at *OTENTRYSUMMARY@cbp.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: For policy-related questions, contact Randy Mitchell, Director, Commercial Operations, Revenue and Entry Division, Trade Policy and Programs, Office of Trade, via email at *OTENTRYSUMMARY@cbp.dhs.gov.* For technical questions related to Automated Broker Interface transmissions, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to the Client Representative Branch at *CLIENTREPOUTREACH@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The National Customs Automation Program (NCAP) was established by Subtitle B of Title VI—Customs Modernization in the North American Free Trade Agreement (NAFTA) Implementation Act (Customs Modernization Act) (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (19 U.S.C. 1411). Through NCAP, the thrust of customs modernization was on trade compliance and the development of the Automated Commercial Environment (ACE), the planned successor to the Automated Commercial System (ACS) as the CBP-authorized electronic data interchange (EDI) system. ACE is an automated and electronic system for commercial trade processing which is intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while ensuring compliance with U.S. laws and regulations and reducing costs for U.S. Customs and Border Protection (CBP) and all of its communities of interest. The ability to meet these objectives depends on successfully modernizing CBP's business functions and the information technology that supports those functions.

CBP's modernization efforts are accomplished through phased releases of ACE component functionality designed to replace specific legacy ACS functions and add new functionality. Section 101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)) provides for the testing of NCAP components. *See* T.D. 95–21, 60 FR 14211 (March 16, 1995).

On June 24, 2011, CBP published a notice in the **Federal Register** (76 FR 37136) that announced a plan to conduct an NCAP test concerning new ACE capabilities allowing importers to file a post-summary correction (PSC) for certain entry summaries using the Automated Broker Interface. Through a series of subsequent **Federal Register** notices, CBP has modified and clarified various aspects of the PSC test. Originally, a PSC had to be transmitted within 270 days after the date of entry, but could not be filed within 20 days prior to the scheduled date of liquidation. However, on November 1, 2017, CBP published a notice in the **Federal Register** (82 FR 50656) modifying the PSC test to require filing within 300 days after the date of entry or up to 15 days prior to the scheduled liquidation date, whichever date is earlier. In the event that liquidation was extended, there was no change to the PSC deadline.

II. Modification of the PSC Test

This document announces that CBP is extending the deadline for filing a PSC in cases where an importer requests and is granted an extension of liquidation pursuant to 19 CFR 159.12. With this modification, after an importer is granted an extension of liquidation, a PSC must be transmitted up to 15 days prior to the scheduled liquidation date. Accordingly, for test participants, a PSC must be transmitted within 300 days after the date of entry or up to 15 days prior to the scheduled liquidation date, whichever is earlier, except in situations involving an extension of liquidation, in which case a PSC must be transmitted up to 15 days prior to the scheduled liquidation date.

This change is being made to increase the amount of time a filer has to submit a PSC in situations involving extensions of liquidation. Except to the extent expressly announced or modified by this document, all aspects, rules, terms, requirements, obligations and conditions announced in previous notices regarding the PSC test remain in effect.

Dated: August 2, 2019.

Brenda B. Smith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2019–17444 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4372–DR; Docket ID FEMA–2019–0001]

Massachusetts; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Massachusetts (FEMA–4372–DR), dated June 25, 2018, and related determinations.

DATES: This change occurred on July 30, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James McPherson, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of James N. Russo as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17454 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4410–DR]; [Docket ID FEMA–2019–0001]

Connecticut; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Connecticut (FEMA–4410–DR), dated December 5, 2018, and related determinations.

DATES: This change occurred on July 30, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James McPherson, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of James N. Russo as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17443 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4451–DR; Docket ID FEMA–2019–0001]

Missouri; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Missouri (FEMA–4451–DR), dated July 9, 2019, and related determinations.

DATES: This amendment was issued August 5, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Missouri is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 9, 2019.

Calloway and Jefferson Counties for Individual Assistance.

Lewis, McDonald, Newton, and Saline Counties for Individual Assistance (already designated for Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17434 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4379–DR; Docket ID FEMA–2019–0001]

Massachusetts; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Massachusetts (FEMA–4379–DR), dated July 19, 2018, and related determinations.

DATES: This change occurred on July 30, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James McPherson, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of James N. Russo as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17445 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4449–DR; Docket ID FEMA–2019–0001]

Kansas; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Kansas (FEMA–4449–DR), dated June 20, 2019, and related determinations.

DATES: This amendment was issued August 5, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Kansas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 20, 2019.

Brown, Ness, Osborne, Smith, Stafford, Wallace, and Wyandotte Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17435 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4445–DR; Docket ID FEMA–2019–0001]

Vermont; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Vermont (FEMA–4445–DR), dated June 14, 2019, and related determinations.

DATES: This change occurred on July 30, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James McPherson, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of James N. Russo as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17439 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4438–DR; Docket ID FEMA–2019–0001]

Oklahoma; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Oklahoma (FEMA–4438–DR), dated June 1, 2019, and related determinations.

DATES: This amendment was issued August 1, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Oklahoma is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 1, 2019.

Caddo, Kiowa, and Woodward Counties for Public Assistance [Categories A–G], including direct federal assistance, under the Public Assistance program.

Kay County for Public Assistance [Categories A–G] (already designated for Individual Assistance and assistance for emergency protective measures [Category B], limited to direct federal assistance under the Public assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17440 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4428–DR]; [Docket ID FEMA–2019–0001]

Kentucky; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Kentucky (FEMA–4428–DR), dated April 17, 2019, and related determinations.

DATES: This amendment was issued August 1, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Kentucky is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 17, 2019.

Hickman County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17441 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4367–DR; Docket ID FEMA–2019–0001]

Maine; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Maine (FEMA–4367–DR), dated May 30, 2018, and related determinations.

DATES: This change occurred on July 30, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James McPherson, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of James N. Russo as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–17458 Filed 8–13–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7015–N–07]

60-Day Notice of Proposed Information Collection: Alternative Inspections—Housing Choice Voucher Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 15, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW, Room 3176 Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Alternative Inspections—Housing Choice Voucher Program.

OMB Approval Number: 2577–0287.

Type of Request: Extension of a currently approved collection.

Form Number N/A.

Description of the need for the information and proposed use: Under the Section 8 housing choice voucher rule, PHAs that elect to rely on an alternative inspection are required to meet the requirements of subpart I of the rule. If the inspection method and standard selected is other than HOME Investment Partnerships (HOME) program, Low-Income Housing Tax Credits (LIHTCs), or that performed by HUD, the PHA must submit a request to HUD. PHAs with approved alternative inspection standards must monitor changes to the standards and requirements of their method and if changes are made must submit to HUD a copy of the revised standards and requirements along with a revised comparison to HQS.

Respondents (*i.e.,* affected public): State, Local or Tribal Governments.

Estimated Number of Respondents: 2280.

Estimated Number of Responses: 33.

Frequency of Response: 1.

Average Hours per Response: 4.

Total Estimated Burdens: 149 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 1, 2019.

Merrie Nichols-Dixon,

Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2019–17456 Filed 8–13–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7015–N–05]

60-Day Notice of Proposed Information Collection: National Standards for the Physical Inspection of Real Estate (NSPIRE) Demonstration

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, PIH, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment. This Information Collection was previously approved as an Emergency PRA, with the specific intent of expeditiously testing revisions to the inspection standards and protocol through a demonstration program to enable enhanced identification and resolution of health and safety deficiencies in HUD-assisted/insured housing. Due to the urgency to expedite the Emergency PRA, a mathematical error was noted in the burden requirement and corrections have been made accordingly. A revision to correct the burden hours is being requested to correct the hours from 11,950 to 12,150 burden hours.

DATES: *Comments Due Date:* October 15, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech

impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: National Standards for the Physical Inspection of Real Estate (NSPIRE) Demonstration.

OMB Approval Number: 2577–0289.

Type of Request: Revision of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: HUD's Real Estate Assessment Center (REAC) has developed a new inspection model entitled the National Standards for the Physical Inspection of Real Estate (NSPIRE). Prior to nationwide implementation, REAC will test NSPIRE through a multistage Demonstration to identify potential adjustments to standards, protocols, and processes. HUD will ask public housing agencies (PHAs), and owners and agents (OAs) (collectively referred to as POAs) to participate in this Demonstration through a voluntary application process and plans to test this model with approximately 4,500 properties.

HUD is developing a standardized electronic system and data exchange standard for this collection and will distribute self-inspection software for properties to collect and submit this data electronically. Within the scope of this collection, HUD requests the following information from participating POAs: An annual self-inspection report or work order receipts; a property profile; copies of building system certificates; local code violations over the rolling calendar year; and participation in feedback sessions.

1. Many POAs have statutory, regulatory, or housing program contractual requirements to conduct an annual self-inspection of the property, including all the dwelling units. POAs will be provided with self-inspection software that will enable them to easily document and submit deficiencies across the rolling calendar year. In lieu of submitting a self-inspection report, POAs can electronically submit work order receipts from across the rolling calendar year. This data provides reasonable assurance that every dwelling unit was evaluated for deficiencies and maintenance needs.

2. POAs will submit a property profile documenting the: Owner/company name, physical address, type of housing (*e.g.* Section 8), structure type, number of buildings, number of floors, number of units, if there is an attached garage, types of fuel-burning appliances, and an updated floor plan.

3. POAs will submit an electronic copy of all building system certificates. These certificates include but are not limited to elevators, fire alarm systems (including carbon monoxide detectors if part of the fire alarm system), sprinkler systems, boilers (HVAC or domestic water), and lead-based paint inspection reports. HUD believes that it is important for POAs to provide this information annually as the inoperability of these systems can have a substantial effect on the resident.

4. POAs will submit a list of local code violations for which the property was cited over the rolling calendar year. HUD regulations, at 24 CFR 5.703(g), require HUD housing to adhere to local code. HUD believes that compliance (or non-compliance) with local code can serve as an important indicator as to whether a property is conducting regular maintenance and whether it is providing acceptable basic housing conditions.

5. Finally, HUD will ask 900 POAs to provide feedback on the NSPIRE Demonstration via one in-person listening session. With this information, HUD will be better able to refine inspection standards and protocols, ensuring resident housing is decent, safe, sanitary, and in good repair.

Without information from the property's annual self-inspection, HUD's interests will not be protected, and HUD will not be able to easily identify risks due to neglected maintenance. Analyzing self-inspection data will allow HUD to better identify these risks and improve the accuracy of property assessments, the consistency of inspections, and ultimately to provide residents with quality affordable housing.

Respondents: POAs participating in the NSPIRE Demonstration.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
	60,000	Annually	4,500	2.7 hours per property	12,150	$22.76	$276,534

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 1, 2019.

Merrie Nichols-Dixon,

Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2019–17455 Filed 8–13–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–38]

30-Day Notice of Proposed Information Collection: FHA Lender Approval, Annual Renewal, Periodic Updates and Required Reports by FHA-Approved Lenders

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the

Paperwork Reduction Act (PRA), HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date: September 13, 2019.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

FOR FURTHER INFORMATION CONTACT: Volky Garcia, Director, Lender Approval and Recertification Division, Office of Lender Activities and Program Compliance, Office of Single Family Housing, U.S. Department of Housing and Urban Development, 490 L'Enfant Plaza East SW, Room P3214, Washington, DC 20024–8000; email *Volky.A.Garcia@hud.gov,* or telephone 202–402–8229. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on March 12, 2019 at 84 FR 8888.

A. Overview of Information Collection

Title of Information Collection: FHA Lender Approval, Annual Renewal, Periodic Updates and Required Reports by FHA-Approved Lenders.

OMB Approval Number: 2502–0005.

Type of Request: Revision of a currently approved collection.

Form Number: Online form (previously HUD–92001–A) and Annual Certification, with no corresponding number.

Description of the need for the information and proposed use: Title II of the National Housing Act, as amended, 12 U.S.C. 1703, 1709, and 1715b, 42 U.S.C. 1436(a) 3535(d), authorizes the Secretary of HUD to prescribe terms and conditions with respect to mortgage insurance under the above act. Criteria for approval to become a Title I lender and/or Title II mortgagee, as well as requirements to maintain that approval, are specified in 24 CFR 202, 24 CFR 203.433, 24 CFR 203.434 and Handbook HUD 4000.1, which became effective on September 14, 2015. The requirements in Handbook HUD 4000.1 represent the consolidation of those previously set forth in Handbooks HUD 4700.2 & 4060.1 and various Title I Letters and Mortgagee Letters.

31 U.S.C. 7701, the Debt Collection Improvement Act of 1986, authorizes ''the head of an agency administering an included Federal loan program'' to collect taxpayer identifying numbers for ''a lender or servicer in a Federal guaranteed or insured loan program administered by the agency.'' Executive Order 9397, as amended by Executive Order 13478, also authorizes federal departments and agencies to use Social Security Numbers ''as a system to organize and identify individual persons.''

The information is used by FHA to verify that lenders meet all approval, renewal and compliance requirements at all times. It is also used to assist FHA in managing its financial risks and to protect consumers from lender noncompliance with FHA regulations.

The figures below were updated by using Fiscal Year 2018 annual lender approval and recertification submission data. This revision reflects a decrease in the entire OMB approval number burden hours which is attributable to a change in the annual certification responses.

Respondents (*i.e.* affected public): Regulatory or compliance.

Estimated Number of Respondents: 2,852.

Estimated Number of Responses: 18,982.

Frequency of Response: Annual/Periodic.

Average Hours per Response: 1 hour.

Total Estimated Burdens: 13,231.

In addition to the 60 days of public comment that HUD provided on this information collection, HUD also provided the public an opportunity to comment on the FHA Annual Lender Certification through FHA's Office of Single Family Housing ''Drafting Table'' at *https://www.hud.gov/program_offices/housing/sfh/SFH_policy_drafts.* HUD received comments that the annual certification statements require overly broad attestation of regulatory and Handbook provisions which already require strict compliance with all HUD regulations and requirements necessary to maintain the Mortgagee's FHA approval as codified in 24 CFR 202.5. Generally, the commenters recommended that HUD: (1) Rescind the annual certification statements since the National Housing Act does not require certification of compliance with FHA eligibility requirements or completion of an annual certification; or (2) revise the annual certification statements to a general acknowledgement of the existence of policies and procedures that are reasonably designed to ensure material compliance. In response to the feedback and recommendations, HUD developed a streamlined FHA Annual Lender Certification attached as Appendix A.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including using the appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 9, 2019.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

Appendix A

FHA Lender Annual Certification Statements (All Mortgagees)
DRAFT as of 7/29/2019

1. I acknowledge that I am a Corporate Officer of the abovementioned Mortgagee (hereinafter referred to as ''the Mortgagee'') authorized to execute these certifications and acknowledgements on behalf of the Mortgagee.

2. I certify that, during the Certification Period, the Mortgagee, or any Corporate

Officer (as defined at HUD Handbook 4000.1 I.A.3.c.iv.(B)) was not:

(a) Subject to a suspension, debarment, or under a Limited Denial of Participation (LDP); or

(b) Refused or had revoked, any license necessary to conduct normal operations in the mortgage loan industry by any State(s) (as defined at 12 U.S.C. 1707(d)) in which the Mortgagee will originate insured mortgages or Title I loans.

3. I certify that during the Certification Period the Mortgagee was not sanctioned by any State(s) (as defined at 12 U.S.C. 1707(d)) in which the Mortgagee will originate insured mortgages or Title I loans.

4. I certify that the preceding statements are materially correct to the best of my knowledge.

WARNING: This warning applies to all certifications made in this document.

Anyone who knowingly submits a false claim, or makes false statements is subject to criminal and civil penalties, including confinement for up to 5 years, fines, and civil penalties. 18 U.S.C. §§ 287, 1001 and 31 U.S.C. §3729

[FR Doc. 2019–17453 Filed 8–13–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

On August 8, 2019, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Colorado in the lawsuit entitled *United States* v. *Guardian Life Insurance Company of America,* Civil Action No. 1:19–cv–02557.

The proposed Consent Decree resolves the United States' claim under Section 107 of the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. 9607, against the Guardian Life Insurance Company of America (''Guardian Life'') for recovery of past response costs incurred at the Widefield PCE Superfund Site (''Site'') in El Paso County, Colorado. The Site comprises a former dry cleaners at 3217 South Academy Boulevard in Colorado Springs and related contamination of soil and groundwater, including of the Widefield Aquifer. Guardian Life was the owner of the 3217 South Academy Boulevard property at the time of disposal of hazardous substances. The proposed Consent Decree requires Guardian Life to pay $700,000 in reimbursement of past response costs incurred by the United States with respect to the Site. The proposed Consent Decree provides Guardian Life with a covenant not to sue for past response costs incurred by the United States in connection with the Site and contribution protection under CERCLA.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Guardian Life Insurance Company of America,* Civil Action No. 1:19–cv–02557 (D. Colo.), D.J. Ref. No. 90–11–3–11721. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $3.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $3.00.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–17379 Filed 8–13–19; 8:45 am]

BILLING CODE 4410–CW–P

DEPARTMENT OF JUSTICE

U.S. Marshals Service

[OMB Number 1105–0099]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension With Change, of a Previously Approved Collection USMS Medical Forms

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), U.S. Marshals Service (USMS), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until October 15, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any additional information, please contact Nicole Timmons either by mail at CG–3, 10th Floor, Washington, DC 20530–0001, by email at *Nicole.Timmons@usdoj.gov,* or by telephone at 202–236–2646.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension and revision of a currently approved collection.

2. *The Title of the Form/Collection:* USMS Medical Forms.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form Numbers:

—USM–522A Physician Evaluation Report for USMS Operational Employees
—USM–522P Physician Evaluation Report for USMS Operational Employees—Pregnancy Only
—USM–600 Physical Requirements of USMS District Security Officers
—CSO–012 Request to Reevaluate Court Security Officer's Medical Qualification

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

- USM–522A Physician Evaluation Report for USMS Operational Employees
  - *Affected public:* Private sector (Physicians)
  - *Brief abstract:* This form is completed by an USMS operational employee's treating physician to report any illness/injury (other than pregnancy) that requires restriction from full performance of duties for longer than 80 consecutive hours.
- USM–522P Physician Evaluation Report for USMS Operational Employees (Pregnancy Only)
  - *Affected public:* Private sector (Physicians)
  - *Brief abstract:* Form USM–522P must be completed by the OB/GYN physician of pregnant USMS operational employees to specify any restrictions from full performance of duties.
- USM–600 Physical Requirements of USMS District Security Officers
  - *Affected public:* Private sector (Physicians)
  - *Brief abstract:* It is the policy of the USMS to ensure a law enforcement work force that is medically able to safely perform the required job functions. All applicants for law enforcement positions must have pre-employment physical examinations; existing District Security Officers (DSOs) must recertify that they are physically fit to perform the duties of their position each year. DSOs are individual contractors, not employees of USMS; Form USM–522 does not apply to DSOs.
- CSO–012 Request to Reevaluate Court Security Officer's Medical Qualification
  - *Affected public:* Private sector (Physicians)
  - *Brief abstract:* This form is completed by the Court Security Officer (CSO)'s attending physician to determine whether a CSO is physically able to return to work after an injury, serious illness, or surgery. The physician returns the evaluation to the contracting company, and if the determination is that the CSO may return to work, the CSO–012 is then signed off on by the contracting company and forwarded to the USMS for final review by USMS' designated medical reviewing official. Court Security Officers are contractors, not employees of USMS; Form USM–522A does not apply to CSOs.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

USM–522A Physician Evaluation Report for USMS Operational Employees

It is estimated that 208 respondents will complete a 20 minute form twice per year.

USM–522P Physician Evaluation Report for USMS Operational Employees (Pregnancy Only)

It is estimated that 7 respondents will complete a 15 minute form twice per year.

USM–600 Physical Requirements of USMS District Security Officers

It is estimated that 2,000 respondents will complete a 20 minute form.

CSO–012 Request to Reevaluate Court Security Officer's Medical Qualification

It is estimated that 300 respondents will complete a 30 minute form.

6. *An estimate of the total public burden (in hours) associated with the collection:*

USM–522A Physician Evaluation Report for USMS Operational Employees

There are an estimated 139 annual total burden hours associated with this collection.

USM–522P Physician Evaluation Report for USMS Operational Employees (Pregnancy Only)

There are an estimated 4 annual total burden hours associated with this collection.

USM–600 Physical Requirements of USMS District Security Officers

There are an estimated 667 annual total burden hours associated with this collection.

CSO–012 Request to Reevaluate Court Security Officer's Medical Qualification

There are an estimated 150 annual total burden hours associated with this collection.

Total Annual Time Burden (Hr): 960.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: August 9, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–17438 Filed 8–13–19; 8:45 am]

BILLING CODE 4410–FY–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 19–045]

Name of Information Collection: Financial Assistant Awards/Grants and Cooperative Agreements

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection; renewal.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections.

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Gatrie Johnson, National Aeronautics and Space Administration, 300 E Street SW, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Gatrie Johnson, NASA Clearance Officer, NASA Headquarters, 300 E Street SW, JF0000, Washington, DC 20546 or email *Gatrie.Johnson@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request to renew OMB control number 2700–0092. This collection is required to ensure proper accounting of Federal funds and property provided under financial assistance awards (grants and cooperative agreements). Reporting and recordkeeping are prescribed at 2 CFR part 1800 for awards issued to nonprofits, institutions of higher educations, government, and commercial firms when cost sharing is not required and 14 CFR part 1274 for awards issued to commercial firms when cost sharing is required.

II. Methods of Collection

Proposals are submitted through the NASA Solicitation and Proposal Integrated Review and Evaluation System (NSPIRES) or *Grants.gov.* The use of these systems reduces the need for proposers to submit multiple copies to the agency. It allows proposers to submit multiple proposals to different funding announcements without registering each time. Electronic funds transfer is used for payment under Treasury guidance, for commercial firms and through the HHS Payment Management System (PMS) for other recipients. In addition, NASA encourages the use of computer technology and is participating in Federal efforts to extend the use of information technology to more Government processes.

Basis of Estimate

Approximately 6,100 NASA financial assistance awards are open at any one time. It is estimated that out of the 7,100 proposals received each year, NASA awards approximately 1,600 new awards. The period of performance for each financial assistance award is usually three to five years. NASA had approximately 120 awards with commercial firms. Commercial firms submit quarterly payment requests directly to NASA, while other recipients submit the Federal Financial Reports (SF 425) on a quarterly basis to the HHS PMS. Performance, Property, and Patent Reports are filed annually. Historical records indicate that, on average, 1,625 changes are submitted annually. The total number of respondents is based on the average number of proposals that are received each year and the average number of active grants that are managed each year. The total number of hours spent on each task was estimated through historical records and experience of former recipients. Using past calculations, the total cost was estimated using the average salary (wages and benefits) for a GS–12 step 5.

III. Data

Title: Financial Assistant Awards/Grants and Cooperative Agreements.

OMB Number: 2700–0092.

Type of Review: Renewal of a previously approved information collection.

Affected Public: Non-profits, institutions of higher educations, government, and commercial firms.

Estimated Number of Respondents: 13,600.

Estimated Total Annual Burden Hours: 717,641.

Estimated Total Annual Cost to Respondents: $25,131,787.82.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Gatrie Johnson,

NASA PRA Clearance Officer.

[FR Doc. 2019–17362 Filed 8–13–19; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Geosciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Geosciences (1755).

Date and Time:

October 17, 2019; 8:30 a.m.–5:00 p.m. EDT

October 18, 2019; 8:30 a.m.–2:00 p.m. EDT

Place: National Science Foundation, 2415 Eisenhower Avenue, Room 2030, Alexandria, Virginia 22314.

Type of Meeting: Open.

Contact Person: Melissa Lane, National Science Foundation, Room C 8000, 2415 Eisenhower Avenue, Alexandria, Virginia 22314. Phone 703–292–8500.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice, recommendations, and oversight on support for geoscience research and education including atmospheric, geospace, earth, ocean and polar sciences.

Agenda

October 17, 2019

Directorate and NSF activities and plans
Budget Updates
Committee Discussion on Follow-On Report to Dynamic Earth
Meeting with the NSF Chief Operating Officer

October 18, 2019

Division Meetings
COV Reports
Summary of AC OPP Spring Meeting and Upcoming Fall Meeting
Action Items/Planning for Spring 2020 Meeting

Dated: August 8, 2019.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2019–17380 Filed 8–13–19; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting; National Science Board

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

TIME AND DATE: Closed teleconference of the Committee on Strategy of the National Science Board, to be held Thursday, August 15, 2019 at 9:00–9:15 a.m. EDT.

PLACE: This meeting will be held by teleconference at the National Science

Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Committee Chair's Opening Remarks; Approval of Prior Minutes; and Discussion of NSF's FY 2021 OMB Budget Submission.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Kathy Jacquart, 2415 Eisenhower Avenue, Alexandria, VA 22314. Telephone: (703) 292–7000. You may find meeting information and updates (time, place, subject matter or status of meeting) at *https://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2019–17511 Filed 8–12–19; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0163]

Use of Listserv for Low-Level Waste Program Correspondence

AGENCY: Nuclear Regulatory Commission.

ACTION: Implementation of electronic distribution of low-level waste program correspondence.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing this document to inform the public that, as of August 15, 2019, publicly-available low-level waste program correspondence originating from the Division of Decommissioning, Uranium Recovery, and Waste Programs (DUWP) in the Office of Nuclear Material Safety and Safeguards (NMSS) will be transmitted by a computer-based email distribution system Listserv to addressees and subscribers. This change does not affect the availability of official agency records in the NRC's Agencywide Documents Access and Management System (ADAMS).

DATES: This initiative will be implemented on August 15, 2019.

ADDRESSES: Please refer to Docket ID NRC–2019–0163 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0163. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Melanie Wong, telephone: 301–415–2432; email: *Melanie.Wong@nrc.gov* or Stephen Dembek, telephone: 301–415–2342; email: *Stephen.Dembek@nrc.gov.* Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: The DUWP currently already uses Listserv to distribute correspondence for Waste Incidental to Reprocessing (WIR) Program Documents (82 FR 33160; July 19, 2017) as well as reactors in decommissioning (83 FR 49434; October 1, 2018). Public feedback regarding this process has been positive, as it allows for other stakeholders to be notified of and receive NRC's correspondence to addressees in a timely manner. Distribution of documents containing safeguards, proprietary or security-related information, or other information that is withheld from public disclosure will not be affected by this initiative.

This initiative of establishing a Low-Level Waste Program ListServ will be implemented on August 15, 2019. For those members of the public who are currently on the NRC low-level waste program email list and are already receiving NRC emails with links to publicly-available low-level waste program documents, your email addresses have already been transferred to the Low-Level Waste Program ListServ. You will continue to receive NRC correspondences via email in the future and do not need to take further action.

If any other members of the public would like to start receiving NRC emails with a link to future publicly-available low-level waste program documents, please sign-up for the ListServ using the following steps: (1) Go to the NRC's public website and select ''Public Meetings & Involvement,'' (2) select ''Subscribe to Email Updates,'' (3) select ''Lyris Subscription Services'' and check the box for ''LLW Distribution,'' (4) enter the email address through which you want to receive the NRC Listserv emails, and (5) click on ''Subscribe.''

Once subscribed, you will receive an email from the NRC with instructions for managing your NRC Listserv subscription, including how to change email addresses and how to unsubscribe.

Dated at Rockville, Maryland, this 8th day of August, 2019.

For the Nuclear Regulatory Commission.

Bo M. Pham,

Deputy Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019–17370 Filed 8–13–19; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Application for Death Benefits Under the Federal Employees Retirement System (SF 3104); and Documentation & Elections in Support of Application for Death Benefits When Deceased Was an Employee at the Time of Death (SF 3104B)

AGENCY: Office of Personnel Management.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection, Application for Death Benefits under the Federal Employees Retirement System (SF 3104); and Documentation & Elections in Support of Application for Death Benefits When Deceased Was an Employee at the Time of Death (SF 3104B).

DATES: Comments are encouraged and will be accepted until September 13, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the

Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0160) was previously published in the **Federal Register** on November 28, 2018, at 83 FR 61176, allowing for a 60-day public comment period. No comments were received for this collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Standard Form 3104, Application for Death Benefits under the Federal Employees Retirement System, is needed to collect information so that OPM can pay death benefits to the survivor of Federal employees and annuitants. SF 3104B, Documentation in Support of Application for Death Benefits When Deceased Was an Employee at the Time of Death, is needed for deaths in service so that survivors can make the needed elections regarding health benefits, military service and payment of the death benefit.

Analysis

Agency: Retirement Services, Office of Personnel Management.

Title: Application for Death Benefits under the Federal Employees Retirement System and Documentation & Elections in Support of Application for Death Benefits When Deceased Was an Employee at the Time of Death.

OMB Number: 3206–0172.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: SF 3104 = 12,734 and SF 3104B = 4,017.

Estimated Time Per Respondent: 60 minutes.

Total Burden Hours: 16,751 hours.

Office of Personnel Management.

Stephen Hickman,

Regulatory Affairs.

[FR Doc. 2019–17414 Filed 8–13–19; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86607; File No. SR–PEARL–2019–23]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Options Regulatory Fee

August 8, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2019, MIAX PEARL, LLC (''MIAX PEARL'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX PEARL Fee Schedule (the ''Fee Schedule'') to amend its Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange charges an ORF in the amount of $0.0028 per contract side. The Exchange proposes to decrease this ORF to $0.0020 per contract side. In light of historical and projected volume changes and shifts in the industry and on the Exchange, as well as changes to the Exchange's regulatory cost structure, the Exchange is proposing to change the amount of ORF that will be collected by the Exchange. The Exchange's proposed change to the ORF should balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The per-contract ORF will continue to be assessed by MIAX PEARL to each MIAX PEARL Member for all options transactions, including Mini Options, cleared or ultimately cleared by the Member which are cleared by the Options Clearing Corporation (''OCC'') in the ''customer'' range, regardless of the exchange on which the transaction occurs. The ORF will be collected by OCC on behalf of MIAX PEARL from either (1) a Member that was the ultimate clearing firm for the transaction or (2) a non-Member that was the ultimate clearing firm where a Member was the executing clearing firm for the transaction. The Exchange uses reports from OCC to determine the identity of the executing clearing firm and ultimate clearing firm.

To illustrate how the ORF is assessed and collected, the Exchange provides the following set of examples. If the transaction is executed on the Exchange and the ORF is assessed, if there is no change to the clearing account of the original transaction, then the ORF is collected from the Member that is the executing clearing firm for the transaction. (The Exchange notes that, for purposes of the Fee Schedule, when there is no change to the clearing account of the original transaction, the executing clearing firm is deemed to be the ultimate clearing firm.) If there is a change to the clearing account of the original transaction (*i.e.,* the executing

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

clearing firm ''gives-up'' or ''CMTAs'' the transaction to another clearing firm), then the ORF is collected from the clearing firm that ultimately clears the transaction—the ultimate clearing firm. The ultimate clearing firm may be either a Member or non-Member of the Exchange. If the transaction is executed on an away exchange and the ORF is assessed, then the ORF is collected from the ultimate clearing firm for the transaction. Again, the ultimate clearing firm may be either a Member or non-Member of the Exchange. The Exchange notes, however, that when the transaction is executed on an away exchange, the Exchange does not assess the ORF when neither the executing clearing firm nor the ultimate clearing firm is a Member (even if a Member is ''given-up'' or ''CMTAed'' and then such Member subsequently ''gives-up'' or ''CMTAs'' the transaction to another non-Member via a CMTA reversal). Finally, the Exchange will not assess the ORF on outbound linkage trades, whether executed at the Exchange or an away exchange. ''Linkage trades'' are tagged in the Exchange's system, so the Exchange can readily tell them apart from other trades. A customer order routed to another exchange results in two customer trades, one from the originating exchange and one from the recipient exchange. Charging ORF on both trades could result in double-billing of ORF for a single customer order, thus the Exchange will not assess ORF on outbound linkage trades in a linkage scenario. This assessment practice is identical to the assessment practice currently utilized by the Exchange's affiliates, Miami International Securities Exchange, LLC (''MIAX'') and MIAX Emerald, LLC (''MIAX Emerald'').[3]

As a practical matter, when a transaction that is subject to the ORF is not executed on the Exchange, the Exchange lacks the information necessary to identify the order entering member for that transaction. There are a multitude of order entering market participants throughout the industry, and such participants can make changes to the market centers to which they connect, including dropping their connection to one market center and establish themselves as participants on another. For these reasons, it is not possible for the Exchange to identify, and thus assess fees such as an ORF, on order entering participants on away markets on a given trading day. Clearing members, however, are distinguished from order entering participants because they remain identified to the Exchange on information the Exchange receives from OCC regardless of the identity of the order entering participant, their location, and the market center on which they execute transactions. Therefore, the Exchange believes it is more efficient for the operation of the Exchange and for the marketplace as a whole to collect the ORF from clearing members.

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter offset ORF.

As discussed below, the Exchange believes it is appropriate to charge the ORF only to transactions that clear as customer at the OCC. The Exchange believes that its broad regulatory responsibilities with respect to a Member's activities supports applying the ORF to transactions cleared but not executed by a Member. The Exchange's regulatory responsibilities are the same regardless of whether a Member enters a transaction or clears a transaction executed on its behalf. The Exchange regularly reviews all such activities, including performing surveillance for position limit violations, manipulation, front-running, contrary exercise advice violations and insider trading. These activities span across multiple exchanges.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of Members' customer options business, including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees and fines, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange notes that its regulatory responsibilities with respect to Member compliance with options sales practice rules have been allocated to the Financial Industry Regulatory Authority (''FINRA'') under a 17d–2 Agreement. The ORF is not designed to cover the cost of options sales practice regulation.

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange will continue to monitor MIAX PEARL regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange will notify Members of adjustments to the ORF via regulatory circular at least 30 days prior to the effective date of the change.

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by Members and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-Members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. While much of this activity relates to the execution of orders, the ORF is assessed on and collected from clearing firms. The Exchange, because it lacks access to information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its Members' clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on Member clearing firms equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'')[4] system in order to

[3] *See* Securities Exchange Act Release Nos. 85162 (February 15, 2019), 84 FR 5783 (February 22, 2019) (SR–MIAX–2019–01); 85251 (March 6, 2019), 84 FR 8931 (March 12, 2019) (SR–EMERALD–2019–01).

[4] COATS effectively enhances intermarket options surveillance by enabling the options

surveil a Member's activities across markets.

In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''),[5] the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading.[6]

The Exchange believes that charging the ORF across markets avoids having Members direct their trades to other markets in order to avoid the fee and to thereby avoid paying for their fair share for regulation. If the ORF did not apply to activity across markets then a Member would send their orders to the least cost, least regulated exchange. Other exchanges do impose a similar fee on their members' activity,[7] including the activity of those members on MIAX PEARL, MIAX and MIAX Emerald.[8] The Exchange notes that there is established precedent for an SRO charging a fee across markets, namely, FINRAs Trading Activity Fee[9] and the NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), Cboe Exchange, Inc. (''CBOE''), Nasdaq PHLX LLC (''Phlx''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and BOX Exchange LLC (''BOX'') ORF. While the Exchange does not have all the same regulatory responsibilities as FINRA, the Exchange believes that, like other exchanges that have adopted an ORF, its broad regulatory responsibilities with respect to a Member's activities, irrespective of where their transactions take place, supports a regulatory fee applicable to transactions on other markets. Unlike FINRA's Trading Activity Fee, the ORF applies only to a Member's customer options transactions.

Additionally, the Exchange specifies in the Fee Schedule that the Exchange may only increase or decrease the ORF semi-annually, and any such fee change will be effective on the first business day of February or August. In addition to submitting a proposed rule change to the Commission as required by the Act to increase or decrease the ORF, the Exchange notifies participants via a Regulatory Circular of any anticipated change in the amount of the fee at least 30 calendar days prior to the effective date of the change. The Exchange believes that by providing guidance on the timing of any changes to the ORF, the Exchange makes it easier for participants to ensure their systems are configured to properly account for the ORF.

The Exchange is proposing to decrease the ORF from $0.0028 to $0.0020, as of August 1, 2019. In light of recent market volumes on the Exchange and changes to the Exchange's regulatory costs, the Exchange is proposing to decrease the amount of ORF that will be collected by the Exchange. As noted above, the Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

In connection with this filing, the Exchange notes that its affiliates, MIAX and MIAX Emerald, will also be adjusting the ORF fees that each of those exchanges charge. Including the proposed adjustments to ORF of both MIAX and MIAX Emerald with the proposed adjustment by the Exchange, MIAX PEARL and its affiliates' ORF will see a net decrease from $0.0063 to $0.0053 with the proposed adjustments for August 1, 2019.

The Exchange notified Members via a Regulatory Circular of the proposed change to the ORF at least thirty (30) calendar days prior to the proposed operative date, on July 1, 2019.[10] The Exchange believes that the prior notification to market participants will ensure market participants are prepared to configure their systems to properly account for the ORF.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[11] in general, and furthers the objectives of Section 6(b)(4) of the Act[12] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act[13] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that decreasing the ORF from $0.0028 to $0.0020, as of August 1, 2019 is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of regulatory costs incurred by the Exchange. The Exchange believes that the proposed adjustments noted herein will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The Exchange believes that decreasing the ORF from $0.0028 to $0.0020, as of August 1, 2019 is equitable and not unfairly discriminatory because it is objectively allocated to Members in that it is charged to all Members on all their transactions that clear as customer at the OCC. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Members that are directly based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-

exchanges to reconstruct the market promptly to effectively surveil certain rules.

[5] ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[6] *See* Section 6(h)(3)(I) of the Act.

[7] Similar regulatory fees have been instituted by Nasdaq PHLX LLC (''Phlx'') (*See* Securities Exchange Act Release No. 61133 (December 9, 2009), 74 FR 66715 (December 16, 2009) (SR–Phlx–2009–100)); Nasdaq ISE, LLC (''ISE'') (*See* Securities Exchange Act Release No. 61154 (December 11, 2009), 74 FR 67278 (December 18, 2009) (SR–ISE–2009–105)); and Nasdaq GEMX, LLC (''GEMX'') (*See* Securities Exchange Act Release No. 70200 (August 14, 2013) 78 FR 51242 (August 20, 2013) (SR–Topaz–2013–01)).

[8] *See supra* note 3.

[9] *See* Securities Exchange Act Release No. 47946 (May 30, 2003), 68 FR 34021 (June 6, 2003) (SR–NASD–2002–148).

[10] *See* MIAX PEARL Regulatory Circular 2019–26 available at *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_PEARL_RC_2019_26.pdf*.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

customer component (*e.g.,* Member proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Members' customer options business including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the proposed decrease to the fee is reasonable.

The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates with advance notice is reasonable because it gives participants certainty on the timing of changes, if any, and better enables them to properly account for ORF charges among their customers. The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates is equitable and not unfairly discriminatory because it will apply in the same manner to all Members that are subject to the ORF and provide them with additional advance notice of changes to that fee.

The Exchange believes that collecting the ORF from non-Members when such non-Members ultimately clear the transaction (that is, when the non-Member is the ''ultimate clearing firm'' for a transaction in which a Member was assessed the ORF) is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange notes that there is a material distinction between ''assessing'' the ORF and ''collecting'' the ORF. The ORF is only assessed to a Member with respect to a particular transaction in which it is either the executing clearing firm or ultimate clearing firm. The Exchange does not assess the ORF to non-Members. Once, however, the ORF is assessed to a Member for a particular transaction, the ORF may be collected from the Member or a non-Member, depending on how the transaction is cleared at OCC. If there was no change to the clearing account of the original transaction, the ORF would be collected from the Member. If there was a change to the clearing account of the original transaction and a non-Member becomes the ultimate clearing firm for that transaction, then the ORF will be collected from that non-Member. The Exchange believes that this collection practice continues to be reasonable and appropriate, and was originally instituted for the benefit of clearing firms that desired to have the ORF be collected from the clearing firm that ultimately clears the transaction.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX PEARL does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, and is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. It also supplements the regulatory revenue derived from non-customer activity. This proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. Unilateral action by MIAX PEARL in establishing fees for services provided to its Members and others using its facilities will not have an impact on competition. In the highly competitive environment for equity options trading, MIAX PEARL does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Act. The Exchange's ORF, as described herein, is comparable to fees charged by other options exchanges for the same or similar services. The Exchange believes that continuing to limit the changes to the ORF to twice a year on specific dates with advance notice is not intended to address a competitive issue but rather to provide Members with better notice of any change that the Exchange may make to the ORF.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[14] and Rule 19b–4(f)(2)[15] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–PEARL–2019–23 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–PEARL–2019–23. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 240.19b–4(f)(2).

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–PEARL–2019–23, and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17387 Filed 8–13–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86604; File No. SR–CBOE–2019–040]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Options Regulatory Fee

August 8, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its Fees Schedule relating to the Options Regulatory Fee. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to increase the Options Regulatory Fee (''ORF'') from $0.0045 per contract to $0.0046 per contract in order to help ensure that revenue collected from the ORF, in combination with other regulatory fees and fines, meets the Exchange's total regulatory costs.

The ORF is assessed by Cboe Options to each Trading Permit Holder (''TPH'') for options transactions cleared by the TPH that are cleared by the Options Clearing Corporation (''OCC'') in the customer range, regardless of the exchange on which the transaction occurs.[3] In other words, the Exchange imposes the ORF on all customer-range transactions cleared by a TPH, even if the transactions do not take place on the Exchange. The ORF is collected by OCC on behalf of the Exchange from the Clearing Trading Permit Holder (''CTPH'') or non-CTPH that ultimately clears the transaction. With respect to linkage transactions, Cboe Options reimburses its routing broker providing Routing Services pursuant to Cboe Options Rule 6.14B for options regulatory fees it incurs in connection with the Routing Services it provides.

Revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, is designed to recover a material portion of the regulatory costs to the Exchange of the supervision and regulation of TPH customer options business. Regulatory costs include direct regulatory expenses and certain indirect expenses for work allocated in support of the regulatory function. The direct expenses include in-house and third party service provider costs to support the day to day regulatory work such as surveillances, investigations and examinations. The indirect expenses include support from such areas as human resources, legal, information technology and accounting. These indirect expenses are estimated to be approximately 10% of Cboe Options' total regulatory costs for 2019. Thus, direct expenses are estimated to be approximately 90% of total regulatory costs for 2019. In addition, it is Cboe Options' practice that revenue generated from ORF not exceed more than 75% of total annual regulatory costs.

The Exchange monitors its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange also notifies TPHs of adjustments to the ORF via regulatory circular.[4] Based on the Exchange's most recent semi-annual review, the Exchange is proposing to increase the amount of ORF that will be collected by the Exchange from $0.0045 per contract side to $0.0046 per contract side. The proposed increase is based on the Exchange's estimated projections for its regulatory costs, balanced with recent options volumes. These expectations are estimated, preliminary and may change. There can be no assurance that the Exchange's final costs for 2019 will not differ materially from these expectations and prior practice, nor can the Exchange predict with certainty whether options volume will remain at the current level going forward; however, the Exchange believes that revenue generated from the

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The ORF also applies to customer-range transactions executed during Extended Trading Hours.

[4] The Exchange endeavors to provide TPHs with such notice at least 30 calendar days prior to the effective date of the change. The Exchange notified TPHs of the proposed rate change for August 1, 2019 on June 25, 2019. *See* Cboe Options Regulatory Circular RF19–023 ''Modification of the Options Regulatory Fee.''

ORF (as amended), when combined with all of the Exchange's other regulatory fees and fines, would cover a material portion, but not all, of the Exchange's regulatory costs.[5]

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[7] which provides that Exchange rules may provide for the equitable allocation of reasonable dues, fees, and other charges among its TPHs and other persons using its facilities. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed fee change is reasonable because the modest increase is necessary to offset the anticipated regulatory costs, and which, in combination with other regulatory fees and fines, still is not expected to exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that would be less than or equal to 75% of the Exchange's regulatory costs, which is consistent with the view of the Commission that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. As discussed above, the Exchange determined to increase ORF after its semi-annual review of its regulatory costs and regulatory revenues, which includes revenues from ORF and other regulatory fees and fines. When taking into account recent options volume, coupled with the anticipated regulatory fees, the Exchange believes it's reasonable to increase the ORF amount by $0.0001 per contract side.

Moreover, the Exchange believes the ORF ensures fairness by assessing higher fees to those TPHs that require more Exchange regulatory services based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* TPH proprietary transactions) of its regulatory program.[9] The Exchange believes the proposed fee change is equitable and not unfairly discriminatory in that it is charged to all TPHs on all their transactions that clear in the customer range at the OCC.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, thereby raising regulatory revenue to offset regulatory expenses. It also supplements the regulatory revenue derived from non-customer activity. The Exchange notes, however, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and paragraph (f) of Rule 19b–4[11] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–CBOE–2019–040 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–CBOE–2019–040. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public

[5] The Exchange notes that its regulatory responsibilities with respect to TPH compliance with options sales practice rules have largely been allocated to FINRA under a 17d–2 agreement. The ORF is not designed to cover the cost of that options sales practice regulation.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78f(b)(5).

[9] If the Exchange changes its method of funding regulation or if circumstances otherwise change in the future, the Exchange may decide to modify the ORF or assess a separate regulatory fee on TPH proprietary transactions if the Exchange deems it advisable.

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f).

Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CBOE–2019–040, and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17384 Filed 8–13–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86611; File No. SR–CboeEDGX–2019–051]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Options Regulatory Fee

August 8, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2019, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') proposes to amend its fee schedule related to the Options Regulatory Fee. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the fee schedule applicable to the Exchange's options platform (''EDGX Options'') to amend the rate of its Options Regulatory Fee (''ORF'').[3] Currently, the Exchange charges an ORF in the amount of $0.0001 per contract side. The Exchange proposes to increase the amount of ORF from $0.0001 per contract side to $0.0002 per contract side. The proposed change to ORF should continue to balance the Exchange's regulatory expenses against the anticipated revenue.

The ORF is assessed by the Exchange on each Member for options transactions cleared by the Member that are cleared by the Options Clearing Corporation (OCC) in the customer range, regardless of the exchange on which the transaction occurs. In other words, the Exchange imposes the ORF on all customer-range transactions cleared by a Member, even if the transactions do not take place on the Exchange. The ORF is collected by OCC on behalf of the Exchange from the Clearing Member or non-Clearing Member that ultimately clears the transaction. With respect to linkage transactions, the Exchange reimburses its routing broker providing Routing Services for options regulatory fees it incurs in connection with the Routing Services it provides.

Revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, is designed to recover a material portion of the regulatory costs to the Exchange of the supervision and regulation of Member customer options business. Regulatory costs include direct regulatory expenses and certain indirect expenses for work allocated in support of the regulatory function. The direct expenses include in-house and third party service provider costs to support the day to day regulatory work such as surveillances, investigations and examinations. The indirect expenses include support from such areas as human resources, legal, information technology and accounting. These indirect expenses are estimated to be approximately 37% of EDGX Options' total regulatory costs for 2019. Thus, direct expenses are estimated to be approximately 63% of total regulatory costs for 2019. In addition, it is EDGX Options' practice that revenue generated from ORF not exceed more than 75% of total annual regulatory costs.

The Exchange monitors its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange also notifies Members of adjustments to the ORF via regulatory circular.[4] Based on the Exchange's most recent semi-annual review, the Exchange is proposing to increase the amount of ORF that will be collected by the Exchange from $0.0001 per contract side to $0.0002 per contract side. The proposed increase is based on the Exchange's estimated projections for its regulatory costs, balanced with recent options volumes. These expectations are estimated, preliminary and may change. There can be no assurance that the Exchange's final costs for 2019 will not differ materially from these expectations and prior practice, nor can the Exchange predict with certainty whether options volume will remain at the current level going forward; however, the Exchange believes that revenue generated from the ORF (as amended), when combined with all of the Exchange's other regulatory fees and fines, would cover a

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed fee change on August 1, 2018 (SR–CboeEDGX–2018–028) for August 1, 2018 effectiveness. On business date August 9, 2018, the Exchange withdrew that filing and submitted this filing. [sic]

[4] The Exchange provides Members with such notice at least 30 calendar days prior to the effective date of the change. The Exchange notified Members of the proposed rate change for August 1, 2019 on June 25, 2019. *See* EDGX Regulatory Circular RG19–020 ''Modification of the Options Regulatory Fee.''

material portion, but not all, of the Exchange's regulatory costs.[5]

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[6] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[7] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using its facilities. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues or providers of routing services if they deem fee levels to be excessive.

The Exchange believes the proposed fee change is reasonable because the modest increase is necessary to offset the anticipated regulatory costs, and which, in combination with other regulatory fees and fines, still is not expected to exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that would be less than or equal to 75% of the Exchange's regulatory costs, which is consistent with the view of the Commission that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. As discussed above, the Exchange determined to increase ORF after its semi-annual review of its regulatory costs and regulatory revenues, which includes revenues from ORF and other regulatory fees and fines. When taking into account recent options volume, coupled with the anticipated regulatory fees, the Exchange believes it's reasonable to increase the ORF amount by $0.0001 per contract side.

Moreover, the Exchange believes the ORF ensures fairness by assessing higher fees to those Members that require more Exchange regulatory services based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Member proprietary transactions) of its regulatory program.[8] The Exchange believes the proposed fee change is equitable and not unfairly discriminatory in that it is charged to all Members on all their transactions that clear in the customer range at the OCC.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, thereby raising regulatory revenue to offset regulatory expenses. It also supplements the regulatory revenue derived from non-customer activity. The Exchange notes, however, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and paragraph (f) of Rule 19b–4[10] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–CboeEDGX–2019–051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–CboeEDGX–2019–051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and

[5] The Exchange notes that its regulatory responsibilities with respect to Member compliance with options sales practice rules have largely been allocated to FINRA under a 17d–2 agreement. The ORF is not designed to cover the cost of that options sales practice regulation.

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] If the Exchange changes its method of funding regulation or if circumstances otherwise change in the future, the Exchange may decide to modify the ORF or assess a separate regulatory fee on Member proprietary transactions if the Exchange deems it advisable.

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f).

printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CboeEDGX–2019–051, and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17391 Filed 8–13–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86606; File No. SR–EMERALD–2019–29]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Options Regulatory Fee

August 8, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2019, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Emerald Fee Schedule (the ''Fee Schedule'') to adjust its Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange charges an ORF in the amount of $0.00060 per contract side. The Exchange proposes to increase this ORF to $0.0013 per contract side. In light of historical and projected volume changes and shifts in the industry and on the Exchange, as well as changes to the Exchange's regulatory cost structure, the Exchange is proposing to change the amount of ORF that will be collected by the Exchange. The Exchange's proposed change to the ORF should balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The per-contract ORF will continue to be assessed by MIAX Emerald to each MIAX Emerald Member for all options transactions, including Mini Options, cleared or ultimately cleared by the Member which are cleared by the Options Clearing Corporation (''OCC'') in the ''customer'' range, regardless of the exchange on which the transaction occurs. The ORF will be collected by OCC on behalf of MIAX Emerald from either (1) a Member that was the ultimate clearing firm for the transaction or (2) a non-Member that was the ultimate clearing firm where a Member was the executing clearing firm for the transaction. The Exchange uses reports from OCC to determine the identity of the executing clearing firm and ultimate clearing firm.

To illustrate how the ORF is assessed and collected, the Exchange provides the following set of examples. If the transaction is executed on the Exchange and the ORF is assessed, if there is no change to the clearing account of the original transaction, then the ORF is collected from the Member that is the executing clearing firm for the transaction. (The Exchange notes that, for purposes of the Fee Schedule, when there is no change to the clearing account of the original transaction, the executing clearing firm is deemed to be the ultimate clearing firm.) If there is a change to the clearing account of the original transaction (*i.e.,* the executing clearing firm ''gives-up'' or ''CMTAs'' the transaction to another clearing firm), then the ORF is collected from the clearing firm that ultimately clears the transaction—the ultimate clearing firm. The ultimate clearing firm may be either a Member or non-Member of the Exchange. If the transaction is executed on an away exchange and the ORF is assessed, then the ORF is collected from the ultimate clearing firm for the transaction. Again, the ultimate clearing firm may be either a Member or non-Member of the Exchange. The Exchange notes, however, that when the transaction is executed on an away exchange, the Exchange does not assess the ORF when neither the executing clearing firm nor the ultimate clearing firm is a Member (even if a Member is ''given-up'' or ''CMTAed'' and then such Member subsequently ''gives-up'' or ''CMTAs'' the transaction to another non-Member via a CMTA reversal). Finally, the Exchange will not assess the ORF on outbound linkage trades, whether executed at the Exchange or an away exchange. ''Linkage trades'' are tagged in the Exchange's system, so the Exchange can readily tell them apart from other trades. A customer order routed to another exchange results in two customer trades, one from the originating exchange and one from the recipient exchange. Charging ORF on both trades could result in double-billing of ORF for a single customer order, thus the Exchange will not assess ORF on outbound linkage trades in a linkage scenario. This assessment practice is identical to the assessment practice currently utilized by the Exchange's affiliates, Miami International Securities Exchange, LLC (''MIAX'') and MIAX PEARL, LLC (''MIAX PEARL'').[3]

As a practical matter, when a transaction that is subject to the ORF is not executed on the Exchange, the Exchange lacks the information necessary to identify the order entering member for that transaction. There are a multitude of order entering market participants throughout the industry,

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 85162 (February 15, 2019), 84 FR 5783 (February 22, 2019) (SR–MIAX–2019–01); 85163 (February 15, 2019), 84 FR 5798 (February 22, 2019) (SR–PEARL–2019–01).

and such participants can make changes to the market centers to which they connect, including dropping their connection to one market center and establish themselves as participants on another. For these reasons, it is not possible for the Exchange to identify, and thus assess fees such as an ORF, on order entering participants on away markets on a given trading day.

Clearing members, however, are distinguished from order entering participants because they remain identified to the Exchange on information the Exchange receives from OCC regardless of the identity of the order entering participant, their location, and the market center on which they execute transactions. Therefore, the Exchange believes it is more efficient for the operation of the Exchange and for the marketplace as a whole to collect the ORF from clearing members.

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter offset ORF.

As discussed below, the Exchange believes it is appropriate to charge the ORF only to transactions that clear as customer at the OCC. The Exchange believes that its broad regulatory responsibilities with respect to a Member's activities supports applying the ORF to transactions cleared but not executed by a Member. The Exchange's regulatory responsibilities are the same regardless of whether a Member enters a transaction or clears a transaction executed on its behalf. The Exchange regularly reviews all such activities, including performing surveillance for position limit violations, manipulation, front-running, contrary exercise advice violations and insider trading. These activities span across multiple exchanges.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of Members' customer options business, including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees and fines, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange notes that its regulatory responsibilities with respect to Member compliance with options sales practice rules have been allocated to the Financial Industry Regulatory Authority (''FINRA'') under a 17d–2 Agreement. The ORF is not designed to cover the cost of options sales practice regulation.

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange will continue to monitor MIAX Emerald regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange will notify Members of adjustments to the ORF via regulatory circular at least 30 days prior to the effective date of the change.

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by Members and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-Members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. While much of this activity relates to the execution of orders, the ORF is assessed on and collected from clearing firms. The Exchange, because it lacks access to information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its Members' clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on Member clearing firms equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'')[4] system in order to surveil a Member's activities across markets.

In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''),[5] the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading.[6]

The Exchange believes that charging the ORF across markets avoids having Members direct their trades to other markets in order to avoid the fee and to thereby avoid paying for their fair share for regulation. If the ORF did not apply to activity across markets then a Member would send their orders to the least cost, least regulated exchange. Other exchanges do impose a similar fee on their members' activity, including the activity of those members on MIAX Emerald,[7] including the activity of those members on MIAX Emerald, MIAX and MIAX PEARL.[8] The Exchange notes that there is established precedent for an SRO charging a fee across markets,

[4] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[5] ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[6] *See* Section 6(h)(3)(I) of the Act.

[7] Similar regulatory fees have been instituted by Nasdaq PHLX LLC (''Phlx'') (*See* Securities Exchange Act Release No. 61133 (December 9, 2009), 74 FR 66715 (December 16, 2009) (SR-Phlx–2009–100)); Nasdaq ISE, LLC (''ISE'') (*See* Securities Exchange Act Release No. 61154 (December 11, 2009), 74 FR 67278 (December 18, 2009) (SR–ISE–2009–105)); and Nasdaq GEMX, LLC (''GEMX'') (*See* Securities Exchange Act Release No. 70200 (August 14, 2013) 78 FR 51242 (August 20, 2013) (SR–Topaz–2013–01)).

[8] *See supra* note 3.

namely, FINRAs Trading Activity Fee [9] and the NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), Cboe Exchange, Inc. (''CBOE''), Nasdaq PHLX LLC (''Phlx''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and BOX Exchange LLC (''BOX'') ORF. While the Exchange does not have all the same regulatory responsibilities as FINRA, the Exchange believes that, like other exchanges that have adopted an ORF, its broad regulatory responsibilities with respect to a Member's activities, irrespective of where their transactions take place, supports a regulatory fee applicable to transactions on other markets. Unlike FINRA's Trading Activity Fee, the ORF applies only to a Member's customer options transactions.

Additionally, the Exchange specifies in the Fee Schedule that the Exchange may only increase or decrease the ORF semi-annually, and any such fee change will be effective on the first business day of February or August. In addition to submitting a proposed rule change to the Commission as required by the Act to increase or decrease the ORF, the Exchange notifies participants via a Regulatory Circular of any anticipated change in the amount of the fee at least 30 calendar days prior to the effective date of the change. The Exchange believes that by providing guidance on the timing of any changes to the ORF, the Exchange makes it easier for participants to ensure their systems are configured to properly account for the ORF.

The Exchange is proposing to increase the ORF from $0.00060 to $0.0013, as of August 1, 2019. In light of recent market volumes on the Exchange and changes to the Exchange's regulatory costs, the Exchange is proposing to increase the amount of ORF that will be collected by the Exchange. As noted above, the Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

In connection with this filing, the Exchange notes that its affiliates, MIAX and MIAX PEARL, will also be adjusting the ORF fees that each of those exchanges charge. Including the proposed adjustments to ORF of both MIAX and MIAX PEARL with the proposed adjustment by the Exchange, MIAX Emerald and its affiliates' ORF will see a net decrease from $0.0063 to $0.0053 with the proposed adjustments for August 1, 2019.

The Exchange notified Members via a Regulatory Circular of the proposed change to the ORF at least thirty (30) calendar days prior to the proposed operative date, on July 1, 2019.[10] The Exchange believes that the prior notification to market participants will ensure market participants are prepared to configure their systems to properly account for the ORF.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(4) of the Act [12] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [13] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that increasing the ORF from $0.00060 to $0.0013, as of August 1, 2019 is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of regulatory costs incurred by the Exchange. The Exchange believes that the proposed adjustments noted herein will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The Exchange believes that increasing the ORF from $0.00060 to $0.0013, as of August 1, 2019, is equitable and not unfairly discriminatory because it is objectively allocated to Members in that it is charged to all Members on all their transactions that clear as customer at the OCC. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Members that are directly based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Member proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Members' customer options business including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the proposed increase to the fee is reasonable.

The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates with advance notice is reasonable because it gives participants certainty on the timing of changes, if any, and better enables them to properly account for ORF charges among their customers. The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates is equitable and not unfairly discriminatory because it will apply in the same manner to all Members that are subject to the ORF and provide them with additional advance notice of changes to that fee.

The Exchange believes that collecting the ORF from non-Members when such non-Members ultimately clear the transaction (that is, when the non-Member is the ''ultimate clearing firm'' for a transaction in which a Member was assessed the ORF) is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange notes that there is a material distinction between ''assessing'' the ORF and ''collecting'' the ORF. The ORF is only assessed to a Member with respect to a particular transaction in which it is either the

[9] *See* Securities Exchange Act Release No. 47946 (May 30, 2003), 68 FR 34021 (June 6, 2003) (SR–NASD–2002–148).

[10] *See* MIAX Emerald Regulatory Circular 2019–61 available at *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Emerald_RC_2019_61.pdf.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

executing clearing firm or ultimate clearing firm. The Exchange does not assess the ORF to non-Members. Once, however, the ORF is assessed to a Member for a particular transaction, the ORF may be collected from the Member or a non-Member, depending on how the transaction is cleared at OCC. If there was no change to the clearing account of the original transaction, the ORF would be collected from the Member. If there was a change to the clearing account of the original transaction and a non-Member becomes the ultimate clearing firm for that transaction, then the ORF will be collected from that non-Member. The Exchange believes that this collection practice continues to be reasonable and appropriate, and was originally instituted for the benefit of clearing firms that desired to have the ORF be collected from the clearing firm that ultimately clears the transaction.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX Emerald does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, and is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. It also supplements the regulatory revenue derived from non-customer activity. This proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. Unilateral action by MIAX Emerald in establishing fees for services provided to its Members and others using its facilities will not have an impact on competition. As a new entrant in the highly competitive environment for equity options trading, MIAX Emerald does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Act. The Exchange's ORF, as described herein, is comparable to fees charged by other options exchanges for the same or similar services. The Exchange believes that continuing to limit the changes to the ORF to twice a year on specific dates with advance notice is not intended to address a competitive issue but rather to provide Members with better notice of any change that the Exchange may make to the ORF.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[14] and Rule 19b–4(f)(2) [15] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–EMERALD–2019–29 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–EMERALD–2019–29. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–EMERALD–2019–29, and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17386 Filed 8–13–19; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 240.19b–4(f)(2).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86605; File No. SR–C2–2019–018]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Options Regulatory Fee

August 8, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2019, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2 Options'') proposes to amend its Fees Schedule relating to the Options Regulatory Fee. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/ctwo/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to increase the Options Regulatory Fee (''ORF'') from $0.0012 per contract to $0.0013 per contract in order to help ensure that revenue collected from the ORF, in combination with other regulatory fees and fines, meets the Exchange's total regulatory costs.

The ORF is assessed by C2 Options to each Trading Permit Holder (''TPH'') for options transactions cleared by the TPH that are cleared by the Options Clearing Corporation (OCC) in the customer range, regardless of the exchange on which the transaction occurs. In other words, the Exchange imposes the ORF on all customer-range transactions cleared by a TPH, even if the transactions do not take place on the Exchange. The ORF is collected by OCC on behalf of the Exchange from the Clearing Trading Permit Holder (''CTPH'') or non-CTPH that ultimately clears the transaction. With respect to linkage transactions, C2 Options reimburses its routing broker providing Routing Services pursuant to C2 Options Rule 6.15 for options regulatory fees it incurs in connection with the Routing Services it provides.

Revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, is designed to recover a material portion of the regulatory costs to the Exchange of the supervision and regulation of TPH customer options business. Regulatory costs include direct regulatory expenses and certain indirect expenses for work allocated in support of the regulatory function. The direct expenses include in-house and third party service provider costs to support the day to day regulatory work such as surveillances, investigations and examinations. The indirect expenses include support from such areas as human resources, legal, information technology and accounting. These indirect expenses are estimated to be approximately 4% of C2 Options' total regulatory costs for 2019. Thus, direct expenses are estimated to be approximately 96% of total regulatory costs for 2019. In addition, it is C2 Options' practice that revenue generated from ORF not exceed more than 75% of total annual regulatory costs.

The Exchange monitors its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange also notifies TPHs of adjustments to the ORF via regulatory circular.[3] Based on the Exchange's most recent semi-annual review, the Exchange is proposing to increase the amount of ORF that will be collected by the Exchange from $0.0012 per contract side to $0.0013 per contract side. The proposed increase is based on the Exchange's estimated projections for its regulatory costs, balanced with recent options volumes. These expectations are estimated, preliminary and may change. There can be no assurance that the Exchange's final costs for 2019 will not differ materially from these expectations and prior practice, nor can the Exchange predict with certainty whether options volume will remain at the current level going forward; however, the Exchange believes that revenue generated from the ORF (as amended), when combined with all of the Exchange's other regulatory fees and fines, would cover a material portion, but not all, of the Exchange's regulatory costs.[4]

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[5] Specifically, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[6] which provides that Exchange rules may provide for the equitable allocation of reasonable dues, fees, and other charges among its TPHs and other persons using its facilities. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed fee change is reasonable because the modest increase is necessary to offset the anticipated regulatory costs, and which, in combination with other regulatory fees and fines, still is not expected to exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that would be less than or equal to 75% of the Exchange's regulatory costs, which is consistent with the view of the Commission that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. As discussed above, the Exchange determined to increase ORF after its semi-annual review of its regulatory costs and regulatory revenues, which includes revenues from ORF and other regulatory fees and fines. When taking into account recent options volume, coupled with the anticipated regulatory fees, the Exchange believes it's reasonable to increase the ORF amount by $0.0001 per contract side.

Moreover, the Exchange believes the ORF ensures fairness by assessing

[3] The Exchange endeavors to provide TPHs with such notice at least 30 calendar days prior to the effective date of the change. The Exchange notified TPHs of the proposed rate change for August 1, 2019 on June 25, 2019. *See* C2 Options Regulatory Circular RG19–023 ''Modification of the Options Regulatory Fee.''

[4] The Exchange notes that its regulatory responsibilities with respect to TPH compliance with options sales practice rules have largely been allocated to FINRA under a 17d–2 agreement. The ORF is not designed to cover the cost of that options sales practice regulation.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78f(b)(5).

higher fees to those TPHs that require more Exchange regulatory services based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* TPH proprietary transactions) of its regulatory program.[8] The Exchange believes the proposed fee change is equitable and not unfairly discriminatory in that it is charged to all TPHs on all their transactions that clear in the customer range at the OCC.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, thereby raising regulatory revenue to offset regulatory expenses. It also supplements the regulatory revenue derived from non-customer activity. The Exchange notes, however, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

[8] If the Exchange changes its method of funding regulation or if circumstances otherwise change in the future, the Exchange may decide to modify the ORF or assess a separate regulatory fee on TPH proprietary transactions if the Exchange deems it advisable.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and paragraph (f) of Rule 19b–4 [10] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–C2–2019–018 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–C2–2019–018. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–C2–2019–018, and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Jill M. Peterson,

Assistant Secretary.

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[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86610; File No. SR–Phlx–2019–27]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend SCAR Credits at Equity 7, Section 3(a)

August 8, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 25, 2019, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend SCAR credits at Equity 7, Section 3(a), as described further below. While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 1, 2019. The text of the proposed rule change is available on the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange's website at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to adopt revised pricing for the recently adopted SCAR routing strategy.[3] In sum, SCAR is a routing option under which orders check the System [4] for available shares and simultaneously route to the other equity markets operated by Nasdaq, Inc., Nasdaq BX, Inc. (''BX'') and The Nasdaq Stock Market LLC (''Nasdaq'').[5]

The Exchange proposes to adopt revised credits for SCAR orders in securities listed on Nasdaq (''Tape C''), NYSE (''Tape A''), and on exchanges other than Nasdaq and NYSE (''Tape B'') (collectively, ''Tapes''), which execute on BX.[6] BX recently updated its fee schedule whereby it generally increased the credits provided for orders that access liquidity,[7] and the Exchange is proposing to adjust its fee schedule relating to SCAR to increase credits provided for SCAR executions occurring on BX Tapes A and C securities and to decrease the credit provided for SCAR executions occurring on BX Tape B securities. Currently in securities priced at $1 or more per share, the Exchange provides a credit of $0.0015 per share for SCAR orders in Tapes A and C securities executed at BX, and a credit of $0.0026 per share for SCAR orders in Tape B securities executed at Nasdaq BX.[8] The Exchange is proposing to provide a credit of $0.0025 per share executed for SCAR orders executed on BX in the securities of any of the Tapes priced at $1 or more per share, which will align the credits with recent changes to the BX fee schedule.[9]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the pricing structure proposed above for SCAR is reasonable, equitable, and not unfairly discriminatory because the new credits are generally set at a level intended to incentivize members to use this new routing strategy. The proposed $0.0025 per share executed credit for orders in any Tape securities priced at $1 or more per share that route to, and execute on, BX using the SCAR routing strategy is significantly higher than the current credit provided in such transactions in securities of Tapes A and C, and is a modest decrease to the credit provided for executions in such transactions in securities of Tape B. This is reflective of the Exchange's desire to increase incentives to members to use the routing strategy and its assessment of the costs incurred in providing the routing strategy. Alignment of the incentive for executions on BX will strike a balance between these factors. In this regard, the Exchange notes that if the order executed directly on BX as the home exchange, (*i.e.,* without using SCAR) the member would be charged the standard transaction fee of $0.0003 per share executed.[12] As such, the proposed SCAR credit is set at a rate that makes it more economical for members to use this routing strategy, especially for those members that do not already add and/or remove volume on BX directly. Last, the Exchange believes that the proposed pricing changes are equitable and not unfairly discriminatory because they will apply uniformly to all members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed pricing for SCAR orders is intended to provide incentive to members to use the Exchange's SCAR routing strategy, balanced against the need to recoup the Exchange's costs associated with providing its completely optional routing services. Because the Exchange's routing services are the subject of competition, including price competition, from other exchanges and broker-dealers that offer routing services, as well as the ability of members to use their own routing capabilities, it is likely that the Exchange will lose market share as a result of the changes if they are unattractive to market participants.

[3] *See* Rule 3315(a)(1)(A). *See also* Securities Exchange Act Release No. 85366 (March 20, 2019), 84 FR 11345 (March 26, 2019) (SR–Phlx–2019–04).

[4] The term ''System'' shall mean the automated system for order execution and trade reporting owned and operated by the Exchange. *See* Rule 3301(a).

[5] If shares remain unexecuted after routing, they are posted on the Exchange's book or cancelled. Once on the book, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center. *See* Rule 3315(a)(1)(A)(x).

[6] The Exchange currently provides pricing for execution on BX using SCAR that is better than a market participant would otherwise receive for removing liquidity from BX if it did not meet certain volume thresholds that would qualify them for a better rate (such as a liquidity removal credit), which is $0.0003 per share executed for orders in any Tape securities priced at $1 or more per share that access liquidity on the Exchange. *See* BX Equity 7, Section 118(a). Thus, the Exchange's current fees are more reflective of the pricing a market participant would receive if it provided certain levels of volume. The Exchange is proposing to adjust the credit provided for BX executions to reflect recent changes to the credits provided to BX members for removing liquidity. *See* Securities Exchange Act Release No. 34–86447 (July 24, 2019) (SR–BX–2019–026) (awaiting publication in the **Federal Register**).

[7] *Id.*

[8] BX operates on the ''taker-maker'' model, whereby it generally pays credits to members that take liquidity and charges fees to members that provide liquidity.

[9] *See supra* note 6.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] This fee would apply unless the member qualifies for a better rate (such as a discounted fee or credit) by meeting certain volume thresholds. *See* BX Equity 7, Section 118(a).

Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2019–27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2019–27. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2019–27, and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17390 Filed 8–13–19; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86608; File No. SR–MIAX–2019–35]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Options Regulatory Fee

August 8, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2019, Miami International Securities Exchange LLC (''MIAX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'') to adjust its Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange charges an ORF in the amount of $0.0029 per contract side. The Exchange proposes to decrease this ORF to $0.0020 per contract side. In light of historical and projected volume changes and shifts in the industry and on the Exchange, as well as changes to the Exchange's regulatory cost structure, the Exchange is proposing to change the amount of ORF that will be collected by the Exchange. The Exchange's proposed change to the ORF should balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The per-contract ORF will continue to be assessed by MIAX to each MIAX Member for all options transactions, including Mini Options, cleared or ultimately cleared by the Member which are cleared by the Options Clearing Corporation (''OCC'') in the ''customer'' range, regardless of the exchange on which the transaction occurs. The ORF will be collected by OCC on behalf of MIAX from either (1) a Member that was the ultimate clearing firm for the transaction or (2) a non-Member that was the ultimate clearing firm where a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Member was the executing clearing firm for the transaction. The Exchange uses reports from OCC to determine the identity of the executing clearing firm and ultimate clearing firm.

To illustrate how the ORF is assessed and collected, the Exchange provides the following set of examples. If the transaction is executed on the Exchange and the ORF is assessed, if there is no change to the clearing account of the original transaction, then the ORF is collected from the Member that is the executing clearing firm for the transaction. (The Exchange notes that, for purposes of the Fee Schedule, when there is no change to the clearing account of the original transaction, the executing clearing firm is deemed to be the ultimate clearing firm.) If there is a change to the clearing account of the original transaction (*i.e.,* the executing clearing firm ''gives-up'' or ''CMTAs'' the transaction to another clearing firm), then the ORF is collected from the clearing firm that ultimately clears the transaction- the ultimate clearing firm. The ultimate clearing firm may be either a Member or non-Member of the Exchange. If the transaction is executed on an away exchange and the ORF is assessed, then the ORF is collected from the ultimate clearing firm for the transaction. Again, the ultimate clearing firm may be either a Member or non-Member of the Exchange. The Exchange notes, however, that when the transaction is executed on an away exchange, the Exchange does not assess the ORF when neither the executing clearing firm nor the ultimate clearing firm is a Member (even if a Member is ''given-up'' or ''CMTAed'' and then such Member subsequently ''gives-up'' or ''CMTAs'' the transaction to another non-Member via a CMTA reversal). Finally, the Exchange will not assess the ORF on outbound linkage trades, whether executed at the Exchange or an away exchange. ''Linkage trades'' are tagged in the Exchange's system, so the Exchange can readily tell them apart from other trades. A customer order routed to another exchange results in two customer trades, one from the originating exchange and one from the recipient exchange. Charging ORF on both trades could result in double-billing of ORF for a single customer order, thus the Exchange will not assess ORF on outbound linkage trades in a linkage scenario. This assessment practice is identical to the assessment practice currently utilized by the Exchange's affiliates, MIAX PEARL, LLC (''MIAX PEARL'') and MIAX Emerald, LLC (''MIAX Emerald'').[3]

As a practical matter, when a transaction that is subject to the ORF is not executed on the Exchange, the Exchange lacks the information necessary to identify the order entering member for that transaction. There are a multitude of order entering market participants throughout the industry, and such participants can make changes to the market centers to which they connect, including dropping their connection to one market center and establish themselves as participants on another. For these reasons, it is not possible for the Exchange to identify, and thus assess fees such as an ORF, on order entering participants on away markets on a given trading day. Clearing members, however, are distinguished from order entering participants because they remain identified to the Exchange on information the Exchange receives from OCC regardless of the identity of the order entering participant, their location, and the market center on which they execute transactions. Therefore, the Exchange believes it is more efficient for the operation of the Exchange and for the marketplace as a whole to collect the ORF from clearing members.

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter offset ORF.

As discussed below, the Exchange believes it is appropriate to charge the ORF only to transactions that clear as customer at the OCC. The Exchange believes that its broad regulatory responsibilities with respect to a Member's activities supports applying the ORF to transactions cleared but not executed by a Member. The Exchange's regulatory responsibilities are the same regardless of whether a Member enters a transaction or clears a transaction executed on its behalf. The Exchange regularly reviews all such activities, including performing surveillance for position limit violations, manipulation, front-running, contrary exercise advice violations and insider trading. These activities span across multiple exchanges.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of Members' customer options business, including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees and fines, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange notes that its regulatory responsibilities with respect to Member compliance with options sales practice rules have been allocated to the Financial Industry Regulatory Authority (''FINRA'') under a 17d–2 Agreement. The ORF is not designed to cover the cost of options sales practice regulation.

The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange will continue to monitor MIAX regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission. The Exchange will notify Members of adjustments to the ORF via regulatory circular at least 30 days prior to the effective date of the change.

The Exchange believes it is reasonable and appropriate for the Exchange to charge the ORF for options transactions regardless of the exchange on which the transactions occur. The Exchange has a statutory obligation to enforce compliance by Members and their associated persons under the Act and the rules of the Exchange and to surveil for other manipulative conduct by market participants (including non-Members) trading on the Exchange. The Exchange cannot effectively surveil for such conduct without looking at and evaluating activity across all options markets. Many of the Exchange's market surveillance programs require the Exchange to look at and evaluate activity across all options markets, such as surveillance for position limit violations, manipulation, front-running and contrary exercise advice violations/expiring exercise declarations. While much of this activity relates to the execution of orders, the ORF is assessed on and collected from clearing firms. The Exchange, because it lacks access to

[3] *See* Securities Exchange Act Release Nos. 85163 (February 15, 2019), 84 FR 5798 (February 22, 2019) (SR–PEARL–2019–01); 85251 (March 6, 2019), 84 FR 8931 (March 12, 2019) (SR–EMERALD–2019–01).

information on the identity of the entering firm for executions that occur on away markets, believes it is appropriate to assess the ORF on its Members' clearing activity, based on information the Exchange receives from OCC, including for away market activity. Among other reasons, doing so better and more accurately captures activity that occurs away from the Exchange over which the Exchange has a degree of regulatory responsibility. In so doing, the Exchange believes that assessing ORF on Member clearing firms equitably distributes the collection of ORF in a fair and reasonable manner. Also, the Exchange and the other options exchanges are required to populate a consolidated options audit trail (''COATS'') [4] system in order to surveil a Member's activities across markets.

In addition to its own surveillance programs, the Exchange works with other SROs and exchanges on intermarket surveillance related issues. Through its participation in the Intermarket Surveillance Group (''ISG''),[5] the Exchange shares information and coordinates inquiries and investigations with other exchanges designed to address potential intermarket manipulation and trading abuses. The Exchange's participation in ISG helps it to satisfy the requirement that it has coordinated surveillance with markets on which security futures are traded and markets on which any security underlying security futures are traded to detect manipulation and insider trading.[6]

The Exchange believes that charging the ORF across markets avoids having Members direct their trades to other markets in order to avoid the fee and to thereby avoid paying for their fair share for regulation. If the ORF did not apply to activity across markets then a Member would send their orders to the least cost, least regulated exchange. Other exchanges do impose a similar fee on their members' activity,[7] including the activity of those members on MIAX, MIAX PEARL and MIAX Emerald.[8] The Exchange notes that there is established precedent for an SRO charging a fee across markets, namely, FINRAs Trading Activity Fee [9] and the NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), Cboe Exchange, Inc. (''CBOE''), Nasdaq PHLX LLC (''Phlx''), Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and BOX Exchange LLC (''BOX'') ORF. While the Exchange does not have all the same regulatory responsibilities as FINRA, the Exchange believes that, like other exchanges that have adopted an ORF, its broad regulatory responsibilities with respect to a Member's activities, irrespective of where their transactions take place, supports a regulatory fee applicable to transactions on other markets. Unlike FINRA's Trading Activity Fee, the ORF applies only to a Member's customer options transactions.

Additionally, the Exchange specifies in the Fee Schedule that the Exchange may only increase or decrease the ORF semi-annually, and any such fee change will be effective on the first business day of February or August. In addition to submitting a proposed rule change to the Commission as required by the Act to increase or decrease the ORF, the Exchange notifies participants via a Regulatory Circular of any anticipated change in the amount of the fee at least 30 calendar days prior to the effective date of the change. The Exchange believes that by providing guidance on the timing of any changes to the ORF, the Exchange makes it easier for participants to ensure their systems are configured to properly account for the ORF.

The Exchange is proposing to decrease the ORF from $0.0029 to $0.0020, as of August 1, 2019. In light of recent market volumes on the Exchange and changes to the Exchange's regulatory costs, the Exchange is proposing to decrease the amount of ORF that will be collected by the Exchange. As noted above, the Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

In connection with this filing, the Exchange notes that its affiliates, MIAX PEARL and MIAX Emerald, will also be adjusting the ORF fees that each of those exchanges charge. Including the proposed adjustments to ORF of both MIAX PEARL and MIAX Emerald with the proposed adjustment by the Exchange, MIAX and its affiliates' ORF will see a net decrease from $0.0063 to $0.0053 with the proposed adjustments for August 1, 2019.

The Exchange notified Members via a Regulatory Circular of the proposed change to the ORF at least thirty (30) calendar days prior to the proposed operative date, on July 1, 2019.[10] The Exchange believes that the prior notification to market participants will ensure market participants are prepared to configure their systems to properly account for the ORF.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(4) of the Act [12] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [13] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that decreasing the ORF from $0.0029 to $0.0020, as of August 1, 2019, is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of regulatory costs incurred by the Exchange. The Exchange believes that the proposed adjustments noted herein will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The Exchange believes that decreasing the ORF from $0.0029 to $0.0020, as of August 1, 2019, is equitable and not unfairly discriminatory because it is

[4] COATS effectively enhances intermarket options surveillance by enabling the options exchanges to reconstruct the market promptly to effectively surveil certain rules.

[5] ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by co-operatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

[6] *See* Section 6(h)(3)(I) of the Act.

[7] Similar regulatory fees have been instituted by Nasdaq PHLX LLC (''Phlx'') (*See* Securities Exchange Act Release No. 61133 (December 9, 2009), 74 FR 66715 (December 16, 2009) (SR–Phlx–2009–100)); Nasdaq ISE, LLC (''ISE'') (*See* Securities Exchange Act Release No. 61154 (December 11, 2009), 74 FR 67278 (December 18, 2009) (SR–ISE–2009–105)); and Nasdaq GEMX, LLC (''GEMX'') (*See* Securities Exchange Act Release No. 70200 (August 14, 2013) 78 FR 51242 (August 20, 2013) (SR–Topaz–2013–01)).

[8] *See supra* note 3.

[9] *See* Securities Exchange Act Release No. 47946 (May 30, 2003), 68 FR 34021 (June 6, 2003) (SR–NASD–2002–148).

[10] *See* MIAX Options Regulatory Circular 2019–42 available at *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Options_RC_2019_42.pdf*.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

objectively allocated to Members in that it is charged to all Members on all their transactions that clear as customer at the OCC. Moreover, the Exchange believes the ORF ensures fairness by assessing fees to those Members that are directly based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Member proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Members' customer options business including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side. In this regard, the Exchange believes that the proposed decrease to the fee is reasonable.

The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates with advance notice is reasonable because it gives participants certainty on the timing of changes, if any, and better enables them to properly account for ORF charges among their customers. The Exchange believes that continuing to limit changes to the ORF to twice a year on specific dates is equitable and not unfairly discriminatory because it will apply in the same manner to all Members that are subject to the ORF and provide them with additional advance notice of changes to that fee.

The Exchange believes that collecting the ORF from non-Members when such non-Members ultimately clear the transaction (that is, when the non-Member is the ''ultimate clearing firm'' for a transaction in which a Member was assessed the ORF) is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange notes that there is a material distinction between ''assessing'' the ORF and ''collecting'' the ORF. The ORF is only assessed to a Member with respect to a particular transaction in which it is either the executing clearing firm or ultimate clearing firm. The Exchange does not assess the ORF to non-Members. Once, however, the ORF is assessed to a Member for a particular transaction, the ORF may be collected from the Member or a non-Member, depending on how the transaction is cleared at OCC. If there was no change to the clearing account of the original transaction, the ORF would be collected from the Member. If there was a change to the clearing account of the original transaction and a non-Member becomes the ultimate clearing firm for that transaction, then the ORF will be collected from that non-Member. The Exchange believes that this collection practice continues to be reasonable and appropriate, and was originally instituted for the benefit of clearing firms that desired to have the ORF be collected from the clearing firm that ultimately clears the transaction.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, and is designed to enable the Exchange to recover a material portion of the Exchange's cost related to its regulatory activities. It also supplements the regulatory revenue derived from non-customer activity. This proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. Unilateral action by MIAX in establishing fees for services provided to its Members and others using its facilities will not have an impact on competition. In the highly competitive environment for equity options trading, MIAX does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Act. The Exchange's ORF, as described herein, is comparable to fees charged by other options exchanges for the same or similar services. The Exchange believes that continuing to limit the changes to the ORF to twice a year on specific dates with advance notice is not intended to address a competitive issue but rather to provide Members with better notice of any change that the Exchange may make to the ORF.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[14] and Rule 19b–4(f)(2)[15] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–MIAX–2019–35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 240.19b–4(f)(2).

All submissions should refer to File No. SR–MIAX–2019–35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–MIAX–2019–35, and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86603; File No. SR–CBOE–2019–044]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change Relating To Adopt Rule 6.49B, Off-Floor RWA Transfers

August 8, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 6, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to adopt Rule 6.49B. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt Rule 6.49B to add an exception to the prohibition in Rule 6.49(a) against off-floor position transfers. Rule 6.49(a) generally requires transactions of option contracts listed on the Exchange for a premium in excess of $1.00 to be effected on the floor of the Exchange or on another exchange. Rule 6.49A(a) specifies the current circumstances[3] under which Trading Permit Holders may effect transfers of positions off the trading floor, notwithstanding the prohibition in Rule 6.49(a).[4]

Proposed Rule 6.49B is intended to facilitate the reduction of risk-weighted assets (''RWA'') attributable to open options positions and make other conforming changes. SEC Rule 15c3–1 (Net Capital Requirements for Brokers or Dealers) (''Net Capital Rules'') requires registered broker-dealers, unless otherwise excepted, to maintain certain specified minimum levels of capital.[5] The Net Capital Rules are designed to protect securities customers, counterparties, and creditors by requiring that broker-dealers have sufficient liquid resources on hand, at all times, to meet their financial obligations. Notably, hedged positions, including offsetting futures and options contract positions, result in certain net capital requirement reductions under the Net Capital Rules.[6]

Subject to certain exceptions, Clearing Trading Permit Holders (''CTPHs'')[7] are subject to the Net Capital Rules.[8] However, a subset of CTPHs are subsidiaries of U.S. bank holding companies, which, due to their affiliations with their parent U.S.-bank holding companies, must comply with additional bank regulatory capital requirements pursuant to rulemaking required under the Dodd-Frank Wall Street Reform and Consumer Protection Act.[9] Pursuant to this mandate, the Board of Governors of the Federal Reserve System, the Office of the Comptroller of the Currency, and the

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The circumstances currently listed include: (1) The dissolution of a joint account in which the remaining Trading Permit Holder assumes the positions of the joint account; (2) the dissolution of a corporation or partnership in which a former nominee of the corporation or partnership assumes the positions; (3) positions transferred as part of a Trading Permit Holder's capital contribution to a new joint account, partnership, or corporation; (4) the donation of positions to a not-for-profit corporation; (5) the transfer of positions to a minor under the Uniform Gifts to Minor law; and (6) a merger or acquisition where continuity of ownership or management results.

[4] *See* SR–CBOE–2019–035, which proposes to amend Rule 6.49A and is currently pending with the Securities and Exchange Commission (the ''Commission''). The Exchange notes the proposed rule change in this rule filing was initially included in SR–CBOE–2019–3035 [sic]; pursuant to Amendment No. 1 to that rule filing, submitted on August 6, 2019, the proposed rule change in this filing was deleted. The Exchange proposes a virtually identical change in this rule filing.

[5] 17 CFR 240.15c3–1.

[6] In addition, the Net Capital Rules permit various offsets under which a percentage of an option position's gain at any one valuation point is allowed to offset another position's loss at the same valuation point (*e.g.* vertical spreads).

[7] All CTPHs must also be clearing members of The Options Clearing Corporation (''OCC'').

[8] Assuming the Commission approves the proposed rule change, in the event federal regulators modify bank capital requirements in the future, the Exchange will reevaluate the proposed rule change at that time to determine whether any corresponding changes to the proposed rule are appropriate.

[9] H.R. 4173 (amending section 3(a) of the Securities Exchange Act of 1934 (the ''Act'') (15 U.S.C. 78c(a))).

Federal Deposit Insurance Corporation have approved a regulatory capital framework for subsidiaries of U.S. bank holding company clearing firms.[10] Generally, these rules, among other things, impose higher minimum capital and higher asset risk weights than were previously mandated for CTPHs that are subsidiaries of U.S. bank holding companies under the Net Capital Rules. Furthermore, the new rules do not fully permit deductions for hedged securities or offsetting options positions.[11] Rather, capital charges under these standards are, in large part, based on the aggregate notional value of short positions regardless of offsets. As a result, in general, CTPHs that are subsidiaries of U.S. bank holding companies must hold substantially more bank regulatory capital than would otherwise be required under the Net Capital Rules.

The Exchange believes these higher regulatory capital requirements may impact liquidity in the listed options market by limiting the amount of capital CTPHs can allocate to their clients' transactions. Specifically, the rules may cause CTPHs to impose stricter position limits on their client clearing members. These stricter position limits may impact the liquidity market participants may provide, including liquidity Market-Makers may provide in their appointed classes. This impact may be compounded when a CTPH has multiple client accounts, each having largely risk-neutral portfolio holdings.[12] The Exchange believes that permitting market participants to efficiently transfer existing options positions through an off-floor transfer process may assist CTPHs and TPHs to address bank regulatory capital requirements and would likely have a beneficial effect on continued liquidity in the options market without adversely affecting market quality.

Liquidity in the listed options market is critically important. However, bank capital regulations that govern bank-affiliated clearing firms are negatively impacting the ability of Trading Permit Holders, including Market-Makers, that clear options transactions through bank-affiliated clearing firms to provide liquidity. In order to mitigate the potential negative effects of these additional bank regulatory capital requirements, the proposed rule change provides market participants with an efficient mechanism to transfer their open options positions from one clearing account to another clearing account. The Exchange believes the proposed rule change will increase liquidity in the listed options market and promote more efficient capital deployment in light of bank regulatory capital requirements.

The Exchange has previously adopted Rules 6.56 and 6.57 to provide Trading Permit Holders with tools to reduce RWA attributable to their open positions in S&P 500 options (''SPX options''). However, the procedures in those rules involve transactions that must occur on the Exchange's trading floor to close open positions. Therefore, a market participant must find a counterparty and be willing to close positions to use either of these tools. As a result, these procedures are less efficient, less flexible, and more burdensome means to reduce RWA attributable to open options positions than an off-floor transfer of such positions. Additionally, these tools are currently limited to SPX options, due to the large notional size of those options, which compounds the negative impact of bank capital requirements, and Rule 6.57 is limited to Market-Makers (Rule 6.56 is available to all Trading Permit Holders). However, bank capital requirements apply to positions in all listed options, and may impact all client clearing members of clearing firms affiliated with U.S.-bank holding companies, and clearing firms may request that Market-Makers and non-Market-Makers reduce positions in listed options in addition to SPX. There is currently no mechanism firms may use to transfer positions between clearing accounts without having to effect a transaction with another party and close a position.

Rule 6.49A(a), as noted above, permits positions to be transferred off the floor of the Exchange in specified limited circumstances. If a Trading Permit Holder wanted to transfer open positions from a clearing account it has with one a bank-affiliated clearing firm to a clearing account it has with a non-bank-affiliated clearing firm, for example, such a transfer would result in no change in ownership. However, the currently permissible off-floor position transfers are non-routine, non-recurring movements of positions, which do not permit use of the off-floor transfer procedure to be used repeatedly or routinely in circumvention of the normal auction market process. To comply with clearing firms' position limits they may impose on market participants' because they need to limit capital they may allocate for those market participants' transactions, market participants may need to regularly reduce open positions or limit additional positions in their accounts with such clearing firms' to accommodate bank capital requirements. Rule 6.49A does not permit regular transfers of positions between accounts at different clearing firms.

Proposed Rule 6.49B is intended to provide market participants with an additional tool they may use to address the issues raised by bank capital requirements for positions in all listed options in an efficient manner that provides market participants with flexibility to do so in accordance with their businesses and risk management practices. Proposed Rule 6.49B provides that notwithstanding Rule 6.49, existing positions in options listed on the Exchange of a Trading Permit Holder or non-Trading Permit Holder (including an affiliate of a Trading Permit Holder) may be transferred on, from, or to the books of a CTPH off the Exchange if the transfer establishes a net reduction of RWA attributable to those options positions (an ''RWA Transfer''). Proposed paragraph (a) adds examples of two transfers that would be deemed to establish a net reduction of RWA, and thus qualify as a permissible RWA Transfer:

- A transfer of options positions from Clearing Corporation member A to Clearing Corporation member B that net (offset) with positions held at Clearing Corporation member B, and thus closes all or part of those positions (as demonstrated in the example below);[13] and
- A transfer of options positions from a bank-affiliated Clearing Corporation member to a non-bank-affiliated Clearing Corporation member.[14]

[10] 12 CFR 50; 79 FR 61440 (Liquidity Coverage Ratio: Liquidity Risk Measurement Standards).

[11] Many options strategies, including relatively simple strategies often used by retail customers and more sophisticated strategies used by broker-dealers, are risk-limited strategies or options spread strategies that employ offsets or hedges to achieve certain investment outcomes. Such strategies typically involve the purchase and sale of multiple options (and may be coupled with purchases or sales of the underlying securities), executed simultaneously as part of the same strategy. In many cases, the potential market exposure of these strategies is limited and defined. While regulatory capital requirements have historically reflected the risk-limited nature of carrying offsetting positions, these positions may now be subject to higher regulatory capital requirements.

[12] A number of TPHs, including Market-Makers, have informed the Exchange that the heightened bank regulatory requirements could impact their ability to provide consistent liquidity in the market unless they are able to efficiently transfer their open positions out of clearing accounts of U.S.-bank affiliated clearing firms.

[13] This transfer would establish a net reduction of RWA attributable to the transferring Person, because there would be fewer open positions and thus fewer assets subject to Net Capital Rules.

[14] This transfer would establish a net reduction of RWA attributable to the transferring Person, because the non-bank-affiliated Clearing

Continued

These transfers will not result in a change in ownership, as they must occur between accounts of the same Person.[15] Rule 1.1 defines ''Person'' as an individual, partnership (general or limited), joint stock company, corporation, limited liability company, trust or unincorporated organization, or any governmental entity or agency or political subdivision thereof. In other words, RWA transfers may only occur between the same individual or legal entity. These are merely transfers from one clearing account to another, both of which are attributable to the same individual or legal entity. A market participant effecting an RWA Transfer is analogous to an individual transferring funds from a checking account to a savings account, or from an account at one bank to an account at another bank—the money still belongs to the same person, who is just holding it in a different account for personal financial reasons.

For example, Market-Maker A clears transactions on the Exchange into an account it has with CTPH X, which is affiliated with a U.S-bank holding company. Market-Maker A opens a clearing account with CTPH Y, which is not affiliated with a U.S.-bank holding company. CTPH X has informed Market-Maker A that its open positions may not exceed a certain amount at the end of a calendar month, or it will be subject to restrictions on new positions it may open the following month. On August 28, Market-Maker A reviews the open positions in its CTPH X clearing account and determines it must reduce its open positions to satisfy CTPH X's requirements by the end of August. It determines that transferring out 1000 short calls in class ABC will sufficiently reduce the RWA capital requirements in the account with CTPH X to avoid additional position limits in September. Market-Maker A wants to retain the positions in accordance with its risk profile. Pursuant to the proposed rule change, on August 31, Market-Maker A transfers 1000 short calls in class ABC to its clearing account with CTPH Y. As a result, Market-Maker A can continue to provide the same level of liquidity in class ABC during September as it did in previous months.

A Trading Permit Holder must give up a CTPH for each transaction it effects on the Exchange, which identifies the CTPH through which the transaction will clear.[16] A Trading Permit Holder may change the give up for a transaction within a specified period of time.[17] Additionally, a Trading Permit Holder may also change the CMTA [18] for a specific transaction.[19] The transfer of positions from an account with one clearing firm to the account of another clearing firm pursuant to the proposed rule change has a similar result as changing a give up or CMTA, as it results in a position that resulted from a transaction moving from the account of one clearing firm to another, just at a different time and in a different manner.[20] In the above example, if Market-Maker A had initially given up CTPH Y rather than CTPH X on the transactions that resulted in the 1000 long calls in class ABC, or had changed the give-up or CMTA to CTPH Y pursuant to Rules 6.21 or 6.67, the ultimate result would have been the same. There are a variety of reasons why firms give up or CMTA transactions to certain clearing firms (and not to non-bank affiliate clearing firms) at the time of a transaction, and the proposed rule change provides firms with a mechanism to achieve the same result at a later time.

Proposed paragraph (b) states RWA Transfers may occur on a routine, recurring basis. As noted in the example above, clearing firms may impose restrictions on the amount of open positions. Permitting transfers on a routine, recurring basis will provide market participants with the flexibility to comply with these restrictions when necessary to avoid position limits on future options activity. Additionally, proposed paragraph (f) provides that no prior written notice to the Exchange is required for RWA Transfers. Because of the potential routine basis on which RWA Transfers may occur, and because of the need for flexibility to comply with the restrictions described above, the Exchange believes it may interfere with the ability of investors firms to comply with any CTPH restrictions describe above, and may be burdensome to provide notice for these routine transfers.

Proposed paragraph (c) states RWA Transfers may result in the netting of positions. Netting is generally prohibited for off-floor transfers.[21] Netting occurs when long positions and short positions in the same series ''offset'' against each other, leaving no or a reduced position. For example, if there were 100 long calls in one account, and 100 short calls of the same option series were added to that account, the positions would offset, leaving no open positions. Currently, the Exchange permits off-floor transfers on behalf of a Market-Maker account for transactions in multiply listed options series on different exchanges, but only if the Market-Maker nominees are trading for the same Trading Permit Holder organization, and the options transactions on the different options exchanges clear into separate exchange-specific accounts because they cannot easily clear into the same Market-Maker account at OCC. In such instances, all Market-Maker positions in the exchange-specific accounts for the multiply listed class would be automatically transferred on their trade date into one central Market-Maker account (commonly referred to as a ''universal account'') at the Clearing Corporation.[22] Positions cleared into a universal account would automatically net against each other.

While RWA Transfers are not occurring because of limitations related to trading on different exchanges, similar reasoning for the above exception applies to why netting should be permissible for the limited purpose of reducing RWA. Firms may maintain different clearing accounts for a variety of reasons, such as the structure of their businesses, the manner in which they trade, their risk management procedures, and for capital purposes. If a Market-Maker clears all transactions into a universal account, offsetting positions would automatically net. However, if a Market-Maker has multiple accounts into which its transactions cleared, they would not automatically net. While there are times when a firm may not want to close out open positions to reduce RWA, there are other times when a firm may determine it is appropriate to close out positions to accomplish a reduction in RWA.

In the example above, suppose after making the RWA Transfer described above, Market-Maker A effects a transaction on September 25 that results in 1000 long calls in class ABC, which clears into its account with CTPH X. If Market-Maker A had not effected its RWA Transfer in August, the 1000 long calls would have offset against the 1000

Corporation member would not be subject to Net Capital Rules, as described above.

[15] *See* proposed paragraph (e).

[16] *See* Rule 6.21.

[17] *See* Rule 6.21(e).

[18] The Clearing Member Trade Assignment (''CMTA'') process at the Options Clearing Corporation (''OCC'') facilitates the transfer of option trades/positions from one OCC clearing member to another in an automated fashion. Changing a CMTA for a specific transaction would allocate the trade to a different OCC clearing member than the one initially identified on the trade.

[19] *See* Rule 6.67(a).

[20] The transferred positions will continue to be subject to OCC rules, as they will continue to be held in an account of an OCC member.

[21] *See* Cboe Options Regulatory Circular RG03–62 (July 24, 2003).

[22] *Id.*

short calls, eliminating both positions and thus any RWA capital requirements associated with them. At the end of August, Market-Maker A did not want to close out the 1000 short calls when it made its RWA Transfer. However, given changed circumstances in September, Market-Maker A has determined it no longer wants to hold those positions. The proposed rule change would permit Market-Maker A to effect an RWA Transfer of the 1000 short calls from its account with CTPH Y to its account with CTPH X (or vice versa), which results in elimination of those positions (and a reduction in RWA associated with them). As noted above, such netting would have occurred if Market-Maker A cleared the September transaction directly into its account with CTPH Y, or had not effected an RWA Transfer in August. Netting provides market participants with appropriate flexibility to conduct their businesses as they see fit while having the ability to reduce RWA capital requirements when necessary.

As is true for all other off-floor transfers permitted under Rule 6.49A, RWA Transfers may not result in preferential margin or haircut treatment.[23] Additionally, RWA Transfers may only be effected for options listed on the Exchange and will be subject to applicable laws, rules, and regulations, including rules of other self-regulatory organizations (including OCC).[24]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[25] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[26] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[27] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, The Exchange believes the proposed rule change to permit RWA Transfers will remove impediments to and perfect the mechanism of a free and open market and a national market system by potentially mitigating the effects bank capital requirements may have on liquidity in the listed options market. As described above, bank capital requirements may impact capital available for options market liquidity providers, for example due to CTPHs' imposition of stricter position limits on firms that clear options transactions with them. The Exchange believes providing market participants with an efficient process to reduce RWA capital requirements attributable to open positions in clearing accounts with U.S. bank-affiliated clearing firms may contribute to additional liquidity in the listed options market, which, in general, protects investors and the public interest.

The proposed rule change, in particular the proposed changes to permit RWA transfers to occur on a routine, recurring basis and result in netting, also provides market participants with sufficient flexibility to reduce RWA capital requirements at times necessary to comply with requirements imposed on them by clearing firms. This will permit market participants respond to then-current market conditions, including volatility and increased volume, by reducing the RWA capital requirements associated with any new positions they may open while those conditions exist. Given the additional capital that may become available to market participants as a result of the RWA Transfers, market participants will be able to continue to provide liquidity to the market, even during periods of increased volume and volatility, which liquidity ultimately benefits investors. It is not possible for market participants to predict what market conditions will exist at a specific time, and when volatility will occur. The proposed rule change to permit routine, recurring RWA Transfers (and to not provide prior written notice) will provide market participants with the ability to respond to these conditions whenever they occur. Additionally, since firms may be subject to restrictions on positions imposed by their clearing firms, permitting transfers on a routine, recurring basis will provide market participants with the flexibility to comply with these restrictions when necessary to avoid position limits on future options activity. In addition, with respect to netting, as discussed above, firms may maintain different clearing accounts for a variety of reasons, such as the structure of their businesses, the manner in which they trade, their risk management procedures, and for capital purposes. Netting may otherwise occur with respect to a firm's positions if it structured its clearing accounts differently, such as by using a universal account. Therefore, the proposed rule change will permit netting while allowing firms to continue to maintain different clearing accounts in a manner consistent with their businesses.

The Exchange recognizes the numerous benefits of executing options transactions occur on an exchanges, including price transparency, potential price improvement, and a clearing guarantee. However, the Exchange believes it is appropriate to permit RWA Transfers to occur off the exchange, as these benefits are inapplicable to RWA Transfers. RWA Transfers have a narrow scope and are intended to achieve a limited, benefit purpose. RWA Transfers are not intended to be a competitive trading tool. There is no need for price discovery or improvement, as the purpose of the transfer is to reduce RWA asset capital requirements attributable to a market participants' positions. Unlike trades on an exchange, the price at which an RWA Transfers occurs is immaterial—the resulting reduction in RWA is the critical part of the transfer. RWA Transfers will result in no change in ownership, and thus they do not constitute trades with a counterparty (and thus eliminating the need for a counterparty guarantee). The transactions that resulted in the open positions to be transferred as an RWA Transfer were already guaranteed by an OCC clearing member, and the positions will continue to be subject to OCC rules, as they will continue to be held in an account with an OCC clearing member. The narrow scope of the proposed rule change and the limited, beneficial purpose of RWA Transfers make allowing RWA Transfers to occur off the floor appropriate and important to support the provision of liquidity in the listed options market.

The proposed rule change does not unfairly discriminate against market

[23] *See* proposed paragraph (d); *see also id.*

[24] *See* proposed introductory paragraph and proposed paragraph (g). Transfers of non-Exchange listed options and other financial instruments are not governed by proposed Rule 6.49B. Any RWA transfers will be subject to all applicable recordkeeping requirements applicable to TPHs and CTPHs under the Securities Exchange Act of 1934, and the rules and regulations thereunder (the ''Act''), such as Rule 17a-3 and 17a-4.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] *Id.*

participants, as all Trading Permit Holders and non-Trading Permit Holders with open positions in options listed on the Exchange may use the proposed off-floor transfer process to reduce the RWA capital requirements of CTPHs.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The purpose of the proposed rule change to permit RWA Transfers is to alleviate the negative impact of bank capital requirements on options market liquidity providers. This process is not intended to be a competitive trading tool. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as use of the proposed process is voluntary. All Trading Permit Holders and non-Trading Permit Holders with open positions in options listed on the Exchange may use the proposed off-floor transfer process to reduce the RWA capital requirements attributable to those positions. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. RWA Transfers have a limited purpose, which is to reduce RWA attributable to open positions in listed options in order to free up capital. Cboe Options believes the proposed rule change may relieve the burden on liquidity providers in the options market by reducing the RWA attributable to their open positions. As a result, market participants may be able to increase liquidity they provide to the market, which liquidity benefits all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2019–044 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2019–044. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2019–044 and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Jill M. Peterson,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86609; File No. SR–NASDAQ–2019–062]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend SCAR Credits at Equity 7, Section 118(a)

August 8, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 25, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend SCAR credits at Equity 7, Section 118(a).

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 1, 2019. The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed

[28] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to adopt revised pricing for the recently adopted SCAR routing strategy.[3] In sum, SCAR is a routing option under which orders check the System [4] for available shares and simultaneously route to the other equity markets operated by Nasdaq, Inc., Nasdaq BX, Inc. (''BX'') and Nasdaq PSX (''PSX'').[5]

The Exchange proposes to adopt revised credits for SCAR orders in securities listed on Nasdaq (''Tape C''), NYSE (''Tape A''), and on exchanges other than Nasdaq and NYSE (''Tape B'') (collectively, ''Tapes''), which execute on BX.[6] BX recently updated its fee schedule whereby it generally increased the credits provided for orders that access liquidity,[7] and the Exchange is proposing to adjust its fee schedule relating to SCAR to increase credits provided for SCAR executions occurring on BX Tapes A and C securities and to decrease the credit provided for SCAR executions occurring on BX Tape B securities. Currently in securities priced at $1 or more per share, the Exchange provides a credit of $0.0015 per share for SCAR orders in Tapes A and C securities executed at BX, and a credit of $0.0026 per share for SCAR orders in Tape B securities executed at Nasdaq BX.[8] The Exchange is proposing to provide a credit of $0.0025 per share executed for SCAR orders executed on BX in the securities of any of the Tapes priced at $1 or more per share, which will align the credits with recent changes to the BX fee schedule.[9]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the pricing structure proposed above for SCAR is reasonable, equitable, and not unfairly discriminatory because the new credits are generally set at a level intended to incentivize members to use this new routing strategy. The proposed $0.0025 per share executed credit for orders in any Tape securities priced at $1 or more per share that route to, and execute on, BX using the SCAR routing strategy is significantly higher than the current credit provided in such transactions in securities of Tapes A and C, and is a modest decrease to the credit provided for executions in such transactions in securities of Tape B. This is reflective of the Exchange's desire to increase incentives to members to use the routing strategy and its assessment of the costs incurred in providing the routing strategy. Alignment of the incentive for executions on BX will strike a balance between these factors. In this regard, the Exchange notes that if the order executed directly on BX as the home exchange, (*i.e.,* without using SCAR) the member would be charged the standard transaction fee of $0.0003 per share executed.[12] As such, the proposed SCAR credit is set at a rate that makes it more economical for members to use this routing strategy, especially for those members that do not already add and/or remove volume on BX directly. Last, the Exchange believes that the proposed pricing changes are equitable and not unfairly discriminatory because they will apply uniformly to all members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed pricing for SCAR orders is intended to provide incentive to members to use the Exchange's SCAR routing strategy, balanced against the need to recoup the Exchange's costs associated with providing its completely optional routing services. Because the Exchange's routing services are the subject of competition, including price competition, from other exchanges and broker-dealers that offer routing services, as well as the ability of members to use their own routing capabilities, it is likely that the Exchange will lose market share as a result of the changes if they are unattractive to market participants. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[3] *See* Nasdaq Rule 4758(a)(1)(A)(xv). *See also* Securities Exchange Act Release No. 85372 (March 20, 2019), 84 FR 11357 (March 26, 2019) (SR–NASDAQ–2019–013).

[4] The term ''System'' shall mean the automated system for order execution and trade reporting owned and operated by The Nasdaq Stock Market LLC. *See* Rule 4701(a).

[5] If shares remain unexecuted after routing, they are posted on the Exchange's book or cancelled. Once on the book, should the order subsequently be locked or crossed by another market center, the System will not route the order to the locking or crossing market center. *See* Rule 4758(a)(1)(A)(xv).

[6] The Exchange currently provides pricing for execution on BX using SCAR that is better that a market participant would otherwise receive for removing liquidity from BX if it did not meet certain volume thresholds that would qualify them for a better rate (such as a liquidity removal credit), which is $0.0003 per share executed for orders in any Tape securities priced at $1 or more per share that access liquidity on the Exchange. *See* BX Equity 7, Section 118(a). Thus, the Exchange's current fees are more reflective of the pricing a market participant would receive if it provided certain levels of volume. The Exchange is proposing to adjust the credit provided for BX executions to reflect recent changes to the credits provided to BX members for removing liquidity. *See* Securities Exchange Act Release No. 34–86447 (July 24, 2019) (SR–BX–2019–026) (awaiting publication in the **Federal Register**).

[7] *Id.*

[8] BX operates on the ''taker-maker'' model, whereby it generally pays credits to members that take liquidity and charges fees to members that provide liquidity.

[9] *See supra* note 6.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] This fee would apply unless the member qualifies for a better rate (such as a discounted fee or credit) by meeting certain volume thresholds. *See* BX Equity 7, Section 118(a).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2019–062 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2019–062. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2019–062 and should be submitted on or before September 4, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–17389 Filed 8–13–19; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Docket No.: SBA–2018–0007]

Surety Bond Guarantee Program Fees

AGENCY: U.S. Small Business Administration.

ACTION: Notification of extension of temporary initiative to test lower fees for an additional year.

SUMMARY: This document announces a one-year extension of the temporary decrease in the guarantee fees that the U.S. Small Business Administration (SBA) charges all Surety companies and Principals on each guaranteed bond (other than a bid bond) issued in SBA's Surety Bond Guarantee (SBG) Program.

DATES: The temporary initiative to test lower fees in the SBG Program, which is currently in effect through September 30, 2019, will be extended for an additional year to apply to all SBA surety bond guarantees approved through September 30, 2020.

FOR FURTHER INFORMATION CONTACT: Jermanne Perry, Management Analyst, Office of Surety Guarantees; (202) 401–8275 or *jermanne.perry@sba.gov.*

SUPPLEMENTARY INFORMATION: Under its SBG Program, the SBA guarantees a certain percentage of bid, payment, and performance bonds for small and emerging contractors who cannot obtain surety bonds through regular commercial channels. The SBA guarantee incentivizes Sureties to provide bonding for small businesses and thereby assists small businesses in obtaining greater access to contracting opportunities. Pursuant to its statutory authority to ''establish such fee or fees for small business concerns and premium or premiums for sureties as it deems reasonable and necessary,'' and to administer the SBG Program ''on a prudent and economically justifiable basis,'' 15 U.S.C. 694b(h), SBA assesses a guarantee fee against both the small business concern (the Principal) and the Surety and deposits these fees into a revolving fund to cover the program's liabilities and certain program expenses.

SBA's rules provide that the amount of the fees to be paid by the Surety and the Principal will be determined by SBA and published in Notices in the **Federal Register** from time to time. *See* 13 CFR 115.32(b) and (c) and 115.66. On July 30, 2018, SBA published a notification in the **Federal Register** (83 FR 36658) that announced that, for all guaranteed bonds approved during the one year period beginning October 1, 2018 through September 30, 2019, the Surety fee would decrease from 26% of the bond premium to 20% of the bond premium, and the Principal fee would decrease from $7.29 per thousand dollars of the contract amount to $6 per thousand dollars of the contract amount (the decrease in the Surety and Principal fees referred to, collectively, as ''lower fees''). SBA invited comments on this temporary initiative and received a total of eight comments, with six comments from surety companies and agents and two comments from trade associations, all of which expressed support for the lower fees.

SBA has determined that it requires more data to fully evaluate the effect of the lower fees on the SBG Program. Accordingly, to provide more time to gather and evaluate the requisite data, SBA is announcing a one-year extension of the temporary initiative to test the lower fees. The lower fees will now apply to all bond guarantees (other than bid bonds) approved through September 30, 2020. During the additional year that the lower fees are in effect, SBA will evaluate how the lower fees affect the SBG Program, including program utilization by surety companies, surety agents and small businesses; the size and characteristics of the portfolio; and the risk level of the program, including cash flow and defaults. After carefully reviewing program performance with the additional data, SBA will determine whether the guarantee fees should remain at these reduced amounts, if they should revert to the higher amounts, or if they should otherwise be changed.

Authority: 13 CFR 115.32(b) and (c) and 115.66.

William M. Manger,

Associate Administrator, Office of Capital Access.

[FR Doc. 2019–17442 Filed 8–13–19; 8:45 am]

BILLING CODE P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2018–0051]

Social Security Ruling 19–3p; Titles II and XVI: Requesting Reconsideration or Hearing by an Administrative Law Judge

AGENCY: Social Security Administration.

ACTION: Notice of Social Security Ruling (SSR).

SUMMARY: We are giving notice of SSR 19–3p. This SSR explains the two options available to claimants appealing our determinations that they are not disabled based on medical factors. In this SSR, we explain both the paper and electronic appeal options for requesting reconsideration or a hearing by an administrative law judge (ALJ), and the similarities and differences between these two options. We explain these options to help claimants make informed decisions when deciding whether to use the paper appeal or electronic appeal option to request reconsideration or a hearing.

DATES: We will apply this notice on August 14, 2019.

FOR FURTHER INFORMATION CONTACT: Alicia Wood-Smith, Office of Income Security Programs, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, 410–965–9243. For information on eligibility or filing for benefits, call our national toll-free number 1–800–772–1213, or TTY 1–800–325–0778, or visit our internet site, Social Security online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: Through SSRs, we make available to the public precedential decisions relating to the Federal old-age, survivors, disability, supplemental security income, and special veterans benefits programs. We may base SSRs on determinations or decisions made at all levels of administrative adjudication, Federal court decisions, Commissioner's decisions, opinions of the Office of the General Counsel, or other interpretations of the law and regulations.

This SSR explains that to use the electronic appeal option to request reconsideration or a hearing, claimants must submit all of the information we need to process their appeals at the time they file their electronic appeals. This is required only in our streamlined electronic appeal procedures. Our manually submitted paper appeal procedures remain unchanged. Claimants can upload and submit evidence simultaneously with their electronic appeals. After claimants have filed their appeals, they can submit evidence by fax, by mail, or in-person at one of our field offices or hearing offices as appropriate. A claimant has an ongoing duty to inform us about or submit all known evidence that relates to whether or not he or she is blind or disabled.[1] An appointed representative must act with reasonable promptness to help obtain the information and evidence the claimant must submit, and forward the information or evidence to us as soon as practicable.[2] When a claim is at the hearing level, the claimant, or representative, generally must inform us about or submit all written evidence no later than five business days before the date of the scheduled hearing.[3]

Although 5 U.S.C. 552(a)(1) and (a)(2) do not require us to publish this SSR, we are doing so under 20 CFR 402.35(b)(1). SSRs do not have the same force and effect as statutes or regulations, but they are binding on all components of the Social Security Administration. 20 CFR 402.35(b)(1).

This SSR will remain in effect until we publish a notice in the **Federal Register** that rescinds it, or we publish a new SSR that replaces or modifies it.

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

Andrew Saul,

Commissioner of Social Security.

Policy Interpretation Ruling

SSR 19–3p: Titles II and XVI: Requesting Reconsideration or Hearing by an Administrative Law Judge

Purpose: The purpose of this SSR is to explain the two options available to claimants appealing our determinations that they are not disabled based on medical factors. This SSR explains both the paper and electronic options for requesting reconsideration or a hearing by an ALJ, and the similarities and differences between these two options. In order to request reconsideration or a hearing using iAppeals, our electronic appeal option, claimants must submit all of the information we need to process their appeals at the time they file their electronic appeals. This requirement is part of our streamlined electronic appeal procedures. Claimants also can upload and simultaneously submit evidence with their electronic appeals. After claimants have filed their appeals, they can submit evidence by fax, by mail, or in-person at one of our field offices or hearing offices as appropriate.

A claimant has an ongoing duty to inform us about or submit all known evidence that relates to whether or not he or she is blind or disabled.[4] An appointed representative must act with reasonable promptness to help obtain the information and evidence the claimant must submit, and forward the information or evidence to us as soon as practicable.[5] When a claim is at the hearing level, the claimant, or representative, generally must inform us about or submit all written evidence no later than five business days before the date of the scheduled hearing.[6] Our paper appeal procedures remain unchanged—a claimant still must timely request his or her appeal in writing, but may separately submit the additional information we need to process the appeal. Through this SSR, we are providing information that enables claimants to make informed decisions when deciding whether to use iAppeals or the paper appeal option to request reconsideration or a hearing.

Citations: Sections 205(a) and (b) of the Social Security Act, as amended; 20 CFR 404.907, 404.909, 404.929, 404.933, 416.1407, 416.1409, 416.1429, 416.1433.

Introduction: Claimants who are dissatisfied with the determinations or decisions on their disability applications may request further review under our administrative review process, also known as our appeal process.[7] The administrative review process consists of three levels: Reconsideration, hearing, and Appeals Council review. Until recent years, the only way for claimants to request an appeal was to use the paper-based option, which consists of paper appeal forms. As part of our efforts to offer alternative service delivery options to

[1] 20 CFR 404.1512 and 416.912.

[2] 20 CFR 404.1740(b)(1) and 416.1540(b)(1).

[3] 20 CFR 404.935 and 416.1435.

[4] 20 CFR 404.1512 and 416.912.

[5] 20 CFR 404.1740(b)(1) and 416.1540(b)(1).

[6] 20 CFR 404.935 and 416.1435.

[7] Section 205(b) of the Social Security Act (Act), 42 U.S.C. 405(b); 20 CFR 404.900, 404.907, 404.909, 404.929, 404.933, 404.967, 404.968, 416.1400, 416.1407, 416.1409, 416.1429, 416.1433, 416.1467, 416.1468. See, *e.g.,* Program Operations Manual System (POMS) GN 03101.125 iAppeals—General and Title II Instructions; DI 81007.050 i3441 Disability Appeal—iAppeals; SI 04005.035 iAppeals—Title XVI.

the public, we developed an electronic appeals system, which we call iAppeals.[8] After we implemented the iAppeals process, we received some questions about it, and how it differed from the traditional, paper-based process. This SSR explains the differences between the paper and electronic appeal procedures for filing a request for reconsideration or a hearing.[9] Claimants have the option of filing a request for reconsideration or a hearing using either the paper-based option or iAppeals.

Policy Interpretation: The Act states that a claimant may request an appeal by making ''a showing in writing.'' [10] Our regulations provide that a claimant who seeks reconsideration or a hearing may do so by filing a ''written request'' within 60 days after receiving notice of our determination.[11] These regulations give us the authority to establish mechanisms by which a claimant can file the ''written request'' to appeal a determination. Accordingly, we have determined that a claimant may file a ''written request'' for appeal using either the paper-based appeals process or iAppeals.[12] While there are some differences between our paper and electronic appeal options for filing a request for reconsideration or a hearing, the substantive standards used to evaluate a claimant's appeal request remain the same regardless of which option the claimant chooses.

The Paper-Based Process for Requesting a Reconsideration or a Hearing

A claimant may file a written request for reconsideration or a hearing by either mail or in-person at one of our field offices. While our rules do not require claimants to use a specific form to request an appeal, the SSA–561 ''Request for Reconsideration'' (OMB No. 0960–0622) and HA–501 ''Request for Hearing by Administrative Law Judge'' (OMB No. 0960–0269) collect basic information we need to process the appeal. The SSA–561 and HA–501 request specific identifying information, such as the claimant's name, Social Security number, date of birth, and contact information. The forms also request the name and contact information for any representative helping the claimant with the appeal, as well as the reason the claimant disagrees with the determination. The HA–501 includes space for the claimant to identify sources who can provide additional evidence.

Generally, a claimant also completes and submits the SSA–3441–BK ''Disability Report—Appeal'' (OMB No. 0960–0144) along with the appeal request. The SSA–3441–BK collects updated information relevant to a claimant's appeal, including:

- The contact information of a friend or relative with knowledge of the claimant's medical condition;
- A description of any change to the claimant's medical condition and any new medical conditions;
- The contact information of and visit dates to all health care providers, and type of treatments, and tests received;
- The name of any medications (prescription or over-the-counter) that the claimant is currently taking, the reasons for taking them, any side effects, and the name of the doctor who recommended or prescribed the medication; and
- A description of any change in daily activities, work, and education.

While claimants do not have to submit the SSA–3441–BK at the time they file their paper appeal requests, a delay in providing the information requested on the SSA–3441–BK impedes our ability to process and forward an appeal request to the Disability Determination Services (DDS) for a reconsideration determination or to the Office of Hearings Operations for a decision by an ALJ. If a claimant does not provide the information requested on the SSA–3441–BK at the time he or she files the appeal request, generally, we attempt to contact the claimant in order to obtain the information before the DDS makes a determination or an ALJ makes a decision.[13]

The iAppeals Process for Requesting Reconsideration or a Hearing

A claimant may file a written request for reconsideration or a hearing using iAppeals, our electronic appeal option.[14] When we first introduced iAppeals in 2007, claimants could submit the electronic disability report form, i3441, ''Disability Report—Appeal,'' after filing the i561, ''Request for Reconsideration,'' or i501, ''Request for Hearing by Administrative Law Judge.'' In 2015, we streamlined iAppeals by merging questions from the standard appeal request forms, i561 or i501, and the disability report, i3441, form, so that all of the information needed to process an appeal is collected and submitted at the same time.

Claimants who choose to use iAppeals to request an appeal must complete the full electronic appeal application in order to file the appeal electronically. Completing the full electronic appeal application requires claimants to answer questions from both the standard appeal request form and the disability report form. However, iAppeals offers several flexibilities for claimants: Permitting claimants to leave questions blank if they are not applicable; allowing claimants to indicate that they need additional time to collect specific evidence; and enabling claimants to partially complete an electronic appeal application, save it, and return to finish it later, so long as they return and submit the appeal within the regulatory appeal period. Claimants must file their appeals, whether using the paper or the electronic administrative appeals process, within the 60-day appeal period.[15]

To ensure that claimants understand the requirements for using the electronic appeal procedures to request reconsideration or a hearing, we have

[8] Social Security Ruling (SSR) 96–10p ''Policy Interpretation Ruling Electronic Service Delivery,'' explains that our electronic service delivery initiatives allow the public to conduct their business in ways that are convenient for them and efficient for both them and us.

[9] Claimants may request Appeals Council (AC) review of administrative hearing decisions by using the HA–520 ''Request for Review of Hearing Decision/Order,'' the electronic i520, or a separate written request filed at one of our offices or by mail. The differences explained in this SSR are between the paper and electronic requests for reconsideration or a hearing and do not apply to the paper and electronic requests for review by the AC because we do not need the same type of information when processing requests for review by the AC.

[10] 42 U.S.C. 405(b)(1) and 1383(c)(1).

[11] 20 CFR 404.909, 404.933, 416.1409, 416.1433.

[12] ''[T]echnologies allow the transfer of information by other than traditional paper-based methods. SSA is adopting a definition of writing which is consistent with modern legal usage and includes electronic information transfer.'' SSR 96–10p.

[13] POMS DI 12005.005—Processing a Reconsideration Request for a Medically Denied Initial Disability Claim; DI 12010.001—Request for Administrative Law Judge (ALJ) Hearing; DI 12010.005—Development of Administrative Law Judge (ALJ) Hearing Cases.

[14] Appointed representatives, as well as family and friends, are permitted to use iAppeals to file appeals on behalf of a claimant. An appointed representative seeking direct payment of his or her fee for services performed on the claim has an affirmative duty to use iAppeals. See 20 CFR 404.1713, 404.1740, 416.1513, 416.1740; 77 FR 4653; POMS *GN 03970.010*B.4. This affirmative duty is only for the appointed representative, not the claimant.

[15] Claimants must complete and submit their appeals within 60 days of receiving the notice of determination they are appealing. Claimants who do not submit their appeals within the applicable 60-day period may request an extension of time. See 20 CFR 404.909, 404.911, 404.933, 416.1409, 416.1411, 416.1433. Claimants may request an extension of time on paper or using iAppeals. If a claimant files an untimely appeal via paper or using iAppeals, but does not provide reasons for why the appeal is untimely, we will request a good cause statement before determining whether to process or dismiss the appeal. See POMS GN 03101.010A.2, GN 03101.020, SI 04005.012B, SI 04005.015.

included the following aids in the iAppeals screen path to assists them:

• Terms of Service (TOS) Screen—The TOS provides information about the types of appeals that claimants can file in iAppeals, information needed to complete an electronic appeal, and the alternative option to file an appeal request by mail or in-person at the local Social Security Office. The Acknowledgement portion of the TOS requires the claimant or a third party on the claimant's behalf to acknowledge that he or she understands certain information, including:

○ The electronic appeal must be completed and filed within the 60-day appeal period.

○ The ''Submit'' button within the ''Submit'' Tab must be selected to file the appeal request with the Social Security Administration.

○ How to submit evidence, both before and after the appeal is filed.

○ When he or she can and cannot re-enter the iAppeals application.

○ How to ensure that the electronic appeal is properly submitted.

○ How to add additional information or change information that has already been submitted.

• Re-entry Number Screen—Claimants who choose not to complete their electronic appeals in one session can use the re-entry number we provide to return to iAppeals to complete and submit their appeals in subsequent sessions. The re-entry number screen explains that the appeal has not been completed or submitted and that claimants who choose to exit iAppeals before completion must return to iAppeals in order to complete and submit their appeals electronically.

• Submit Tab: Claimants will see the Submit Tab throughout the electronic appeal application path. The Submit Tab remains available to select until claimants complete and submit their electronic appeal. The Submit Tab will not be available once the electronic appeal is submitted.

Conclusion

iAppeals is an efficient and convenient self-service option that allows claimants who are dissatisfied with our determination to electronically complete and submit a request for reconsideration or a hearing. The paper-based administrative appeals process remains available for claimants who wish to use it. While the use of iAppeals promotes our ability to process cases faster, it is the claimant's choice whether to use the paper or electronic administrative appeals process. Claimants can obtain more information about iAppeals and our paper appeal process by visiting our website *www.ssa.gov.* Claimants can find information about the iAppeals user experience in our Program Operations Manual System at *https://secure.ssa.gov/apps10/poms.nsf/lnx/0203101125.*

[FR Doc. 2019–17359 Filed 8–13–19; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Delegation of Authority No. 475]

Delegation of Section 108A MECEA Approval Authority to the Assistant Secretary for Educational and Cultural Affairs

By virtue of the authority vested in the Under Secretary for Public Diplomacy and Public Affairs pursuant to Delegation of Authority No. 234 (October 1, 1999) and delegated to me pursuant to Delegation of Authority No. 461–1 (February 5, 2019), and to the extent permitted by law, I hereby delegate to the Assistant Secretary of State for Educational and Cultural Affairs the authority in Section 108A of the Mutual Educational and Cultural Exchange Act of 1961 (MECEA) (22 U.S.C. 2458a) relating to the approval of foreign government-funded cultural exchange programs.

The Secretary, the Deputy Secretary, or I (pursuant to Delegation of Authority 461–1) may at any time exercise the authority delegated herein.

This Delegation of Authority does not revoke or otherwise affect any other delegation of authority currently in effect.

Any reference in this Delegation of Authority to any statute or delegation of authority shall be deemed to be a reference to such statute or delegation of authority as amended from time to time.

This Delegation of Authority shall be published in the **Federal Register**.

Dated: August 1, 2019.

Michelle Giuda,

Assistant Secretary for Public Affairs, U.S. Department of State.

[FR Doc. 2019–17470 Filed 8–13–19; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 303 (Sub-No. 51X)]

Wisconsin Central Ltd.—Discontinuance of Service Exemption—in Trempealeau and Buffalo Counties, Wis.

Wisconsin Central Ltd. (WCL) has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue common carrier service over approximately 16.9 miles of rail line between milepost 195.0 near Arcadia in Trempealeau County, Wis., and milepost 211.9 at East Winona in Buffalo County, Wis. (the Line). The Line traverses U.S. Postal Service Zip Codes 54612, 54630, 54661, and 54629.

WCL has certified that: (1) No local traffic has moved over the Line for at least two years; (2) overhead traffic (to the extent any exists) can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) [1] to subsidize continued rail service has been received, this exemption will be effective on September 13, 2019, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues must be filed by August 23, 2019, and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2) [2] must be filed by August 26, 2019.[3] Petitions for reconsideration

[1] Persons interested in submitting an OFA to subsidize continued rail service must first file a formal expression of intent to file an offer, indicating the intent to file an OFA for subsidy and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The filing fee for OFAs can be found at 49 CFR 1002.2(f)(25).

[3] Because this is a discontinuance proceeding and not an abandonment, trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require environmental review.

must be filed by September 3, 2019, with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to WCL's representative, Bradon J. Smith, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available at *www.stb.gov.*

Decided: August 8, 2019.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–17437 Filed 8–13–19; 8:45 am]

BILLING CODE 4915–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2019–0011]

Request for Comments and Notice of Public Hearing Concerning Russia's Implementation of Its WTO Commitments

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments and notice of public hearing.

SUMMARY: The interagency Trade Policy Staff Committee (TPSC) will convene a public hearing and seek public comment to assist the Office of the United States Trade Representative (USTR) in the preparation of its annual report to Congress on Russia's implementation of its obligations as a Member of the World Trade Organization (WTO).

DATES: September 27, 2019 at midnight EST: Deadline for submission of written comments and for filing requests to appear and a summary of expected testimony at the public hearing. October 8, 2019: The TPSC will convene a public hearing in Rooms 1 & 2, 1724 F Street NW, Washington DC 20508 beginning at 9:30 a.m.

ADDRESSES: USTR strongly prefers electronic submissions made through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments in section III below. The docket number is USTR–2019–0011. For alternatives to online submissions, please contact Yvonne Jamison at (202) 395–3475 before transmitting a comment and in advance of the relevant deadline.

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning written comments, contact Yvonne Jamison at (202) 395–3475. Direct all other questions to Betsy Hafner, Deputy Assistant United States Trade Representative for Russia and Eurasia, at (202) 395–9124.

SUPPLEMENTARY INFORMATION:

I. Background

Russia became a Member of the WTO on August 22, 2012, and on December 21, 2012, following the termination of the application of the Jackson-Vanik amendment to Russia and the extension of permanent normal trade relations to the products of Russia, the United States and Russia both filed letters with the WTO withdrawing their notices of non-application and consenting to have the WTO Agreement apply between them. In accordance with Section 201(a) of the Russia and Moldova Jackson-Vanik Repeal and Sergei Magnitsky Rule of Law Accountability Act of 2012 (Pub. L. 112–208), USTR is required to submit annually a report to Congress on the extent to which Russia is implementing the WTO Agreement, including the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Trade Related Aspects of Intellectual Property Rights. The report also must assess Russia's progress on acceding to and implementing the Information Technology Agreement (ITA) and the Government Procurement Agreement (GPA). In addition, to the extent that USTR finds that Russia is not implementing fully any WTO agreement or is not making adequate progress in acceding to the ITA or the GPA, USTR must describe in the report the actions it plans to take to encourage Russia to improve its implementation and/or increase its accession efforts. In accordance with Section 201(a), and to assist it in preparing this year's report, the TPSC is soliciting public comment.

The terms of Russia's accession to the WTO are contained in the Marrakesh Agreement Establishing the World Trade Organization and the Protocol on the Accession of the Russian Federation to the WTO (including its annexes) (Protocol). The Report of the Working Party on the Accession of the Russian Federation (Working Party Report) provides detail and context to the commitments listed in the Protocol. You can find the Protocol and Working Party Report on USTR's website at *https://ustr.gov/node/5887* or on the WTO website at *http://docsonline.wto.org* (document symbols: WT/ACC/RUS/70, WT/MIN(11)/2, WT/MIN(11)/24, WT/L/839, WT/ACC/RUS/70/Add.1, WT/MIN(11)/2/Add.1, WT/ACC/RUS/70/Add.2, and WT/MIN(11)/2/Add.1.)

II. Public Comment and Hearing

USTR invites written comments and/or oral testimony of interested persons on Russia's implementation of the commitments made in connection with its accession to the WTO, including, but not limited to, commitments in the following areas:

a. Import regulation (*e.g.,* tariffs, tariff-rate quotas, quotas, import licenses).
b. Export regulation.
c. Subsidies.
d. Standards and technical regulations.
e. Sanitary and phytosanitary measures.
f. Trade-related investment measures (including local content requirements).
g. Taxes and charges levied on imports and exports.
h. Other internal policies affecting trade.
i. Intellectual property rights (including intellectual property rights enforcement).
j. Services.
k. Government procurement.
l. Rule of law issues (*e.g.,* transparency, judicial review, uniform administration of laws and regulations).
m. Other WTO commitments.

USTR must receive your written comments no later than Friday, September 27, 2019 at midnight EST.

The TPSC will convene a public hearing on Tuesday, October 8, 2019, in Rooms 1 & 2, 1724 F Street NW, Washington DC 20508. Persons wishing to testify at the hearing must provide written notification of their intention no later than September 27, 2019 at midnight EST. The intent to testify notification must be made in the ''Type Comment'' field under docket number USTR–2019–0011 on the *www.regulations.gov* website and should include the name, address, and telephone number of the person presenting the testimony. You should attach a summary of the testimony by using the ''Upload File'' field. The name of the file also should include who will be presenting the testimony. Remarks at the hearing will be limited to no more than five minutes to allow for possible questions from the TPSC.

III. Requirements for Submissions

Persons submitting a notification of intent to testify and/or written comments must do so in English and must identify (on the first page of the submission) ''Russia's WTO Implementation of its WTO Commitments.'' The deadline for

submission is Friday, September 27, 2019 at midnight EST. In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *www.regulations.gov* website. To submit comments via *www.regulations.gov,* enter docket number USTR–2019–0011 on the home page and click ''search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled ''comment now!''. For further information on using the *www.regulations.gov* website, please consult the resources provided on the website by clicking on ''How to Use Regulations.gov'' on the bottom of the home page.

The *www.regulations.gov* website allows users to provide comments by filling in a ''type comment'' field, or by attaching a document using an ''upload file'' field. USTR prefers that you provide comments in an attached document. If a document is attached, it is sufficient to type ''see attached'' in the ''type comment'' field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the ''type comment'' field.

Filers submitting comments containing no business confidential information should name their file using the name of the person or entity submitting the comments. For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC''. Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. Filers of submissions containing business confidential information also must submit a public version of their comments. The file name of the public version should begin with the character ''P''. The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments. Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

As noted, USTR strongly urges that you file submissions through *www.regulations.gov.* You must make any alternative arrangements with Yvonne Jamison at (202) 395–3475 before transmitting a comment and in advance of the relevant deadline.

We will post comments in the docket for public inspection, except business confidential information. You can view comments on the *https://www.regulations.gov* website by entering docket number USTR–2019–0011 in the search field on the home page. General information concerning USTR is available at *www.ustr.gov.*

Edward Gresser,

Chair of the Trade Policy Staff Committee, Office of the United States Trade Representative.

[FR Doc. 2019–17393 Filed 8–13–19; 8:45 am]

BILLING CODE 3290–F9–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2019–0010]

Request for Comments and Notice of Public Hearing Concerning China's Compliance With WTO Commitments

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of public hearing and request for comments.

SUMMARY: The interagency Trade Policy Staff Committee (TPSC) invites interested persons to submit written comments and participate in a public hearing to assist the Office of the United States Trade Representative (USTR) in the preparation of its annual report to the Congress on China's compliance with the commitments made in connection with its accession to the World Trade Organization (WTO).

DATES: September 18, 2019 at midnight EDT: Deadline for submission of comments, and requests to appear and summaries of testimony at the October 2, 2019 public hearing. October 2, 2019: The TPSC will convene a public hearing in Rooms 1 and 2, 1724 F Street NW, Washington DC 20508, beginning at 9:30 a.m.

ADDRESSES: USTR strongly prefers electronic submissions made through the Federal eRulemaking Portal: *http://www.regulations.gov.* The instructions for submitting notification of intent to testify and/or written comments are in sections 3 and 4 below. The docket number is USTR–2019–0010. For alternatives to on-line submissions, contact Yvonne Jamison at (202) 395–3475 before transmitting a comment and in advance of the relevant deadline.

FOR FURTHER INFORMATION CONTACT: Yvonne Jamison at (202) 395–3475 for procedural questions concerning written comments or participation in the public hearing. Direct all other questions to Terrence J. McCartin, Acting Assistant United States Trade Representative for China Affairs, at (202) 395–3900, or Philip D. Chen, Chief Counsel for China Enforcement, at (202) 395–3150.

SUPPLEMENTARY INFORMATION:

1. Background

China became a Member of the WTO on December 11, 2001. In accordance with section 421 of the U.S.-China Relations Act of 2000 (Pub L. 106–286), USTR is required to submit, by December 11 of each year, a report to Congress on China's compliance with commitments made in connection with its accession to the WTO, including both multilateral commitments and any bilateral commitments made to the United States. In accordance with section 421, and to assist it in preparing this year's report, the TPSC is soliciting public comments. You can find last year's report on USTR's website at *https://ustr.gov/sites/default/files/2018-USTR-Report-to-Congress-on-China%27s-WTO-Compliance.pdf.*

The terms of China's accession to the WTO are contained in the Protocol on the Accession of the People's Republic of China (including its annexes) (Protocol), the Report of the Working Party on the Accession of China (Working Party Report), and the WTO agreements. You can find the Protocol and Working Party Report on the WTO website at *http://docsonline.wto.org* (document symbols: WT/L/432, WT/MIN(01)/3, WT/MIN(01)/3/Add.1, WT/MIN(01)/3/Add.2).

2. Topics on Which the TPSC Seeks Information

The TPSC invites written comments and/or oral testimony of interested persons on China's compliance with commitments made in connection with its accession to the WTO, including, but not limited to, commitments in the following areas:

A. Trading rights.

B. Import regulation (*e.g.,* tariffs, tariff-rate quotas, quotas, import licenses).

C. Export regulation.

D. Internal policies affecting trade (*e.g.,* subsidies, standards and technical regulations, sanitary and phytosanitary measures, government procurement, trade-related investment measures, taxes and charges levied on imports and exports).

E. Intellectual property rights (including intellectual property rights enforcement).

F. Services.

G. Rule of law issues (*e.g.,* transparency, judicial review, uniform administration of laws and regulations) and status of legal reform.

H. Other WTO commitments.

In addition, given the United States' view that China should be held accountable as a full participant in, and beneficiary of, the international trading system, USTR requests that interested persons specifically identify unresolved compliance issues that warrant review and evaluation by USTR's China Enforcement Task Force.

3. Notice of Public Hearing

The TPSC will hold a hearing on October 2, 2019, beginning at 9:30 a.m., to receive information regarding China's compliance with WTO commitments. The hearing will be held in Rooms 1 and 2, 1724 F Street NW, Washington, DC 20508, and will be open to the public and to the press. A transcript of the hearing will be available on *www.regulations.gov* within approximately two weeks after the date of the hearing. All interested parties wishing to make an oral presentation at the hearing must submit, following the Requirements for Submissions below, the name, address, telephone number, and email address, if available, of the witness(es) representing their organization no later than midnight on September 18, 2019. Requests to present oral testimony must be accompanied by a written summary of the proposed testimony, in English. The TPSC will limit oral testimony to five-minute presentations that summarize or supplement information contained in briefs or statements submitted for the record to allow for possible questions from the TPSC.

4. Requirements for Submissions

In order to be assured of consideration, we must receive your notification of intent to testify and/or written comments in English by 11:59 p.m. on September 18, 2019. USTR strongly encourages commenters to make on-line submissions, using *www.regulations.gov.* On the first page, please identify the submission as ''China's WTO Compliance.''

To submit comments via *www.regulations.gov,* enter docket number USTR–2019–0010 on the home page and click ''search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled ''comment now!''. For further information on using the *www.regulations.gov* website, please consult the resources provided on the website by clicking on ''How to Use Regulations.gov'' on the bottom of the home page. USTR will not accept hand-delivered submissions.

The *www.regulations.gov* website allows users to submit comments by filling in a ''type comment'' field or by attaching a document using an ''upload file'' field. USTR prefers that you submit comments in an attached document. If you attach a document, it is sufficient to type ''see attached'' in the ''type comment'' field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If you use an application other than those two, please indicate the name of the application in the ''type comment'' field.

Filers submitting comments containing no business confidential information should name their file using the name of the person or entity submitting the comments. For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC''. Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. Filers of submissions containing business confidential information also must submit a public version of their comments that we will place in the docket for public inspection. The file name of the public version should begin with the character ''P''. The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

As noted, USTR strongly urges you to file submissions through *www.regulations.gov.* You must make any alternative arrangements with Yvonne Jamison at (202) 395–3475 before transmitting a comment and in advance of the relevant deadline.

USTR will post comments in the docket for public inspection, except business confidential information. You can view comments on the *https://www.regulations.gov* website by entering docket number USTR–2019–0010 in the search field on the home page. General information concerning USTR is available at *www.ustr.gov.*

Edward Gresser,

Chair of the Trade Policy Staff Committee, Office of the United States Trade Representative.

[FR Doc. 2019–17392 Filed 8–13–19; 8:45 am]

BILLING CODE 3290–F9–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. FAA–2019–40]

Petition for Exemption; Summary of Petition Received; Aurora Flight Sciences

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 3, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0172 using any of the following methods:

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal

information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy*.

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Linda Lane (202) 267–7280, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 7, 2019.

Brandon Roberts,

Acting Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–0172.
Petitioner: Aurora Flight Sciences.
Section(s) of 14 CFR Affected: § 133.19 (a)(1) and (3).
Description of Relief Sought: Aurora Flight Sciences (Aurora) is seeking relief from § 133.19 (a)(1) and (3) to allow Aurora to apply for an External Load Operators Certificate under 14 CFR § 133.17 utilizing Aurora's Bell UH–1H helicopter operating under a Special Airworthiness Certificate in the Experimental Category, for the purposes of research and development, crew training, and market survey.

[FR Doc. 2019–17367 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2019–33]

Petition for Exemption; Summary of Petition Received; Textron Aviation, Inc.

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 3, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0357 using any of the following methods:

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Linda Lane (202) 267–7280, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 7, 2019.

Brandon Roberts

Acting Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–0357.
Petitioner: Textron Aviation, Inc.
Section(s) of 14 CFR Affected: 21.17(d)(2) at Amendment 21–100.
Description of Relief Sought: Textron Aviation, Inc. (Textron) is requesting relief from § 21.17(d)(2) of Title 14, Code of Federal Regulations (14 CFR) to allow Textron to file for an extension of the original application for Type Certification for Model 220 (Denali) without having to meet the newer standards in part 23.

[FR Doc. 2019–17366 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent of Waiver With Respect to Land; Indianapolis International Airport, Indianapolis, Indiana

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA is considering a proposal to change 69.784 acres of airport land from aeronautical use to non-aeronautical use and to authorize the sale of airport property located at Indianapolis International Airport, Indianapolis, Indiana. The aforementioned land is not needed for aeronautical use.

The land consists of 6 original airport acquired parcels. The parcels were acquired under grants 3–18–0038–017 and local funding.

There are no impacts to the airport by allowing the Indianapolis Airport Authority to dispose of the property. The land is not needed for future aeronautical development.

DATES: Comments must be received on or before September 13, 2019.

ADDRESSES: Documents are available for review by appointment at the FAA Chicago Airports District Office, Melanie Myers, Program Manager, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7525/Fax: (847) 294–7046 and Eric Anderson, Director of Properties, Indianapolis Airport Authority, 7800 Col. H. Weir Cook Memorial Drive, Indianapolis, IN 46241. Telephone: 317–487–5135.

Written comments on the Sponsor's request must be delivered or mailed to:

Melanie Myers, Program Manager, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7525/Fax: (847) 294–7046.

FOR FURTHER INFORMATION CONTACT: Melanie Myers, Program Manager, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7525/Fax: (847) 294–7046.

SUPPLEMENTARY INFORMATION: In accordance with section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

The disposition of proceeds from the sale of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999 (64 FR 7696).

This notice announces that the FAA is considering the release of the subject airport property at the Indianapolis International Airport, Indianapolis, Indiana from federal land covenants, subject to a reservation for continuing right of flight as well as restrictions on the released property as required in FAA Order 5190.6B section 22.16. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA.

Land Description

Part of the West Half of the Southeast Quarter of Section 32, Township 15 North, Range 2 East, Hendricks County, Indiana, more particularly described as follows:

Commencing at the Northwest corner of said Southeast Quarter Section; thence North 89 degrees 13 minutes 54 seconds East along the North line thereof 212.67 feet to the northeast corner of a land parcel deeded to the State of Indiana for Ronald Reagan Parkway right of way, recorded as Instrument Number 201705758 in the Office of the Hendricks County Recorder, being the Point of Beginning; thence continuing North 89 degrees 13 minutes 54 seconds East along said North line 1,117.32 feet to the Northeast corner of the West Half of said Half Quarter Section; thence South 00 degrees 13 minutes 31 seconds East along the East line of said Half Section 1,326.57 feet to the Southeast corner of the Northwest Quarter of the Southeast Quarter of said Section; thence South 74 degrees 57 minutes 24 seconds West 318.38 feet; thence South 13 degrees 10 minutes 24 seconds West 355.81 feet; thence South 00 degrees 21 minutes 40 seconds East 901.46 feet to the South line of said Quarter section; thence South 89 degrees 25 minutes 13 seconds West along said South line 465.32 feet to the east line of the aforementioned right of way of Ronald Reagan Parkway per Instrument number 201705758, the remaining (8) courses being along the east lines of said right of way;

(1) Thence North 44 degrees 40 minutes 57 seconds West 112.26 feet;

(2) Thence North 26 degrees 22 minutes 15 seconds West 275.75 feet:

(3) Thence North 15 degrees 51 minutes 10 seconds West 275.75 feet:

(4) Thence North 00 degrees 50 minutes 28 seconds West 475.42 feet:

(5) Thence North 03 degrees 48 minutes 39 seconds West 500.89 feet:

(6) Thence North 00 degrees 22 minutes 38 seconds West 1,000.00 feet:

(7) Thence North 42 degrees 19 minutes 52 seconds East 73.75 feet;

(8) Thence North 00 degrees 46 minutes 06 seconds West 25.00 feet to the Point of Beginning.

Containing 57.255 acres, more or less.

Right-of-Way

A part of the Southeast Quarter of Section 32, Township 15 North, Range 3 East, Hendricks County, Indiana, and being that part of the grantor's land lying within the right-of-way depicted on the attached Right-of-Way Parcel Plat, marked EXHIBIT ''B'' described as follows: Beginning at the northwest corner of said quarter section designated as point ''S'' on said plat; thence North 89 degrees 39 minutes 05 seconds East 64.821 meters (212.67 feet) along the north line of said quarter section to point ''766'' on said plat; thence South 0 degrees 20 minutes 55 seconds East 7.620 meters (25.00 feet) to the south boundary of Stafford Road to point ''759'' on said plat; thence South 42 degrees 45 minutes 03 seconds West 22.480 meters (73.75 feet) to point ''751'' on said plat; thence South 0 degrees 02 minutes 33 seconds West 304.00 meters (1,000 feet) to point ''752'' on said plat; thence South 0 degrees 25 minutes 17 seconds East 144.907 meters (475.42 feet) to point ''754'' on said plat; thence South 15 degrees 25 minutes 59 seconds East 84.048 meters (275.75 feet) to point ''755'' on said plat; thence South 25 degrees 57 minutes 04 seconds East 84.048 meters (275.75 feet) to point ''756'' on said plat; thence South 44 degrees 15 minutes 46 seconds East 35.232 meters (115.59 feet) to the south line of said quarter section to point ''760'' on said plat; thence North 89 degrees 52 minutes 22 seconds West 106.941 meters (350.86 feet) along said south line to point ''732'' on said plat; thence North 21 degrees 29 minutes 47 seconds West 11.044 meters (36.23 feet) to the west of said quarter section to point ''743'' on said plat; thence North 0 degrees 09 minutes 39 seconds East 728.743 meters (2,384.33 feet) along said west line to the point of beginning.

Issued in Des Plaines, Illinois, on July 31, 2019.

Jose DeLeon,

Acting Manager, Chicago Airports District Office, FAA, Great Lakes Region.

[FR Doc. 2019–17372 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent of Waiver With Respect to Land; Indianapolis International Airport, Indianapolis, Indiana

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA is considering a proposal to change 8.712 acres of airport land from aeronautical use to non-aeronautical use and to authorize the sale of airport property located at Indianapolis International Airport, Indianapolis, Indiana. The aforementioned land is not needed for aeronautical use.

The land consists of 6 original airport acquired parcels. The parcels were acquired under grants 3–18–0038–032, 3–18–0038–067, 3–18–0038–083, 3–18–0038–094, and 3–18–0038–098 and local funding.

There are no impacts to the airport by allowing the Indianapolis Airport Authority to dispose of the property. The land is not needed for future aeronautical development.

DATES: Comments must be received on or before September 13, 2019.

ADDRESSES: Documents are available for review by appointment at the FAA Chicago Airports District Office, Melanie Myers, Program Manager, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7525/Fax: (847) 294–7046 and Eric Anderson, Director of Properties, Indianapolis Airport Authority, 7800 Col. H. Weir Cook Memorial Drive, Indianapolis, IN 46241 Telephone: 317–487–5135.

Written comments on the Sponsor's request must be delivered or mailed to: Melanie Myers, Program Manager, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7525/Fax: (847) 294–7046.

FOR FURTHER INFORMATION CONTACT: Melanie Myers, Program Manager, Federal Aviation Administration, Chicago Airports District Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–7525/Fax: (847) 294–7046.

SUPPLEMENTARY INFORMATION: In accordance with section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

The disposition of proceeds from the sale of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999 (64 FR 7696).

This notice announces that the FAA is considering the release of the subject airport property at the Indianapolis International Airport, Indianapolis, Indiana from federal land covenants, subject to a reservation for continuing right of flight as well as restrictions on the released property as required in FAA Order 5190.6B section 22.16. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA.

Land Description

Instrument No. 1997–0055620

A portion of the West Half of the Northeast Quarter of Section 21, Township 15 North, Range 2 East, in Marion County, Indiana, and said portion being more particularly described as follows:

Beginning at the intersection of the center line of the National road with the East line of said Half-Quarter Section to a point 372 feet South of the Northeast corner of said Half-Quarter Section; and running thence South with the East line of said Half-Quarter Section 574.2 feet to the North line of the Right-of-Way of the Vandalia railroad; thence Southwesterly with the North line of said Right-of-way 320.3 feet; thence North 21 degrees West 515 feet to the center of the National Road at a point 523 feet from the Beginning; and thence North 69 degrees East in the center of said National Road 523 feet to the Place of Beginning.

Instrument No. 1997–0134267

A part of the East Half of the Northeast Quarter of Section 21, Township 15 North, Range 2 East, Marion County, Indiana, being described as follows:

Commencing at an iron pin which marks the accepted Northwest corner of the above captioned Northeast Quarter; thence North 88 degrees 40 minutes 08 seconds East (assumed bearing) with the North line of said Northeast Quarter 1338.46 feet to the midpoint of the North line of the Northeast Quarter, said point also being the Northwest corner of the East Half of the Northeast Quarter; thence South 00 degrees 00 minutes 01 seconds West with the West line of the East Half of the Northeast Quarter 387.78 feet to a PK nail on the centerline of Washington Street (U.S. 40) and the point of beginning of the parcel herein described; thence continuing South 00 degrees 00 minutes 01 seconds West 563.67 feet to an iron pin (Schneider Engr.) found in place on the North line of the former Vandalia Railroad right-of-way, now the property of the Indianapolis Airport Authority; thence with said North right-of-way line North 72 degrees 43 minutes 49 seconds East 212.07 feet (formerly described as 199.7 feet) to an iron pin on the West line of Lot No. 310 of A.V. Brown's Fourth Section of Western Heights Subdivision as recorded in Plat Book 21, page 135; thence North 00 degrees 57 minutes 35 seconds West, with the West line of said Brown's subdivision, 297.65 feet to an iron pin; thence South 87 degrees 47 minutes 39 seconds West 111.77 feet to an iron pin; thence North 00 degrees 00 minutes 01 seconds East 41.98 feet to an iron pin; thence North 05 degrees 17 minutes 31 seconds West 192.68 feet to a PK nail on the center line of Washington Street (U.S. 40); thence with said center line South 68 degrees 34 minutes 32 seconds West 73.13 feet to the point of beginning.

Instrument No. 1997–0087189

A part of the East Half of the Northeast Quarter of Section 21, Township 15 North, Range 2 East, Marion County, Indiana, being described as follows:

Commencing at an iron pin which marks the accepted Northwest corner of the above captioned Northeast Quarter; thence North 88 degrees 40 minutes 08 seconds East (assumed bearing) with the North line of said Northeast Quarter 1338.46 feet to the midpoint of the North line of the Northeast Quarter said point also being the Northwest corner of the East Half of the Northeast Quarter; thence South no degrees no minutes 01 seconds West with the West lien of the East Half of the Northeast Quarter 387.78 feet to a PK nail on the center line of Washington Street (U.S. 40); thence with said center line North 68 degrees 34 minutes 32 seconds East 73.13 feet to a PK nail and the Point of Beginning of the parcel herein described; thence South 05 degrees 17 minutes 31 seconds East 192.68 feet to an iron pin; thence South no degrees no minutes 01 seconds West 41.98 feet to an iron pin on the West line of Lot No. 310 of A.V. Brown's Fourth Section of Western Heights Subdivision as recorded in Plat 21, Page 135; thence North no degrees 57 minutes 35 seconds West 278.54 feet to a PK nail on the center line of Washington Street (U.S. 40); thence with said center line South 68 degrees 34 minutes 32 seconds West 134.06 feet to the Point of Beginning.

Instrument No. 920156761

Lot number Three Hundred Ten (310) in Arthur V. Brown's Fourth Section Western Heights, an Addition to the City of Indianapolis, the plat of which is recorded in Plat Book 21, page 135, in the Office of the Recorder of Marion County, Indiana except a strip of ground of the uniform width of Fifteen and Seven-tenths (15.7) feet taken by parallel lines off of the entire South side thereof.

Instrument No. 2005–0162883

Lot Number 309 in Arthur V. Brown's Fourth Section Western Heights, an addition to the City of Indianapolis, the plat of which is recorded in Plat Book 21, Page 135, in the office of the Recorder of Marion County, Indiana, *except* the part conveyed to the Pittsburgh, Cincinnati, Chicago and St. Louis Railroad Company in Land Record 82, Page 197.

Excepting therefrom that part of the described real estate conveyed to the State of Indiana by deed dated February 15, 2000 and recorded in Volume 2000–00067326.

Issued in Des Plaines, Illinois on July 31, 2019.

Jose DeLeon,

Acting Manager, Chicago Airports District Office, FAA, Great Lakes Region.

[FR Doc. 2019–17373 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Limitation on Claims Against Proposed Public Transportation Projects

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: This notice announces final environmental actions taken by the Federal Transit Administration (FTA) for the Transbay Joint Powers Authority Transbay Terminal/Caltrain Downtown Extension/Redevelopment Project. The purpose of this notice is to announce publicly the environmental decisions by FTA on the subject project and to activate the limitation on any claims that may challenge these final environmental actions.

DATES: By this notice, FTA is advising the public of final agency actions subject to 23 U.S.C. 139(l). A claim seeking judicial review of FTA actions announced herein for the listed public transportation project will be barred unless the claim is filed on or before January 13, 2020.

FOR FURTHER INFORMATION CONTACT: Nancy-Ellen Zusman, Assistant Chief Counsel, Office of Chief Counsel, (312) 353–2577 or Juliet Bochicchio, Environmental Protection Specialist, Office of Environmental Programs, (202) 366–9348. FTA is located at 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 9:00 a.m. to 5:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FTA has taken final agency actions by issuing certain approvals for the public transportation project listed below. The actions on the project, as well as the laws under which such actions were taken, are described in the documentation issued in connection with the project to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA environmental project file for the project. Interested parties may contact either the project sponsor or the relevant FTA Regional Office for more information. Contact information for FTA's Regional Offices may be found at *https://www.fta.dot.gov.*

This notice applies to all FTA decisions on the listed project as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to, NEPA [42 U.S.C. 4321–4375], Section 4(f) requirements [23 U.S.C. 138, 49 U.S.C. 303], Section 106 of the National Historic Preservation Act [54 U.S.C. 306108], and the Clean Air Act [42 U.S.C. 7401–7671q]. This notice does not, however, alter or extend the limitation period for challenges of project decisions subject to previous notices published in the **Federal Register**. The project and actions that are the subject of this notice follow: *Project name and location:* The Transbay Joint Powers Authority Transbay Terminal/Caltrain Downtown Extension/Redevelopment Project, in San Francisco, California. *Project Sponsor:* The Transbay Joint Powers Authority. *Project description:* The Transbay Terminal/Caltrain Downtown Extension/Redevelopment Project, also known as the Transbay Program, as adopted in 2004, includes the Downtown Rail Extension (DTX), the establishment of a redevelopment area plan, and the construction of the Transit Center on the site of the former Transbay Terminal at First and Mission Streets, which was demolished in 2011. The purpose of the Transbay Program is to improve public access to bus and rail services, modernize the Transbay Terminal and improve service, reduce non-transit vehicle usage, alleviate blight, and revitalize the Transbay Terminal area. The proposed project is to design, construct, and operate the downtown rail extension, redevelopment area plan and transit center along with the specified refinements to the previously approved Phase 2 of the Transbay Program and other transportation improvements within the City and County of San Francisco. The decisions and determinations made in the 2005 Record of Decision (ROD) remain unaltered, except as expressly altered by this amended ROD.

Final agency action: The Transbay Joint Powers Authority Transbay Terminal/Caltrain Downtown Extension/Redevelopment Project Amended Record of Decision, dated July 22, 2019. *Supporting Documentation:* FTA's Transbay Program Final Environmental Impact Statement/Environmental Impact Report, April 2004; FTA's Transbay Program Record of Decision, February 2005; FTA's Transbay Terminal/Caltrain Downtown Extension/Redevelopment Project Draft Supplemental Environmental Impact Statement/Environmental Impact Report (SEIS/EIR), December 2015; FTA's Transbay Terminal/Caltrain Downtown Extension/Redevelopment Project Final SEIS/EIR, November 2018.

Authority: 23 U.S.C. 139(l)(1).

Felicia L. James,

Associate Administrator for Planning and Environment.

[FR Doc. 2019–17412 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0093]

Deepwater Port License Application: Texas GulfLink LLC; Extension of Scoping Period

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of extension of the public scoping comment period.

SUMMARY: By **Federal Register** notice of Wednesday, July 3, 2019, titled *Deepwater Port License Application: Texas Gulflink LLC,* the U.S. Coast Guard (USCG), in coordination with the Maritime Administration (MARAD), announced the intent to prepare an environmental impact statement (EIS) as part of the environmental review of the Texas GulfLink LLC (Texas GulfLink) deepwater port license application. Publication of that notice began a 30-day scoping process, announced the date and location of a public scoping meeting as well as requested public participation to assist in the identification and determination of the environmental issues to be addressed in the EIS.

During the Texas GulfLink public scoping meeting held in Lake Jackson, Texas on Wednesday, July 17, 2019, USCG and MARAD advised that the public scoping period would be extended. This extension is due to delays in getting the application properly posted on the docket. This **Federal Register** Notice announces the date of the extended scoping period.

DATES: Comments or related material on the Texas GulfLink deepwater port license application must be received by August 30, 2019.

ADDRESSES: The public docket for the Texas GulfLink deepwater port license application is maintained by the U.S. Department of Transportation, Docket Management Facility, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The license application is available for viewing at the *Regulations.gov* website: *http://www.regulations.gov* under docket number MARAD–2019–0093.

We encourage you to submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* If you submit your comments electronically, it is not necessary to also submit a hard copy. If you cannot submit material using *http://www.regulations.gov,* please contact either Mr. Patrick Clark, USCG or Yvette Fields, MARAD, as listed in the following **FOR FURTHER INFORMATION CONTACT** section of this document, which also provides alternate instructions for submitting written comments. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted. Anonymous comments will be accepted. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. The Federal Docket Management Facility's telephone number is 202–366–9317 or 202–366–9826, the fax number is 202–493–2251.

FOR FURTHER INFORMATION CONTACT: Mr. Patrick Clark, U.S. Coast Guard, telephone: 202–372–1358, email: *Patrick.W.Clark@uscg.mil* or Ms. Yvette Fields, Maritime Administration, telephone: 202–366–0926, email: *Yvette.Fields@dot.gov.* For questions regarding viewing the Docket, call Docket Operations, telephone: 202–366–9317 or 202–366–9826.

SUPPLEMENTARY INFORMATION:

Request for Comments

We request public comment on this proposal. The comments may relate to, but are not limited to, the environmental impact of the proposed action. All comments will be accepted. You may submit comments directly to the Federal Docket Management Facility during the public comment period (see **DATES**). We will consider all comments and material received during the extended scoping period.

The license application, comments and associated documentation, as well as the draft and final EISs (when published), are available for viewing at the Federal Docket Management System (FDMS) website: *http://www.regulations.gov* under docket number MARAD–2019–0093.

Public comment submissions should include:

- Docket number MARAD–2019–0093.
- Your name and address.

Submit comments or material using only one of the following methods:

- Electronically (preferred for processing) to the Federal Docket Management System (FDMS) website: *http://www.regulations.gov* under docket number MARAD–2019–0093.
- By mail to the Federal Docket Management Facility (MARAD–2019–0093), U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- By personal delivery to the room and address listed above between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.
- By fax to the Federal Docket Management Facility at 202–493–2251.

Faxed, mailed or hand delivered submissions must be unbound, no larger than 8½ by 11 inches and suitable for copying and electronic scanning. The format of electronic submissions should also be no larger than 8½ by 11 inches. If you mail your submission and want to know when it reaches the Federal Docket Management Facility, please include a stamped, self-addressed postcard or envelope.

Regardless of the method used for submitting comments, all submissions will be posted, without change, to the FDMS website (*http://www.regulations.gov*) and will include any personal information you provide. Therefore, submitting this information to the docket makes it public. You may wish to read the Privacy and Use Notice that is available on the FDMS website and the Department of Transportation Privacy Act Notice that appeared in the **Federal Register** on April 11, 2000 (65 FR 19477), see Privacy Act. You may view docket submissions at the Federal Docket Management Facility or electronically on the FDMS website.

Privacy Act

The electronic form of all comments received into the FDMS can be searched by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). The Department of Transportation Privacy Act Statement can be viewed in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, pages 19477–78) or by visiting *http://www.regulations.gov.*

Authority: 33 U.S.C. 1501, *et seq.,* 49 CFR 1.93(h).

Dated: August 6, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–17131 Filed 8–13–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, September 11, 2019.

FOR FURTHER INFORMATION CONTACT: Robert Rosalia at 1–888–912–1227 or (718) 834–2203.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Wednesday, September 11, 2019, at 2:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Robert Rosalia. For more information please contact Robert Rosalia at 1–888–912–1227 or (718) 834–2203, or write TAP Office, 2 Metrotech Center, 100 Myrtle Avenue, Brooklyn, NY 11201 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 9, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–17421 Filed 8–13–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting

public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, September 26, 2019.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Thursday, September 26, 2019, at 1:30 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: August 9, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–17423 Filed 8–13–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Line Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Line Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, September 11, 2019.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be held Wednesday, September 11, 2019, 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 9, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–17418 Filed 8–13–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, September 11, 2019.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or 202–317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be held Wednesday, September 11, 2019, at 11:00 a.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 9, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–17419 Filed 8–13–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Special Projects Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, September 12, 2019.

FOR FURTHER INFORMATION CONTACT: Fred Smith at 1–888–912–1227 or (202) 317–3087.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be held Thursday, September 12, 2019, at 11:00 a.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Fred Smith. For more information please contact Fred Smith at 1–888–912–1227 or (202) 317–3087, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.*

Dated: August 9, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–17422 Filed 8–13–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, September 10, 2019.

FOR FURTHER INFORMATION CONTACT: Carolyn Duckworth at 1–888–912–1227 or (336) 690–6217.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Taxpayer Communications Project Committee will be held Tuesday, September 10, 2019, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Carolyn Duckworth. For more information please contact Carolyn Duckworth at 1–888–912–1227 or (336) 690–6217, or write TAP Office, 1222 Spruce, St. Louis, MO 63103 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: August 9, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–17420 Filed 8–13–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, September 12, 2019.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Project Committee will be held Thursday, September 12, 2019, at 3:00 p.m. Eastern time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: August 9, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–17424 Filed 8–13–19; 8:45 am]

BILLING CODE 4830–01–P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Public Hearing

AGENCY: U.S.-China Economic and Security Review Commission

ACTION: Notice of open public hearing

SUMMARY: Notice is hereby given of the following hearing of the U.S.-China Economic and Security Review Commission.

The Commission is mandated by Congress to investigate, assess, and report to Congress annually on ''the national security implications of the economic relationship between the United States and the People's Republic of China.'' Pursuant to this mandate, the Commission will hold a public hearing in Washington, DC on September 4, 2019 on ''U.S.-China Relations in 2019: A Year in Review.''

DATES: The hearing is scheduled for Wednesday, September 4, 2019 at 9:30 a.m.

ADDRESSES: TBD, Washington, DC. A detailed agenda for the hearing will be posted on the Commission's website at *www.uscc.gov.* Also, please check the Commission's website for possible changes to the hearing schedule. *Reservations are not required to attend the hearing.*

FOR FURTHER INFORMATION CONTACT: Any member of the public seeking further information concerning the hearing should contact Leslie Tisdale Reagan, 444 North Capitol Street NW, Suite 602, Washington DC 20001; telephone: 202–624–1496, or via email at *lreagan@uscc.gov. Reservations are not required to attend the hearing.*

SUPPLEMENTARY INFORMATION:

Background

This is the eighth public hearing the Commission will hold during its 2019 report cycle. The hearing will review key developments in the U.S.-China relationship in 2019. Panel 1 will evaluate developments in China's political economy and the impact of U.S.-China trade frictions on the Chinese economy. Panel 2 will assess the implications of Chinese military activities and modernization in 2019 for the United States and U.S. allies and partners. Panel 3 will review the implications of economic, political, and security developments between China and Taiwan for regional security, and explore the escalating situation in Hong Kong. The hearing will be co-chaired by Vice Chairman Robin Cleveland and Commissioner Jeffrey Fiedler. Any interested party may file a written statement by September 4, 2019 by mailing to the contact above. A portion of each panel will include a question and answer period between the Commissioners and the witnesses.

Authority

Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Pub. L. 106–398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), as amended by Public Law 109–108 (November 22, 2005), as amended by Public Law 113–291 (December 19, 2014).

Dated: August 9, 2019.

Daniel W. Peck,

Executive Director, U.S.-China Economic and Security Review Commission.

[FR Doc. 2019–17475 Filed 8–13–19; 8:45 am]

BILLING CODE 1137–00–P



FEDERAL REGISTER

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Book 2 of 3 Books

Pages 40481–41289

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 410, 415, 416, et al.

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 410, 414, 415, 416, 418, 424, 425, 489, and 498

[CMS–1715–P]

RIN 0938–AT72

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

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

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program quality reporting requirements; Medicaid Promoting Interoperability Program requirements for eligible professionals; the establishment of an ambulance data collection system; updates to the Quality Payment Program; Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 27, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1715–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1715–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1715–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786–2064, for any issues not identified below.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, and impacts.

Geri Mondowney, (410) 786–1172, or Tourette Jackson, (410) 786–4735, for issues related to malpractice RVUs and geographic practice cost indicies (GPCIs).

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Lindsey Baldwin, (410) 786–1694, or Emily Yoder, (410) 786–1804, for issues related to telehealth services.

Pierre Yong, (410) 786–8896, or Lindsey Baldwin, (410) 786–1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs (OTPs).

Lindsey Baldwin, (410) 786–1694, for issues related to bundled payments under the PFS for substance use disorders.

Emily Yoder, (410) 786–1804, or Christiane LaBonte, (410) 786–7237, for issues related to the comment solicitation on opportunities for bundled payments under the PFS.

Regina Walker-Wren, (410) 786–9160, for issues related to physician supervision for physician assistant (PA) services and review and verification of medical record documentation.

Ann Marshall, (410) 786–3059, Emily Yoder, (410) 786–1804, Liane Grayson, (410) 786–6583, or Christiane LaBonte, (410) 786–7237, for issues related to care management services.

Kathy Bryant, (410) 786–3448, for issues related to coinsurance for colorectal cancer screening tests.

Pamela West, (410) 786–2302, for issues related to therapy services.

Ann Marshall, (410) 786–3059, Emily Yoder, (410) 786–1804, or Christiane LaBonte, (410) 786–7237, for issues related to payment for evaluation and management services.

Kathy Bryant, (410) 786–3448, for issues related to global surgery data collection.

Thomas Kessler, (410) 786–1991, for issues related to ambulance physician certification statement.

Felicia Eggleston, (410) 786–9287, or Amy Gruber, (410) 786–1542, for issues related to the ambulance fee schedule-BBA of 2018 requirements for Medicare ground ambulance services data collection system.

Linda Gousis, (410) 786–8616, for issues related to intensive cardiac rehabilitation.

David Koppel, (303) 844–2883, or Elizabeth LeBreton, (202) 615–3816, for issues related to the Medicaid Promoting Interoperability Program.

Fiona Larbi, (410) 786–7224, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality Measures.

Katie Mucklow, (410) 786–0537, or Diana Behrendt, (410) 786–6192, for issues related to open payments.

Cheryl Gilbreath, (410) 786–5919, for issues related to home infusion therapy benefit.

Joseph Schultz, (410) 786–2656, for issues related to Medicare enrollment of opioid treatment programs, and enhancements to provider enrollment regulations concerning improper prescribing and patient harm.

Jacqueline Leach, (410) 786–4282, for issues related to Deferring to State Scope of Practice Requirements: Ambulatory Surgical Centers (ASC).

Mary Rossi-Coajou, (410) 786–6051, for issues related to Deferring to State Scope of Practice Requirements: Hospice.

1877AdvisoryOpinion@cms.hhs.gov, for issues related to Advisory Opinions on Application of the Physician Self-referral law.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Megan Hyde, (410) 786–3247, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS Website

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-*

for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2020 PFS proposed rule, refer to item CMS–1715–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact Jamie Hermansen at (410) 786–2064.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major proposed rule proposes to revise payment polices under the Medicare PFS and make other policy changes, including proposals to implement certain provisions of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment, applicable to services furnished in CY 2020 and thereafter. In addition, this proposed rule includes proposals related to payment policy changes that are addressed in section III. of this proposed rule. We are requesting public comments on all of the proposals being made in this proposed rule.

1. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work; practice expense (PE); and malpractice (MP) expense. In addition, the statute requires that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major proposed rule, we are proposing to establish RVUs for CY 2020 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes discussions and proposals regarding several other Medicare Part B payment policies, Medicare Shared Savings Program quality reporting requirements, Medicaid Promoting Interoperability Program requirements for eligible professionals, the establishment of an ambulance data collection system, updates to the Quality Payment Program, Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations. This proposed rule addresses:

- Practice Expense RVUs (section II.B.)
- Malpractice RVUs (section II.C.)
- Geographic Practice Cost Indices (GPCIs) (section II.D.)
- Potentially Misvalued Services Under the PFS (section II.E.)
- Telehealth Services (section II.F.)
- Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (section II.G.)
- Bundled Payments Under the PFS for Substance Use Disorders (section II.H.)
- Physician Supervision for Physician Assistant (PA) Services (section II.I.)
- Review and Verification of Medical Record Documentation (section II.J.)
- Care Management Services (section II.K.)
- Coinsurance for Colorectal Cancer Screening Tests (section II.L.)
- Therapy Services (section II.M.)
- Valuation of Specific Codes (section II.N.)
- Comment Solicitation on Opportunities for Bundled Payments Under the PFS (section II.O.)
- Payment for Evaluation and Management (E/M) Services (section II.P.)
- Ambulance Coverage Services—Physician Certification Statement (section III.A.)
- Ambulance Fee Schedule—Medicare Ground Ambulance Services Data Collection System (section III.B.)
- Intensive Cardiac Rehabilitation (section III.C.)
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (section III.D.)
- Medicare Shared Savings Program Quality Measures (section III.E.)
- Open Payments (section III.F.)
- Home Infusion Therapy Benefit (section III.G.)
- Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm (section III.H.)
- Deferring to State Scope of Practice Requirements (section III.I.)
- Advisory Opinions on the Application of the Physician Self-Referral Law (section III.J.)
- Updates to the Quality Payment Program (section III.K.)

2. Summary of Costs and Benefits

We have determined that this major proposed rule is economically significant. For a detailed discussion of the economic impacts, *see* section VI. of this proposed rule.

II. Provisions of the Proposed Rule for the PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, ''Payment for Physicians' Services.'' The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this major proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

1. Development of the RVUs

a. Work RVUs

The work RVUs established for the initial fee schedule, which was

implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding MP expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA of 1997) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA of 1997 provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in the November 2, 1998 final rule (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 PFS final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some resource costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those specific facility resource costs is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA of 1997 amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' MP insurance premium data from all the states, the District of Columbia, and Puerto Rico. For more information on MP RVUs, *see* section II.C. of this proposed rule, Determination of Malpractice Relative Value Units.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed 5-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VI. of this proposed rule, the Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component. Please refer to the CY 2017 PFS final rule with comment period for a discussion of the last GPCI update (81 FR 80261 through 80270).

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia CF, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate CF for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work relative value units under the PFS and proposed changes to the practice expense methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of

American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file called ''CY 2020 PFS Proposed Rule PE/HR'' on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2020, we have incorporated the available utilization data for two new specialties, each of which became a recognized Medicare specialty during 2018. These specialties are Medical Toxicology and Hematopoietic Cell Transplantation and Cellular Therapy. We are proposing to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Medical Toxicology from Emergency Medicine; and
- Hematopoietic Cell Transplantation and Cellular Therapy from Hematology/Oncology.

These updates are reflected in the ''CY 2020 PFS Proposed Rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Next, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be

furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file called ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we instead use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 59283) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

For CY 2020, we are proposing to clarify the expected specialty assignment for a series of cardiothoracic services. Prior to the creation of the expected specialty list for low volume services in CY 2018, we previously finalized through rulemaking a crosswalk to the thoracic surgery specialty for a series of cardiothoracic services that typically had fewer than 100 services reported each year (*see,* for example, the CY 2012 PFS final rule (76 FR 73188–73189)). However, we noted that for many of the affected codes, the expected specialty list for low volume services incorrectly listed a crosswalk to the cardiac surgery specialty instead of the thoracic surgery specialty. We are proposing to update the expected specialty list to accurately reflect the previously finalized crosswalk to thoracic surgery for these services. The affected codes are shown in Table 1.

TABLE 1—PROPOSED UPDATES TO EXPECTED SPECIALTY

CPT code	CY 2019 expected specialty	Updated CY 2020 expected specialty
33414 ..	Cardiac Surgery	Thoracic Surgery.
33468 ..	Cardiac Surgery	Thoracic Surgery.
33470 ..	Cardiac Surgery	Thoracic Surgery.
33471 ..	Cardiac Surgery	Thoracic Surgery.
33476 ..	Cardiac Surgery	Thoracic Surgery.
33478 ..	Cardiac Surgery	Thoracic Surgery.
33502 ..	Cardiac Surgery	Thoracic Surgery.
33503 ..	Cardiac Surgery	Thoracic Surgery.
33504 ..	Cardiac Surgery	Thoracic Surgery.
33505 ..	Cardiac Surgery	Thoracic Surgery.
33506 ..	Cardiac Surgery	Thoracic Surgery.
33507 ..	Cardiac Surgery	Thoracic Surgery.
33600 ..	Cardiac Surgery	Thoracic Surgery.
33602 ..	Cardiac Surgery	Thoracic Surgery.
33606 ..	Cardiac Surgery	Thoracic Surgery.
33608 ..	Cardiac Surgery	Thoracic Surgery.
33610 ..	Cardiac Surgery	Thoracic Surgery.
33611 ..	Cardiac Surgery	Thoracic Surgery.
33612 ..	Cardiac Surgery	Thoracic Surgery.
33615 ..	Cardiac Surgery	Thoracic Surgery.
33617 ..	Cardiac Surgery	Thoracic Surgery.
33619 ..	Cardiac Surgery	Thoracic Surgery.
33620 ..	Cardiac Surgery	Thoracic Surgery.
33621 ..	Cardiac Surgery	Thoracic Surgery.
33622 ..	Cardiac Surgery	Thoracic Surgery.
33645 ..	Cardiac Surgery	Thoracic Surgery.
33647 ..	Cardiac Surgery	Thoracic Surgery.
33660 ..	Cardiac Surgery	Thoracic Surgery.
33665 ..	Cardiac Surgery	Thoracic Surgery.
33670 ..	Cardiac Surgery	Thoracic Surgery.
33675 ..	Cardiac Surgery	Thoracic Surgery.
33676 ..	Cardiac Surgery	Thoracic Surgery.
33677 ..	Cardiac Surgery	Thoracic Surgery.
33684 ..	Cardiac Surgery	Thoracic Surgery.
33688 ..	Cardiac Surgery	Thoracic Surgery.
33690 ..	Cardiac Surgery	Thoracic Surgery.
33692 ..	Cardiac Surgery	Thoracic Surgery.
33694 ..	Cardiac Surgery	Thoracic Surgery.
33697 ..	Cardiac Surgery	Thoracic Surgery.
33702 ..	Cardiac Surgery	Thoracic Surgery.
33710 ..	Cardiac Surgery	Thoracic Surgery.
33720 ..	Cardiac Surgery	Thoracic Surgery.
33722 ..	Cardiac Surgery	Thoracic Surgery.
33724 ..	Cardiac Surgery	Thoracic Surgery.
33726 ..	Cardiac Surgery	Thoracic Surgery.
33730 ..	Cardiac Surgery	Thoracic Surgery.
33732 ..	Cardiac Surgery	Thoracic Surgery.
33735 ..	Cardiac Surgery	Thoracic Surgery.
33736 ..	Cardiac Surgery	Thoracic Surgery.

TABLE 1—PROPOSED UPDATES TO EXPECTED SPECIALTY—Continued

CPT code	CY 2019 expected specialty	Updated CY 2020 expected specialty
33737 ..	Cardiac Surgery	Thoracic Surgery.
33750 ..	Cardiac Surgery	Thoracic Surgery.
33755 ..	Cardiac Surgery	Thoracic Surgery.
33762 ..	Cardiac Surgery	Thoracic Surgery.
33764 ..	Cardiac Surgery	Thoracic Surgery.
33766 ..	Cardiac Surgery	Thoracic Surgery.
33767 ..	Cardiac Surgery	Thoracic Surgery.
33768 ..	Cardiac Surgery	Thoracic Surgery.
33770 ..	Cardiac Surgery	Thoracic Surgery.
33771 ..	Cardiac Surgery	Thoracic Surgery.
33774 ..	Cardiac Surgery	Thoracic Surgery.
33775 ..	Cardiac Surgery	Thoracic Surgery.
33776 ..	Cardiac Surgery	Thoracic Surgery.
33777 ..	Cardiac Surgery	Thoracic Surgery.
33778 ..	Cardiac Surgery	Thoracic Surgery.
33779 ..	Cardiac Surgery	Thoracic Surgery.
33780 ..	Cardiac Surgery	Thoracic Surgery.
33781 ..	Cardiac Surgery	Thoracic Surgery.
33782 ..	Cardiac Surgery	Thoracic Surgery.
33783 ..	Cardiac Surgery	Thoracic Surgery.
33786 ..	Cardiac Surgery	Thoracic Surgery.
33788 ..	Cardiac Surgery	Thoracic Surgery.
33800 ..	Cardiac Surgery	Thoracic Surgery.
33802 ..	Cardiac Surgery	Thoracic Surgery.
33803 ..	Cardiac Surgery	Thoracic Surgery.
33813 ..	Cardiac Surgery	Thoracic Surgery.
33814 ..	Cardiac Surgery	Thoracic Surgery.
33820 ..	Cardiac Surgery	Thoracic Surgery.
33822 ..	Cardiac Surgery	Thoracic Surgery.
33824 ..	Cardiac Surgery	Thoracic Surgery.
33840 ..	Cardiac Surgery	Thoracic Surgery.
33845 ..	Cardiac Surgery	Thoracic Surgery.
33851 ..	Cardiac Surgery	Thoracic Surgery.
33852 ..	Cardiac Surgery	Thoracic Surgery.
33853 ..	Cardiac Surgery	Thoracic Surgery.
33917 ..	Cardiac Surgery	Thoracic Surgery.
33920 ..	Cardiac Surgery	Thoracic Surgery.
33922 ..	Cardiac Surgery	Thoracic Surgery.
33924 ..	Cardiac Surgery	Thoracic Surgery.
33925 ..	Cardiac Surgery	Thoracic Surgery.
33926 ..	Cardiac Surgery	Thoracic Surgery.
35182 ..	Cardiac Surgery	Thoracic Surgery.

We note that the cardiac surgery and thoracic surgery specialties are similar to one another, sharing the same PE/HR data for PE valuation and nearly identical MP risk factors for MP valuation. As a result, we do not anticipate this proposal having a discernible effect on the valuation of the codes listed above. For additional discussion on this issue, we refer readers to section II.C of this proposed rule, Malpractice. The complete list of expected specialty assignments for individual low volume services, including the assignments for the codes identified in Table 1, is available on our website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file called ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (*Note:* For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See ''Specialties excluded from ratesetting calculation'' later in this proposed rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable

adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

• *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 2.

TABLE 2—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, *e.g.,* private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (*e.g.,* drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
A8	Grocery store.
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007).
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.
B4	Rehabilitation Agency.
B5	Ocularist.
C1	Centralized Flu.
C2	Indirect Payment Procedure.
C5	Dentistry.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (*Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only*), is associated with the global service, CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 3 details the manner in which the modifiers are applied.

TABLE 3—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant.	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of work time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

• *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate) − life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally 150,000 minutes.

usage = variable, *see* discussion below in this proposed rule.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, *see* discussion below in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Stakeholders have often suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce the equipment utilization rate based on these recommendations. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items. However, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome the submission of data that would support an alternative rate.

Maintenance: This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We do not believe that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we do not believe that we have sufficient information at present to propose a variable maintenance factor for equipment cost per minute pricing. We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Interest Rate: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (*see* 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). We are not proposing any changes to these interest rates for CY 2020. The Interest rates are listed in Table 4.

TABLE 4—SBA MAXIMUM INTEREST RATES

Price	Useful life years	Interest rate (%)
<$25K	<7	7.50
$25K to $50K	<7	6.50
>$50K	<7	5.50
<$25K	7+	8.00
$25K to $50K	7+	7.00
>$50K	7+	6.00

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2020 direct PE input public use files, which are available on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640–67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS.'' Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values.

We also finalized standard times for clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902) at 4 minutes for ''Accession specimen/prepare for examination'', 0.5 minutes for ''Assemble and deliver slides with paperwork to pathologists'', 0.5 minutes for ''Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation'', 1 minute for ''Clean room/equipment following procedure'', 1 minute for ''Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste'', and 1 minute for ''Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).'' We do not believe these activities would be dependent on number of blocks or batch size, and we believe that these values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (''Review patient clinical extant information and questionnaire'') in the preservice period, and CA014 (''Confirm order, protocol exam'') in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463–59464).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2020, we are continuing to display two versions of the Labor Task Detail public use file: One version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended, along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during the review of the recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope, the associated video system, and any scope accessories that might be typical as distinct equipment items for each code. Under this approach, we proposed standalone prices for each scope, and separate prices for the video systems and accessories that are used with scopes.

(1) Scope Equipment

Beginning in the CY 2017 PFS proposed rule (81 FR 46176 through 46177), we proposed standardizing refinements to the way scopes have

been defined in the direct PE input database. We believe that there are four general types of scopes: Non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the scope video systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channeled) and therapeutic (or channeled) scopes. We proposed to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We proposed to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We planned to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated prices for the equipment items related to scopes utilized by these services. We did not propose to apply these policies to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we could consider proposing to apply to other codes in future rulemaking. We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believed there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. Therefore, we made further proposals in the CY 2018 PFS proposed rule (82 FR 33961 through 33962) to continue clarifying scope equipment inputs, and sought comments regarding the new set of scope proposals. We considered creating a single scope equipment code for each of the five categories detailed in this rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We stated our belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions, and we believed that creating and pricing a single scope equipment code for each category would help provide additional clarity. We sought public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

After considering the comments on the CY 2018 PFS proposed rule, we did not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified. Instead, we supported the recommendation from the commenters to create scope equipment codes on a per-specialty basis for six categories of scopes as applicable, including the addition of a new sixth category of multi-channeled flexible video scopes. Our goal was to create an administratively simple scheme that would be easier to maintain and help to reduce administrative burden. In 2018, the RUC convened a Scope Equipment Reorganization Workgroup to incorporate feedback from expert stakeholders with the intention of making recommendations to us on scope organization and scope pricing. Since the workgroup was not convened in time to submit recommendations for the CY 2019 PFS rulemaking cycle, we delayed proposals for any further changes to scope equipment until CY 2020 in order to incorporate the feedback from the aforementioned workgroup.

(2) Scope Video System

We proposed in the CY 2017 PFS proposed rule (81 FR 46176 through 46177) to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we proposed to use for this re-pricing. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule (81 FR 80188). We finalized our proposal to price the system at $33,391, based on component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, and $1,750 for the cart. In the CY 2018 PFS final rule (82 FR 52991 through 52993), we outlined, but did not finalize, a proposal to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. We also described a proposal to increase the price of the scope video system by $1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.). With the addition of the LED light (equipment code EQ382 at a price of $1,915), the updated total price of the scope video system would be set at $36,306.

We did not finalize this updated pricing to the scope video system in CY 2018, but we did propose and finalize the updated pricing for CY 2019 to $36,306 along with changing the name of the ES031 equipment item to ''scope video system (monitor, processor, digital capture, cart, printer, LED light)'' to reflect the fact that the use of the ES031 scope video system is not limited to endoscopy procedures.

(3) Scope Accessories

We understand that there may be other accessories associated with the use of scopes. We finalized a proposal in the CY 2017 PFS final rule (81 FR 80188) to separately price any scope accessories outside the use of the scope video system, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

(4) Scope Proposals for CY 2020

The Scope Equipment Reorganization Workgroup organized by the RUC submitted detailed recommendations to CMS for consideration in the CY 2020 rule cycle, describing 23 different types of scope equipment, the HCPCS codes associated with each scope type, and a series of invoices for scope pricing. We

appreciate the information provided by the workgroup and continue to welcome additional comments and feedback from stakeholders. Based on the recommendations from the workgroup, we are proposing to establish 23 new scope equipment codes (*see* Table 5).

TABLE 5—CY 2020 PROPOSED NEW SCOPE EQUIPMENT CODES

CMS code	Proposed scope equipment description	Proposed price	Number of invoices
ES070	rigid scope, cystoscopy		0
ES071	rigid scope, hysteroscopy		0
ES072	rigid scope, otoscopy		0
ES073	rigid scope, nasal/sinus endoscopy		0
ES074	rigid scope, proctosigmoidoscopy		0
ES075	rigid scope, laryngoscopy	$3,966.08	5
ES076	rigid scope, colposcopy	14,500.00	1
ES077	non-channeled flexible digital scope, hysteroscopy		0
ES078	non-channeled flexible digital scope, nasopharyngoscopy		0
ES079	non-channeled flexible digital scope, bronchoscopy		0
ES080	non-channeled flexible digital scope, laryngoscopy	21,485.51	7
ES081	channeled flexible digital scope, cystoscopy		0
ES082	channeled flexible digital scope, hysteroscopy		0
ES083	channeled flexible digital scope, bronchoscopy		0
ES084	channeled flexible digital scope, laryngoscopy	18,694.39	5
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	17,360.00	1
ES086	multi-channeled flexible digital scope, colonoscopy	38,058.81	6
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)		0
ES088	multi-channeled flexible digital scope, esophagoscopy	34,585.35	5
ES089	multi-channeled flexible digital scope, ileoscopy		0
ES090	multi-channeled flexible digital scope, pouchoscopy		0
ES091	ultrasound digital scope, endoscopic ultrasound		0
ES092	non-video flexible scope, laryngoscopy	5,078.04	4

We note that we did not receive invoices for many of the new scope equipment items. There also was some inconsistency in the workgroup recommendations regarding the non-channeled flexible digital scope, laryngoscopy (ES080) equipment item and the non-video flexible scope, laryngoscopy (ES092) equipment item. These scopes were listed as a single equipment item in some of the workgroup materials and listed as separate equipment items in other materials. We are proposing to establish them as separate equipment items based on the submitted invoices, which demonstrated that these were two different types of scopes with distinct price points of approximately $17,000 and $5,000 respectively.

We noted a similar issue with the submitted invoices for the rigid scope, laryngoscopy (ES075) equipment item. Among the eight total invoices, five of them were clustered around a price point of approximately $4,000 while the other three invoices had prices of roughly $15,000 apiece. The invoices indicated that these prices came from two distinct types of equipment, and as a result we are proposing to consider these items separately. We are proposing to use the initial five invoices to establish a proposed price of $3,966.08 for the rigid scope, laryngoscopy (ES075) equipment item. We note that this is a close match for the current price of $3,178.08 used by the endoscope, rigid, laryngoscopy (ES010) equipment, which is the closest equivalent scope equipment. The other three invoices appear to describe a type of stroboscopy system rather than a scope, and they have an average price of $14,737. This is a reasonably close match for the price of our current stroboscoby system (ES065) equipment, which has a CY 2020 price of $17,950.28 as it transitions to a final CY 2022 destination price of $16,843.87 (*see* the 4-year pricing transition of the market-based supply and equipment pricing update discussed later in this section for more information). We believe that these invoices reinforce the value established by the market-based pricing update for the stroboscoby system carried out last year, and we are not proposing to update the price of the ES065 equipment at this time. However, we are open to feedback from stakeholders if they believe it would be more accurate to assign a price of $14,737 to the stroboscoby system based on these invoice submissions, as opposed to maintaining the current pricing transition to a CY 2022 price of $16,843.87.

For the eight new scope equipment items where we have submitted invoices for pricing, we are proposing to replace the existing scopes with the new scope equipment. We received recommendations from the RUC's scope workgroup regarding which HCPCS codes make use of the new scope equipment items, and we are proposing to make this scope replacement for approximately 100 HCPCS codes in total (*see* Table 6).

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TABLE 6: Proposed Scope Equipment Replacement

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
31505	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31510	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31511	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31512	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31515	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31525	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31570	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
56820	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
56821	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57420	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57421	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57452	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57454	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57455	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57456	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57460	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57461	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
31551	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31552	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31553	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31554	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31574	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31575	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31579	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31580	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31584	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31587	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31591	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31592	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92612*	ES027	video system, FEES (scope, camera, light source, image capture, monitor, printer, cart)	$21,675.00	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92614*	ES028	video system, FEESST (scope, sensory stimulator, camera, light source, image capture, monitor, printer, cart)	$25,420.25	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92616*	ES028	video system, FEESST (scope, sensory stimulator, camera,	$25,420.25	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
		light source, image capture, monitor, printer, cart)				
31572	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31573	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31576	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31577	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31578	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
45330	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45331	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45332	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45333	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45334	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45335	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45338	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45340	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45346	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
G0104	ES021	fiberscope, flexible, sigmoidoscopy	$10,976.97	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45378	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45379	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45380	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45381	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45382	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45384	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible	$38,058.81

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
					digital scope, colonoscopy	
45385	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45386	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45388	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45398	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
G0105	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
G0121	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44388	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44389	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44390	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44391	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44392	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44394	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44401	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44404	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44405	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
43197	ES026	video add-on camera system w-monitor (endoscopy)	$9,514.13	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43198	ES026	video add-on camera system w-monitor (endoscopy)	$9,514.13	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43200	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43201	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43202	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43206	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43213	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43215	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible	$34,585.35

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
					digital scope, esophagoscopy	
43216	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43217	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43220	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43226	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43227	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43229	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
31590	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31300	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31360	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31365	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31367	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31368	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31370	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31375	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31380	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31382	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31390	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31395	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31400	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31420	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04

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In all but three cases, we are proposing for the new scope equipment item to replace the existing scope with the identical amount of equipment time. For CPT codes 92612 (*Flexible endoscopic evaluation of swallowing by cine or video recording*), 92614 (*Flexible endoscopic evaluation, laryngeal sensory testing by cine or video recording*), and 92616 (*Flexible endoscopic evaluation of swallowing and laryngeal sensory testing by cine or video recording*), the current scopes in use are the FEES video system (ES027) and the FEESST video system (ES028). Since we are proposing the use of a non-channeled flexible digital scope that requires a corresponding scope video system, we are adding the ES080 equipment at the same equipment time

to these three procedures rather than replacing the ES027 and ES028 equipment. In all other cases, we are proposing to replace the current scope equipment listed in Table 6 with the new scope equipment, while maintaining the same amount of equipment time.

We identified inconsistencies with the workgroup recommendations for a small number of HCPCS codes. CPT code 45350 (*Sigmoidoscopy, flexible; with band ligation(s) (e.g., hemorrhoids)*) was recommended to include a multi-channeled flexible digital scope, flexible sigmoidoscopy (ES085), however, we noted that this CPT code does not include any scopes among its current direct PE inputs. CPT code 31595 was recommended to include a non-channeled flexible digital scope, laryngoscopy (ES080) but it no longer exists as a CPT code after having been deleted for CY 2019. CPT code 43232 (*Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/ biopsy(s)*) was recommended to include a multi-channeled flexible digital scope, esophagoscopy (ES088), but it does not include a scope amongst its direct PE inputs any longer following clarification from the same workgroup recommendations that CPT code 43232 is never performed in the nonfacility setting. In all three of these cases, we are not proposing to add one of the new scope equipment items to these procedures.

We did not receive pricing information along with the workgroup recommendations for the other 15 new scope equipment items. For CY 2020, we are proposing to establish new equipment codes for these scopes as detailed in Table 5. However, due to a lack of pricing information, we are not proposing to replace existing scope equipment with the new equipment items as we did for the other eight new scope equipment items for CY 2020. We welcome additional feedback from stakeholders regarding the pricing of these scope equipment items, especially the submission of detailed invoices with pricing data. We are proposing to transition the scopes for which we do have pricing information over to the new equipment items for CY 2020, and we look forward to engaging with stakeholders to assist in pricing and then transitioning the remaining scopes in future rulemaking.

c. Technical Corrections to Direct PE Input Database and Supporting Files

Subsequent to the publication of the CY 2019 PFS final rule, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We are proposing to correct these inconsistencies as described below and reflected in the CY 2020 proposed direct PE input database displayed on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For CY 2020, we are proposing to address the following inconsistencies:

- The RUC's Scope Equipment Reorganization Workgroup recommended deletion of the non-facility inputs for CPT codes 43231 (*Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination*) and 43232 (*Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/ biopsy(s)*). The gastroenterology specialty societies stated that these services are never performed in the non-facility setting. After our own review of these services, we agree with the workgroup's recommendation, and we are proposing to remove the non-facility direct PE inputs for these two CPT codes.

- In rulemaking for CY 2018, we reviewed a series of CPT codes describing nasal sinus endoscopy surgeries. At that time, we sought comments on whether the broader family of nasal sinus endoscopy surgery services should be subject to the special rules for multiple endoscopic procedures instead of the standard multiple procedure payment reduction. We received very few comments in response to our solicitation. In the CY 2018 PFS final rule (82 FR 53043), we indicated that we would continue to explore this option for future rulemaking. We are proposing to apply the special rule for multiple endoscopic procedures to this family of codes beginning in CY 2020. This proposal would treat this group of CPT codes consistently with other similar endoscopic procedures when codes within the CPT code family are billed together with another endoscopy service in the same family. Similar to other similar endoscopic procedure code families, we are proposing that CPT code 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*) would be the base procedure for the remainder of nasal sinus endoscopies. The codes affected by this proposal are as follows (*see* Table 7).

TABLE 7—PROPOSED NASAL SINUS ENDOSCOPY CODES SUBJECT TO SPECIAL RULES FOR MULTIPLE ENDOSCOPIC PROCEDURES

CPT code	Short descriptor
31231	Nasal endoscopy dx.
31233	Nasal/sinus endoscopy dx.
31235	Nasal/sinus endoscopy dx.
31237	Nasal/sinus endoscopy surg.
31238	Nasal/sinus endoscopy surg.
31239	Nasal/sinus endoscopy surg.
31240	Nasal/sinus endoscopy surg.
31241	Nsl/sins ndsc w/artery lig.
31253	Nsl/sins ndsc total.
31254	Nsl/sins ndsc w/prtl ethmdct.
31255	Nsl/sins ndsc w/tot ethmdct.
31256	Exploration maxillary sinus.
31257	Nsl/sins ndsc tot w/sphendt.
31259	Nsl/sins ndsc sphn tiss rmvl.
31267	Endoscopy maxillary sinus.
31276	Nsl/sins ndsc frnt tiss rmvl.
31287	Nasal/sinus endoscopy surg.
31288	Nasal/sinus endoscopy surg.
31290	Nasal/sinus endoscopy surg.
31291	Nasal/sinus endoscopy surg.
31292	Nasal/sinus endoscopy surg.
31293	Nasal/sinus endoscopy surg.
31294	Nasal/sinus endoscopy surg.
31295	Sinus endo w/balloon dil.
31296	Sinus endo w/balloon dil.
31297	Sinus endo w/balloon dil.
31298	Nsl/sins ndsc w/sins dilat.

Special rules for multiple endoscopic procedures would apply if any of the procedures listed in Table 7 are billed together for the same patient on the same day. We apply the multiple endoscopy payment rules to a code family before ranking the family with other procedures performed on the same day (for example, if multiple endoscopies in the same family are reported on the same day as endoscopies in another family, or on the same day as a non-endoscopic procedure). If an endoscopic procedure is reported together with its base procedure, we do not pay separately for the base procedure. Payment for the base procedure is included in the payment for the other endoscopy. For additional information about the payment adjustment under the special rule for multiple endoscopic services, we refer readers to the CY 1992 PFS final rule where this policy was established (56 FR 59515) and to Pub. 100–04, Medicare Claims Processing Manual, Chapter 23 (available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c23.pdf*).

d. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public

requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2020, we are proposing the following price updates for existing direct PE inputs.

We are proposing to update the price of one supply and one equipment item in response to the public submission of invoices. As these pricing updates were each part of the formal review for a code family, we are proposing that the new pricing take effect for CY 2020 for these items instead of being phased in over 4 years. For the details of these proposed price updates, please refer to Table 22, Proposed CY 2020 Invoices Received for Existing Direct PE Inputs in section II.N., Proposed Valuation of Specific Codes, of this proposed rule.

We are also proposing to update the name of the EP001 equipment item from ''DNA/digital image analyzer (ACIS)'' to ''DNA/Digital Image Analyzer'' due to clarification from stakeholders regarding the typical use of this equipment.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- **Federal Register**, current DPEI data, historical proposed and final rules prior to CY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in hierarchical order considering both data representativeness and reliability.

(1) If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of equipment and a more precise reference for the RP.

(2) If no data were available for commercial products, the current CMS prices were used as the RP.

GSA prices were not used to calculate the StrategyGen recommended prices, due to our concern that the GSA system curtails the number and type of suppliers whose products may be accessed on the GSA Advantage website, and that the GSA prices may often be lower than prices that are available to non-governmental purchasers. After reviewing the StrategyGen report, we proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicated that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties would experience increases or decreases in their Medicare payments if CMS were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, in the CY 2019 PFS proposed rule we proposed to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the ''bottom-

up'' PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We proposed to implement this phase-in over 4 years so that supply and equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 8.

TABLE 8—EXAMPLE OF DIRECT PE PRICING TRANSITION

Current Price	$100	
Final Price	200	
Year 1 (CY 2019) Price	125	¼ difference between $100 and $200.
Year 2 (CY 2020) Price	150	⅓ difference between $125 and $200.
Year 3 (CY 2021) Price	175	½ difference between $150 and $200.
Final (CY 2022) Price	200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we proposed to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We also proposed that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we proposed to implement the established invoice price as the updated price and to phase in the new price over the remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we proposed to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We also proposed to phase in any updated pricing we establish during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal was intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer time frame will allow more opportunities for public comment and submission of additional, applicable data. We welcomed feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

We received many comments regarding the market-based supply and equipment pricing proposal following the publication of the CY 2019 PFS proposed rule. For a full discussion of these comments, we direct readers to the CY 2019 PFS final rule (83 FR 59475–59480). In each instance in which a commenter raised questions about the accuracy of a supply or equipment code's recommended price, the StrategyGen contractor conducted further research on the item and its price with special attention to ensuring that the recommended price was based on the correct item in question and the clarified unit of measure. Based on the commenters' requests, the StrategyGen contractor conducted an extensive examination of the pricing of any supply or equipment items that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified supply and equipment codes for accuracy and proper pricing. In most cases, the contractor also reached out to a team of nurses and their physician panel to further validate the accuracy of the data and pricing information. In some cases, the pricing for individual items needed further clarification due to a lack of information or due to significant variation in packaged items. After consideration of the comments and this additional price research, we updated the recommended prices for approximately 70 supply and equipment codes identified by the commenters. Table 9 in the CY 2019 PFS final rule lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing (83 FR 59479–59480).

After consideration of the public comments, we finalized our proposals associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. We continue to believe that implementing the proposed updated prices with a 4-year phase-in will improve payment

accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. We continue to welcome feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

For CY 2020, we received invoice submissions for approximately 30 supply and equipment codes from stakeholders as part of the second year of the market-based supply and equipment pricing update. These invoices were reviewed by the StrategyGen contractor and the submitted invoices were used in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. The contractor reviewed the invoices, as well as prior data for the relevant supply/equipment codes to make sure the item in the invoice was representative of the supply/equipment item in question and aligned with past research. Based on this research, we are proposing to update the prices of the following supply and equipment items:

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TABLE 9: Proposed CY 2020 Market-Based Supply and Equipment Pricing Updates

CMS CODE	Description	CMS 2019 Price	Prior CMS 2022 Price	Prior CMS 2020 Price	Updated CMS 2022 Price	Updated CMS 2020 Price
SA047	pack, EM visit	$4.176	$7.750	$5.367	$5.468	$4.606
SA099	Kit, probe, cryoablation, prostate (Galil-Endocare)	$3,909.890	$1,539.560	$3,119.780	$4,000.000	$3,939.927
SA106	kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)	$2,543.478	$2,374.330	$2,487.095	$2,338.000	$2,474.985
SD005	biopsy sponge (Histo-Prep)	$0.048	$0.030	$0.042	$0.267	$0.121
SF030	laser tip, diffuser fiber	$699.375	$247.500	$548.750	$730.000	$709.583
SH056	phenylephrine 2.5% ophth (Mydfrin)	$0.391	$0.391	$0.391	$5.465	$2.082
SH058	proparacaine 0.5% ophth (Ophthaine, Alcaine)	$0.615	$0.670	$0.633	$2.353	$1.194
SH084	Kenalog 40 inj	$1.963	$2.360	$2.095	$10.578	$4.834
SJ041	povidone soln (Betadine)	$0.016	$0.040	$0.024	$0.380	$0.137
SL012	antibody IgA FITC	$38.391	$30.025	$35.603	$87.500	$54.761
SL058	embedding cassette	$0.149	$0.120	$0.140	$0.181	$0.160
SL182	mounting media (DAPI II counterstain)	$63.750	$54.000	$60.500	$95.280	$74.260
SL184	slide, negative control, Her-2	$29.400	$29.400	$29.400	$27.500	$28.767
SL195	kit, FISH paraffin pretreatment	$20.850	$20.850	$20.850	$22.000	$21.233
SL196	kit, HER-2/neu DNA Probe	$98.513	$79.050	$92.025	$119.740	$105.588
SL484	Bluing reagent (Ventana 760-2037)	$3.504	$0.450	$2.486	$4.247	$3.751
SL497	(EBER) DNA Probe Cocktail	$8.475	$8.189	$8.379	$10.810	$9.253
EL015	room, ultrasound, general	$369,945.000	$369,945.000	$369,945.000	$410,303.322	$383,397.774
EL016	room, ultrasound, vascular	$466,492.000	$466,492.000	$466,492.000	$479,753.320	$470,912.440
EP001	DNA/digital image analyzer	$193,749.959	$28,160.937	$138,553.619	$225,143.420	$204,214.446
EP007	centrifuge (with rotor)	$4,442.759	$4,896.085	$4,593.868	$4,896.085	$4,593.868
EP015	grossing station w-heavy duty disposal	$21,200.775	$24,276.600	$22,226.050	$25,734.940	$22,712.163
EP017	hood, fume	$4,769.200	$4,741.420	$4,759.940	$5,978.210	$5,172.203
EP024	microscope, compound	$10,066.336	$5,401.295	$8,511.323	$9,764.720	$9,965.798
EP026	microscope, electron, transmission (TEM)	$350,736.063	$445,074.250	$382,182.125	$486,912.125	$396,128.083
EP031	paraffin dispenser (five-gallon)	$2,222.500	$2,222.500	$2,222.500	$2,500.000	$2,315.000
EP033	slide coverslipper, robotic	$30,143.000	$30,143.000	$30,143.000	$52,970.000	$37,752.000
EP036	slide stainer, automated, high-volume throughput	$19,334.532	$35,081.087	$24,583.384	$37,012.544	$25,227.202
EP039	tissue embedding center	$9,612.753	$11,161.000	$10,128.835	$12,560.500	$10,595.335
EP043	water bath, general purpose (lab)	$757.256	$849.673	$788.062	$950.337	$821.616
EP054	water bath, FISH procedures (lab)	$1,977.253	$1,576.010	$1,843.505	$1,576.100	$1,843.535
EP088	ThermoBrite	$5,788.750	$4,795.000	$5,457.500	$4,625.073	$5,400.858
EP089	Camera (Olympus DP21)	$7,719.300	$7,719.300	$7,719.300	$8,715.000	$8,051.200
EP111	Automated Casette Labeler	$9,541.385	$26,579.539	$15,220.770	$26,700.265	$15,261.011
ER041	microtome	$14,087.605	$16,243.420	$14,806.210	$17,709.840	$15,295.017
ER043	microtome, ultra	$33,628.850	$31,378.400	$32,878.700	$35,015.480	$34,091.060

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For most supply and equipment items, there was an alignment between the research carried out by the StrategyGen contractor and the submitted invoice. The updated CY 2020 pricing was calculated using an average between the previous market research and the newly submitted invoices in these cases. In some cases the submitted invoices were not representative of market prices, such as for the centrifuge with rotor (EP007) equipment item where the invoice price of $8,563 appeared to be an outlier. We did not use the invoices to calculate our pricing recommendation in these situations and instead continued to rely on our prior pricing data. In other instances, such as for the kit, probe, cryoablation, prostate (Galil-Endocare)

(SA099) supply item, our research indicated that the submitted invoice price was more representative of the commercial price than our CY 2019 research and pricing. We are proposing the new invoice prices for these supply and equipment items due to our belief in their greater accuracy.

For some of the remaining supply and equipment items, such as the five-gallon paraffin (EP031) equipment and the Olympus DP21 camera (EP089) equipment, we maintained the extant pricing for CY 2019 due to a lack of sufficient data to update the pricing. In these situations where we did not have an updated price for CY 2019, we believe that the newly submitted invoices are more representative of the current commercial prices that are being paid on the market. We are again proposing the new invoice prices for these supply and equipment items due to our belief in their greater accuracy.

In addition, we were alerted by stakeholders that the price of the EM visit pack (SA047) supply did not match the sum of the component prices of the supplies included in the pack. After reviewing the prices of the individual component supplies, we agree with the stakeholders that there was a discrepancy in the previous pricing of this supply pack. We are proposing to update the price of the EM visit pack to $5.47 to match the sum of the prices of the component supplies, and proposing to continue to transition towards this price over the remaining years of the phase-in period.

We finalized a policy last year to phase in the new supply and equipment pricing over 4 years so that supply and equipment values transition smoothly from their current prices to the final updated prices in CY 2022. We finalized our proposal to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price was implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 8. For CY 2020, one third of the difference between the CY 2019 price and the final price will be implemented as per the previously finalized policy.

The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

(2) Invoice Submission

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. For CY 2020, we noted that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February 10th deadline established for code valuation recommendations. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we would consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

(3) Adjustment to Allocation of Indirect PE for Some Office-Based Services

In the CY 2018 PFS final rule (82 FR 52999 through 53000), we established criteria for identifying the services most affected by the indirect PE allocation anomaly that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. We also finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services. The methodology, as described, is based on the difference between the ratio of indirect PE to work RVUs for each of the codes meeting eligibility criteria and the ratio of indirect PE to work RVU for the most commonly reported visit code. We refer readers to the CY 2018 PFS final rule (82 FR 52999 through 53000) for a discussion of our process for selecting services subject to the revised methodology, as well as a description of the methodology, which we began implementing for CY 2018 as the first year of a 4-year transition. For CY 2020, we are proposing to continue with the third year of the transition of this adjustment to the standard process for allocating indirect PE.

C. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: Work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs, *see* the CY 2015 proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596). In the CY 2018 proposed rule (82 FR 33965 through 33970), we proposed to update the specialty-level risk factors used in the calculation of MP RVUs, prior to the next required 5 year update (CY 2020), using the updated MP premium data that were used in the eighth Geographic Practice Cost Index (GPCI) update for CY 2017; however the proposal was ultimately not finalized for CY 2018.

We consider the following factors when we determine MP RVUs for individual PFS services: (1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners; (2) service-level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service-level risk factor based on either the higher of the work RVU or clinical labor portion of the direct PE RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the

clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code was 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor was applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the three most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty-level risk factor to individual codes based on the same utilization assumptions we make regarding specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-level risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

Section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years. For CY 2020, we are conducting the statutorily required 3-year review of the GPCIs, which coincides with the statutorily required 5-year review of the MP RVUs. We note that the MP premium data used to update the MP GPCIs are the same data used to determine the specialty-level risk factors, which are used in the calculation of MP RVUs. Going forward, we believe it would be logical and efficient to align the update of MP premium data used to determine the MP RVUs with the update of the MP GPCI. Therefore, we are proposing to align the update of MP premium data with the update to the MP GPCIs, that is, we are proposing to review, and if necessary update the MP RVUs at least every 3 years, similar to our review and update of the GPCIs. If we align the two updates, we would conduct the next statutorily-mandated review and update of both the GPCI and MP RVU for implementation in CY 2023. We are proposing to implement the fourth comprehensive review and update of MP RVUs for CY 2020 and are seeking comment on these proposals.

2. Methodology for the Proposed Revision of Resource-Based Malpractice RVUs

a. General Discussion

We calculated the proposed MP RVUs using updated malpractice premium data obtained from state insurance rate filings. The methodology used in calculating the proposed CY 2020 review and update of resource-based MP RVUs largely parallels the process used in the CY 2015 update; however, we are proposing to incorporate several methodological refinements, which are described below in this proposed rule. The MP RVU calculation requires us to obtain information on specialty-specific MP premiums that are linked to specific services, and using this information, we derive relative risk factors for the various specialties that furnish a particular service. Because MP premiums vary by state and specialty, the MP premium information must be weighted geographically and by specialty. We calculated the proposed MP RVUs using four data sources: Malpractice premium data presumed to be in effect as of December 31, 2017; CY 2018 Medicare payment and utilization data; higher of the CY 2020 proposed work RVUs or the clinical labor portion of the direct PE RVUs; and CY 2019 GPCIs. We will use the higher of the CY 2020 final work RVUs or clinical labor portion of the direct PE RVUs in our calculation to develop the CY 2020 final MP RVUs while maintaining overall PFS budget neutrality.

Similar to the CY 2015 update, the proposed MP RVUs were calculated using specialty-specific malpractice premium data because they represent the expense incurred by practitioners to obtain malpractice insurance as reported by insurers. For CY 2020, the most current malpractice premium data available, with a presumed effective date of no later than December 31, 2017, were obtained from insurers with the largest market share in each state. We identified insurers with the largest market share using the National Association of Insurance Commissioners (NAIC) market share report. This annual report provides state-level market share for entities that provide premium liability insurance (PLI) in a state. Premium data were downloaded from the System for Electronic Rates & Forms Filing Access Interface (SERFF) (accessed from the NAIC website) for participating states. For non-SERFF states, data were downloaded from the state-specific website (if available online) or obtained directly from the state's alternate access to filings. For SERFF states and non-SERFF states with online access to filings, the 2017 market share report was used to select companies. For non-SERFF states without online access to filings, the 2016 market share report was used to identify companies. These were the most current data available during the data collection and acquisition process.

Malpractice insurance premium data were collected from all 50 States, and the District of Columbia. Efforts were made to collect filings from Puerto Rico; however, no recent filings were submitted at the time of data collection and therefore filings from the previous update were used. Consistent with the CY 2015 update, no filings were collected for the other U.S. territories: American Samoa, Guam, Virgin Islands, or Northern Mariana Islands. Malpractice premiums were collected for coverage limits of $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering losses occurring, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. Adjustments were made to the premium data to reflect mandatory surcharges for patient compensation funds (PCF, funds used to pay for any claim beyond the state's statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in states where participation in such funds is mandatory.

Premium data were included for all physician and NPP specialties, and all risk classifications available in the collected rate filings. Although premium data were collected from all states, the District of Columbia, and previous filings for Puerto Rico were utilized, not all specialties had distinct premium data in the rate filings from all states. In previous updates, specialties for which premium data were not available for at least 35 states, and specialties for which there were not distinct risk groups (surgical, non-surgical, and surgical with obstetrics) among premium data in the rate filings, were crosswalked to a similar specialty, either conceptually or based on available premium data. This resulted in not using those premium data because

the 35 state threshold was not met. In this proposed CY 2020 update, we note that the proposed methodological improvement discussed below in this proposed rule expands the specialties and amount of filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs.

b. Proposed Methodological Refinements

For the CY 2020 update, we are proposing the following methodological improvements to the development of MP premium data:

(1) Downloading and using a broader set of filings from the largest market share insurers in each state, beyond those listed as ''physician'' and ''surgeon'' to obtain a more comprehensive data set.

(2) Combining minor surgery and major surgery premiums to create the surgery service risk group, which yields a more representative surgical risk factor. In the previous update, only premiums for major surgery were used in developing the surgical risk factor.

(3) Utilizing partial and total imputation to develop a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings, which sometimes use unique specialty names.

In instances where insurers report data for some (but not all) specialties that explicitly corresponded to a CMS specialty, where those data were missing, we propose to use partial imputation based on available data to establish what the premiums would likely have been had that specialty been delineated in the filing. In instances where there are no data corresponding to a CMS specialty in the filing, we propose to use total imputation to establish premiums.

For example, if a specialty of Sleep Medicine is listed on the insurer's rate filing, this rate will be matched to the CMS specialty Sleep Medicine (C0). However, if the Sleep Medicine specialty is not listed on the insurer's rate filing, under our proposed methodology, the insurer's rate filing for General Practice would be matched to the CMS specialty of Sleep Medicine (C0). In this example, we believe General Practice is likely to be consistent with the rate that a Sleep Medicine provider would be charged by that insurer. This proposed methodological improvement means that instead of discarding specialty-specific information from some insurers' filings because other insurers lacked that same level of detail, we would instead impute the missing rates at the insurer/specialty level in an effort to utilize as much of the information from the filings as possible.

We are seeking comment on these proposed methodological improvements. Additional technical details are available in our interim report, ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' on our website. It is located under the supporting documents section for the CY 2020 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

c. Steps for Calculating Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 final rule with comment period (79 FR 67591), along with the above proposed methodological improvements. The specialty-weighted approach bases the MP RVUs for a given service on a weighted average of the risk factors of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are reflected in the calculation of the MP RVUs. The steps for calculating the proposed MP RVUs are described below.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area malpractice premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2013–2017 American Community Survey (ACS) 5-year estimates). This is in contrast to the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We refer readers to the CY 2016 PFS final rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on share of total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as reflected by the 2019 GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium service risk groups to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of malpractice claims if they occur. To account for the presence of different classes in the malpractice premium data and the task of mapping these premiums to procedures, we calculated distinct risk factors for surgical, surgical with obstetrics, and nonsurgical procedures where applicable. However, the availability of data by surgery and non-surgery varied across specialties. Historically, no single approach accurately addressed the variability in premium class among specialties, and we previously employed several methods for calculating average premiums by specialty. These methods are discussed below.

Developing Distinct Service Risk Groups: We determined that there were sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 15 specialties (there were 10 such specialties in the CY 2015 update). These specialties are listed in Table 10. Additionally, as described in the proposed methodological refinements, in some instances, we combined minor surgery and major surgery premiums to create a premium to develop the surgery service risk group, rather than discard minor surgery premium data as was done in the previous update. Therefore, we calculated a national average surgical premium and non-surgical premium for those specialties. For all other specialties (those that are not listed in Table 10) that typically do not distinguish premiums as described above, a single risk factor was calculated, and that specialty risk factor was applied to all services performed by those specialties.

This is consistent with prior practice; however, we have refined the nomenclature to more precisely describe that some specialties are delineated into service risk groups, as is the case for surgical, non-surgical, and surgical with obstetrics, and some specialties are not further delineated into service risk subgroups and are instead referred to as ''All''—meaning that all services performed by that specialty receive the same risk factor.

TABLE 10—PROPOSED SPECIALTIES SUBDIVIDED INTO SERVICE RISK GROUPS

Service risk groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93).
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16).

Step (3): Calculate a risk factor for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty-level risk factor. These risk factors are calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest premiums for which we had sufficient and reliable data, which remains allergy and immunology (03). For specialties with rate filings that are indicative of sufficient surgical and non-surgical premium data, we recognized those service-risk groups (that is, surgical, and non-surgical) as risk groups of the specialty and we calculated both a surgical and non-surgical risk factor. Similarly, for specialties with rate filings that distinguished surgical premiums with obstetrics, we recognized that service-risk subgroup of the specialty and calculated a separate surgical with obstetrics risk factor.

(a) Technical Component (TC) Only Services

We note that for determining the risk factor for suppliers of TC-only services in the CY 2015 update, we updated the premium data for independent diagnostic testing facilities (IDTFs) that we used in the CY 2010 update. Those data were obtained from a survey conducted by the Radiology Business Management Association (RBMA) in 2009; we ultimately used those data to calculate an updated TC specialty risk factor. We applied the updated TC specialty risk factor to suppliers of TC-only services. In the CY 2015 final rule with comment period (79 FR 67595), RBMA voluntarily submitted updated MP premium information collected from IDTFs in 2014, and requested that we use the data for calculating the CY 2015 MP RVUs for TC-only services. We declined to utilize the data and stated that we believe further study is necessary and we would consider this matter and propose any changes through future rulemaking. We continue to believe that data for a broader set of TC-only services are needed, and are working to acquire a broader set of data.

For CY 2020, we propose to assign a risk factor of 1.00 for TC-only services, which corresponds to the lowest physician specialty-level risk factor. We assigned the risk factor of 1.00 to the TC-only services because we do not have sufficient comparable professional liability premium data for the full range of clinicians that furnish TC-only services. In lieu of comprehensive, comparable data, we propose to assign 1.00, the lowest physician specialty-level risk factor calculated using the updated premium data, as the default minimum risk factor. However, we seek information on the most comparable and appropriate proxy for the broader set of TC-only services for future use, as well as any empirical information that would support assignment of an alternative risk factor for these services.

Table 11 shows the proposed risk factors by specialty type and service risk group.

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TABLE 11: CY 2020 Proposed Risk Factors by Specialty and Service Risk Group

Medicare Specialty Code and Name	2020 Service Risk Group	2020 Risk Factor
01-General practice	NO SURG	1.63
01-General practice	SURG	2.86
01-General practice	OB	3.70
02-General surgery	ALL	6.81
03-Allergy/immunology	ALL	1.00
04-Otolaryngology	NO SURG	1.64
04-Otolaryngology	SURG	3.10
05-Anesthesiology	ALL	2.20
06-Cardiology	NO SURG	1.89
06-Cardiology	SURG	6.06
07-Dermatology	NO SURG	1.16
07-Dermatology	SURG	2.14
08-Family practice	NO SURG	1.63
08-Family practice	SURG	2.58
08-Family practice	OB	3.69
09-Interventional pain management	ALL	2.80
10-Gastroenterology	NO SURG	1.90
10-Gastroenterology	SURG	2.51
11-Internal medicine	ALL	1.76
12-Osteopathic manipulative therapy	ALL	1.00
13-Neurology	NO SURG	2.24
13-Neurology	SURG	9.60
14-Neurosurgery	ALL	9.60
15-Speech language pathology	ALL	1.00
16-Obstetrics/gynecology	NO SURG	1.86
16-Obstetrics/gynecology	SURG	3.72
16-Obstetrics/gynecology	OB	7.81
17-Hospice & palliative care	ALL	1.00
18-Ophthalmology	NO SURG	1.17
18-Ophthalmology	SURG	2.01
19-Oral surgery	ALL	2.41
20-Orthopedic surgery	ALL	5.51
21-Cardiac electrophysiology	ALL	1.89
22-Pathology	ALL	1.51
23-Sports medicine	ALL	1.66
24-Plastic and reconstructive surgery	ALL	4.97
25-Physical medicine and rehabilitation	ALL	1.38
26-Psychiatry	ALL	1.02
27-Geriatric psychiatry	ALL	1.02
28-Colorectal surgery	ALL	3.57
29-Pulmonary disease	ALL	2.06
30-Diagnostic radiology	ALL	2.25
31-Intensive cardiac rehab	ALL	1.89
32-Anesthesiologist assistants	ALL	0.60
33-Thoracic surgery	ALL	6.43
34-Urology	NO SURG	1.75
34-Urology	SURG	3.07
35-Chiropractic	ALL	0.52
36-Nuclear medicine	ALL	1.23
37-Pediatric medicine	ALL	1.78

Medicare Specialty Code and Name	2020 Service Risk Group	2020 Risk Factor
38-Geriatric medicine	NO SURG	1.49
38-Geriatric medicine	SURG	2.34
39-Nephrology	NO SURG	1.67
39-Nephrology	SURG	2.50
40-Hand surgery	ALL	4.42
41-Optometry	ALL	0.17
42-Certified nurse midwife	ALL	2.06
43-CRNA	ALL	0.68
44-Infectious disease	ALL	2.11
45-Mammography screening center	ALL	1.00
46-Endocrinology	NO SURG	1.59
46-Endocrinology	SURG	2.67
47-Independent diagnostic testing facility	ALL	1.00
48-Podiatry	NO SURG	1.27
48-Podiatry	SURG	2.10
62-Psychologist	ALL	1.00
63-Portable x-ray supplier	ALL	1.00
64-Audiologist	ALL	1.00
65-Physical therapist	ALL	1.00
66-Rheumatology	ALL	1.63
67-Occupational therapist	ALL	1.00
68-Clinical psychologist	ALL	1.00
69-Clinical laboratory	ALL	1.00
70-Multispecialty clinic or group practice	ALL	2.10
71-Registered dietician/nutrition professional	ALL	1.00
72-Pain management	ALL	2.77
75-Slide preparation facilities	ALL	1.00
76-Peripheral vascular disease	ALL	6.75
77-Vascular surgery	ALL	6.75
78-Cardiac surgery	ALL	6.06
79-Addiction medicine	ALL	1.00
80-Licensed clinical social worker	ALL	1.00
81-Critical care (intensivists)	ALL	2.27
82-Hematology	ALL	1.79
83-Hematology/oncology	ALL	1.85
84-Preventive medicine	ALL	1.38
85-Maxillofacial surgery	ALL	2.61
86-Neuropsychiatry	ALL	1.02
90-Medical oncology	ALL	1.86
91-Surgical oncology	ALL	6.46
92-Radiation oncology	ALL	2.03
93-Emergency medicine	NO SURG	3.00
93-Emergency medicine	SURG	4.92
94-Interventional radiology	ALL	2.76
98-Gynecologist/oncologist	ALL	3.72
99-Unknown physician specialty	ALL	2.10
C0-Sleep medicine	ALL	1.61
C0-Sleep medicine	ALL	1.61
C3-Interventional cardiology	ALL	5.92
C6-Hospitalist	ALL	2.13
C7-Advanced heart failure & transplant cardiology	ALL	6.06

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Step (4): Calculate malpractice RVUs for each CPT/HCPCS code.

Resource-based MP RVUs were calculated for each CPT/HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective CPT/HCPCS code. This

percentage was then multiplied by each respective specialty's risk factor as calculated in Step 3. The products for all specialties for the CPT/HCPCS code were then added together, yielding a specialty-weighted service specific risk factor reflecting the weighted malpractice costs across all specialties furnishing that procedure. The service specific risk factor was multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service, to reflect differences in the complexity and risk-of-service between services.

Low volume service codes: As we discussed above in this proposed rule, for low volume services code, we finalized the proposal in the CY 2018 PFS final rule (82 FR 53000 through 53006) to apply the list of expected specialties instead of the claims-based specialty mix for low volume services to address stakeholder concerns about the year to year variability in PE and MP RVUs for low volume services (which also includes no volume services); these are defined as codes that have 100 allowed services or fewer. These service-level overrides are used to determine the specialty for low volume procedures for both PE and MP.

In the CY 2018 PFS final rule (82 FR 53000 through 53006), we also finalized our proposal to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we indicated that we would continue to consider, in conjunction with annual recommendations, specific recommendations regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, the specialty mix assumption for a new or revised code would derive from the analytic crosswalk in the first year, followed by the introduction of actual claims data, which is consistent with our approach for developing PE RVUs.

For CY 2020, we are soliciting public comment on the list of expected specialties. We also note that the list has been updated to include a column indicating if a service is identified as a low volume service for CY 2020, and therefore, whether or not the service-level override is being applied for CY 2020. The proposed list of codes and expected specialties is available on our website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource based MP RVUs are equal to the total current resource based MP RVUs scaled by the ratio of the pools of the proposed and current MP and work RVUs. This scaling is necessary to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

Specialties Excluded from Ratesetting Calculation: In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we discuss specialties that are excluded from ratesetting for the purposes of calculating PE RVUs. We are proposing to treat those excluded specialties in a consistent manner for the purposes of calculating MP RVUs. We note that all specialties are included for purposes of calculating the final BN adjustment. The list of specialties excluded from the ratesetting calculation for the purpose of calculating the PE RVUs that we are proposing to also exclude for the purpose of calculating MP RVUs is available in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units. The proposed resource based MP RVUs are shown in Addendum B, which is available on the CMS website under the downloads section of the CY 2020 PFS rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

Because a different share of the resources involved in furnishing PFS services is reflected in each of the three fee schedule components, implementation of the resource-based MP RVU update will have much smaller payment effects than implementing updates of resource-based work RVUs and resource-based PE RVUs. On average, work represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about 1 percent. Estimates of the effects on payment by specialty type can be found in section VI. of this proposed rule, Regulatory Impact Analysis.

Additional information on our proposed methodology for updating the MP RVUs is available in the ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' which is available on the CMS website under the downloads section of the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). We discuss the localities established under the PFS below in this section. Although the statute requires that the PE and MP GPCIs reflect full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2017. Section 50201 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, enacted February 9, 2018) amended the statute to extend the 1.0 floor for the work GPCIs through CY 2019 (that is, for services furnished no later than December 31, 2019).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, since the previous GPCI update was implemented in CYs 2017 and 2018, we are proposing to phase in ½ of the latest GPCI adjustment in CY 2020.

We have completed a review of the GPCIs and are proposing new GPCIs in this proposed rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each PFS localities work, PE and MP expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As noted above, section 50201 of the BBA of 2018 extended the 1.0 work GPCI floor for services furnished only through December 31, 2019. Therefore, the proposed CY 2020 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. However, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2020. See Addenda D and E to this proposed rule for the CY 2020 proposed GPCIs and summarized proposed GAFs available on the CMS website under the supporting documents section of the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

2. Payment Locality Background

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments under this system largely reflected the charging patterns of physicians, which resulted in large differences in payment for physicians' services among types of services, physician specialties and geographic payment areas.

Local Medicare carriers initially established 210 payment localities, to reflect local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. In 1994, we undertook a study that culminated in a comprehensive locality revision (based on locality resource cost differences as reflected by the GPCIs) that we implemented in 1997. The development of the current locality structure is described in detail in the CY 1997 PFS final rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). The revised locality structure reduced the number of localities from 210 to 89, and increased the number of statewide localities from 22 to 34.

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, enacted April 1, 2014) required modifications to the payment localities in California for payment purposes beginning with 2017. As a result, in the CY 2017 PFS final rule (81 FR 80265 through 80268) we established 23 additional localities, increasing the total number of PFS localities from 89 to 112. The 112 payment localities include 34 statewide areas (that is, only one locality for the entire state) and 75 localities in the other 16 states, with 10 states having two localities, two states having three localities, one state having four localities, and three states having five or more localities. The remainder of the 112 PFS payment localities are comprised as follows: The combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands. We note that the localities generally represent a grouping of one or more constituent counties.

The current 112 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate locality adjusted payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74384 through 74386) for further discussion regarding additional information about locality configuration considerations.

3. GPCI Update

As required by the statute, we developed GPCIs to measure relative cost differences among payment localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). We describe the data sources and methodologies we use to calculate each of the three GPCIs below in this section. Additional information on the CY 2020 GPCI update is available in an interim report, ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' on our website located under the supporting documents section for the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

a. Work GPCIs

The work GPCIs are designed to reflect the relative cost of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a

replacement for the 2006 through 2008 data to compute the work GPCIs; and for the CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed below, the employee wage component and purchased services component of the PE GPCI). Therefore, for the proposed CY 2020 GPCI update, we used updated BLS OES data (2014 through 2017) as a replacement for the 2011 through 2014 data to compute the work GPCIs.

b. Practice Expense (PE) GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs (not including MP expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2017), we used 2011 through 2014 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed previously in this section, because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2020 GPCI update, we used updated BLS OES data (2014 through 2017) as a replacement for the 2011 through 2014 data for purposes of calculating the employee wage component and purchased service index component of the PE GPCI. In calculating the proposed CY 2020 GPCI update, for the office rent index component of the PE GPCI we used the most recently available, 2013 through 2017, American Community Survey (ACS) 5-year estimates as a replacement for the 2009 through 2013 ACS data.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than losses occurring during the policy term). For the CY 2017 GPCI update, we used 2014 and 2015 malpractice premium data. The proposed CY 2020 MP GPCI update reflects premium data presumed in effect as of December 30, 2017. We note that we finalized a few technical refinements to the MP GPCI methodology in CY 2017, and refer readers to the CY 2017 PFS final rule (81 FR 80270) for additional discussion.

d. GPCI Cost Share Weights

For CY 2020 GPCIs, we are proposing to continue to use the current cost share weights for determining the PE GPCI values and locality GAFs. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that we also finalized for use in the CY 2017 GPCI update.

The proposed GPCI cost share weights for CY 2020 are displayed in Table 12.

TABLE 12—PROPOSED COST SHARE WEIGHTS FOR CY 2020 GPCI UPDATE

Expense category	Current cost share weight (%)	Proposed CY 2020 cost share weight (%)
Work	50.866	50.866
Practice Expense	44.839	44.839
—Employee Compensation	16.553	16.553
—Office Rent	10.223	10.223
—Purchased Services	8.095	8.095
—Equipment, Supplies, Other	9.968	9.968
Malpractice Insurance	4.295	4.295
Total	100.000	100.000

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier states effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in states determined to be frontier states. In general, a frontier state is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that

have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the states identified as Frontier States for the CY 2020 PFS proposed rule. The qualifying states are: Montana; Wyoming; North Dakota; South Dakota; and Nevada. In accordance with statute, we would apply a 1.0 PE GPCI floor for these states in CY 2020.

f. Methodology for Calculating GPCIs in the U.S. Territories

Prior to CY 2017, for all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories had minimal impact on GPCIs because we used either the Hawaii GPCIs (for the Pacific territories: Guam; American Samoa; and Northern Mariana Islands) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, in the CY 2017 PFS final rule (81 FR 80268 through 80270), we finalized a policy to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We refer readers to the CY 2017 PFS final rule for a comprehensive discussion of this policy.

g. California Locality Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure increased its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure; although for the purposes of payment the actual number of localities under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational consideration.

Section 1848(e)(6)(D) of the Act defined transition areas as the fee schedule areas for 2013 that were the rest-of-state locality, and locality 3, which was comprised of Marin County, Napa County, and Solano County. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the current PFS locality structure. That is, the GPCI values applicable for these areas during this transition period are a blend of what the GPCI values would have been for California under the current locality structure, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represents the fourth year, the applicable GPCI values for counties that were previously in rest-of-state or locality 3 and are now in MSAs are a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality structure, and ⅓ of the GPCI value calculated for the year under the current locality structure. The proportions continue to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas are a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the current locality structure. Beginning in CY 2022, the applicable GPCI values for counties in transition areas are the values calculated solely under the new MSA-based locality structure. For clarity, we reiterate that this incremental phase-in is only applicable to those counties that are in transition areas that are now in MSAs, which are only some of the counties in the 2013 California rest-of state locality and locality 3.

Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless for transition areas beginning with CY 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the current locality structure. There are a total of 58 counties in California, 50 of which are in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that are not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we finalized the policy to start by calculating the national GPCIs as if the current localities are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is implemented for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. However, since section 1848(e)(6)(B) of the Act provides for a gradual phase in of the GPCI values under the new MSA-based locality structure for California, specifically in one-sixth increments over 6 years, if we were to also apply the requirement to phase in ½ of the adjustment in year 1 of the GPCI update then the first year increment would effectively be 1/12. Therefore, in CY 2017, we finalized a policy that the requirement at section 1848(e)(1)(C) of the Act to phase in ½ of the adjustment in year 1 of the GPCI update would not apply to counties that were previously in the rest-of-state or locality 3 and are now in MSAs that are subject to the blended phase-in as described above in this section. We reiterate that this is only applicable through CY 2021 since, beginning in CY 2022, the GPCI values for such areas in an MSA would be fully based on the values calculated under the new MSA-based locality structure for California. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

h. Refinements to the GPCI Methodology

In the process of calculating GPCIs for the purposes of this proposed rule, we identified two technical refinements to the methodology that yield improvements over the current method; these refinements are applicable to the work GPCI and the employee wage index and purchased services index components of the PE GPCI. We are proposing to weight by total employment when computing county median wages for each occupation code which addresses the fact that the occupation wage can vary by industry within a county. Additionally, we are also proposing to use a weighted average when calculating the final county-level wage index; this removes the possibility that a county index would imply a wage of 0 for any occupation group not present in the county's data. These proposed methodological refinements yield improved mathematical precision. Additional information on the GPCI methodology and the proposed refinements are available in the interim report, ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule'' on our website located under the supporting documents section of the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

i. Proposed GPCI Update Summary

As explained above in the Background section above, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The proposed CY 2020 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on our website under the supporting documents section of the CY 2020 PFS proposed rule web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

E. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.N. of this proposed rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the RUC, MedPAC, and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the

same service between different sites of service.

- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well. Individuals and stakeholder groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare and Medicaid Service, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes''. Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed approximately 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; Final Rule (76 FR 73052 through 73055) (hereinafter referred to as the CY 2012 PFS final rule with comment period). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (77 FR 68892) (hereinafter referred to as the CY 2013 PFS final rule with comment period), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (73 FR 38589) (hereinafter referred to the CY 2009 PFS proposed rule), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time).

In the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 final rule with comment period (80 FR 70886) (hereinafter referred to as the CY 2016 PFS final rule with comment period), we finalized for review a list of potentially misvalued services, which included eight codes in the neurostimulators analysis-programming family (CPT codes 95970–95982). We also finalized as potentially misvalued 103 codes identified through our screen of high expenditure services across specialties.

In the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements final rule (81 FR 80170) (hereinafter referred to as the CY 2017 PFS final rule), we finalized for review a list of potentially misvalued services, which included eight codes in the end-stage renal disease home dialysis family (CPT codes 90963–90970). We also finalized as potentially misvalued 19 codes

identified through our screen for 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

In the CY 2018 PFS final rule, we finalized arthrodesis of sacroiliac joint (CPT code 27279) as potentially misvalued. Through the use of comment solicitations with regard to specific codes, we also examined the valuations of other services, in addition to, new potentially misvalued code screens (82 FR 53017 through 53018).

3. CY 2020 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

We received three submissions that nominated codes for review under the potentially misvalued code initiative, prior to our February 10, 2019 deadline. In addition to three public nominations, CMS also nominated one additional code for review.

One commenter requested that CMS consider CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*) for nomination as potentially misvalued. We note that these two CPT codes were recently reviewed within a family of 13 similar codes. Our review of these codes and our rationale for finalizing the current values are discussed extensively in the CY 2019 PFS final rule (83 FR 59517). For CPT code 10021, the RUC recommended a 32 percent reduction from its previous physician time and a 5 percent reduction in the work RVU. The commenter disagreed with this change and stated that there was a change in intensity of the procedure now as compared to what it was in 1995 when this code was last evaluated. The commenter also stated that there was a change in intensity of the work performed due to use of more complicated equipment, more stringent specimen sampling that allow for extensive examination of smaller and deeper lesions within the body. The commenter disagreed with the CMS' crosswalked CPT code 36440 (*Push blood transfusion, patient 2 years or younger*) and presented CPT codes 40490 (*Biopsy of lip*) and 95865 (*Needle measurement and recording of electrical activity of muscles of voice box*) as more appropriate crosswalks.

Another commenter requested that CMS consider HCPCS code G0166 (*External counterpulsation, per treatment session*) as potentially misvalued. This code was reviewed for the CY 2019 PFS final rule (83 FR 59578), and the work RVU and direct PE inputs as recommended by the AMA RUC were finalized by CMS. We finalized the valuation of this code with no refinements. However, the commenter noted that the PE inputs that were considered for this code did not fully reflect the total resources required to deliver the service. We will review the commenter's submission of additional new data and public comments received in combination with what was previously presented in the CY 2019 PFS final rule.

CMS nominated CPT code 76377 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation*) as potentially misvalued. CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*) was reviewed by the AMA RUC at the April 2018 RUC meeting. However, CPT code 76377, which is very similar to CPT code 76376, was not reviewed, and is likely now misvalued, in light of the similarities between the two codes. The specialty societies noted that the two codes are different because they are utilized by different patient populations (as evidenced by the ICD–10 diagnoses); however, we view both codes to be similar enough that CPT code 76377 should be reviewed to maintain relativity in the code family.

We are proposing the aforementioned public and CMS nominated codes as potentially misvalued and welcome public comment on these codes.

Another commenter provided information to CMS in which they stated that the work involved in furnishing services represented by the office/outpatient evaluation and management (E/M) code set (CPT codes 99201–99215) has changed sufficiently to warrant revaluation. Specifically, the commenter stated that these codes have not been reviewed in over 12 years and in that time have suffered passive devaluation as more and more procedures and other services have been added to the CPT code set, which are subsequently valued in a budget neutral manner, through notice and comment rulemaking, on the Medicare PFS. The commenter also stated that re-evaluation of these codes is critical to the success

of CMS' objective of advancing value-based care through the introduction of advanced alternative payment models (APMs) as these APMs rely on the underlying E/M codes as the basis for payment or reference price for bundled payments.

We acknowledge the points made by the commenter, and continue to consider the best ways to recognize the significant changes in healthcare practice as discussed by the commenter. We agree, in principle, that the existing set of office/outpatient E/M CPT codes may not be correctly valued. In recent years, we have specifically considered how best to update and revalue the E/M codes, which represent a significant proportion of PFS expenditures, and have also engaged in ongoing dialogue with the practitioner community. In the CY 2019 PFS proposed and final rules, in part due to these ongoing stakeholder discussions, we proposed and finalized changes to E/M payment and documentation requirements to implement policy objectives focused on reducing provider documentation burden (83 FR 59625). Concurrently, the CPT Editorial Panel, under similar burden reduction guiding principles, convened a workgroup and proposed to refine and revalue the existing E/M office/outpatient code set. We thank the commenter for the views represented in their comment. As stated earlier in this section, we agree in principle that the existing set of office/outpatient E/M CPT codes may not be correctly valued, and therefore, we will continue to consider opportunities to revalue these codes, in light of their significance to payment for services billed under Medicare.

Table 13 lists the HCPCS and CPT codes that we are proposing as potentially misvalued.

TABLE 13—HCPCS AND CPT CODES PROPOSED AS POTENTIALLY MISVALUED

CPT/HCPCS code	Short description
10005	Fna bx w/us gdn 1st les.
10021	Fna bx w/o img gdn 1st les.
76377	3d render w/intrp postproces.
G0166	Extrnl counterpulse, per tx.

F. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in this rule and in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. For further details, *see* the full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and in 42 CFR 410.78 and 414.65.

1. Adding Services to the List of Medicare Telehealth Services

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us. Under this process, we assign any submitted request to add to the list of telehealth services to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The list of telehealth services, including the proposed additions described later in this section, can be located on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Historically, requests to add services to the list of Medicare telehealth services had to be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. However, beginning in CY 2019 we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC. For example, to be considered during PFS rulemaking for CY 2021, requests to add services to the list of Medicare telehealth services must be submitted and received by February 10, 2020. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the list of Medicare telehealth services, requesters should be advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the list of Medicare telehealth services, including where to mail these requests, *see* our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

2. Requests To Add Services to the List of Telehealth Services for CY 2020

Under our current policy, we add services to the telehealth list on a Category 1 basis when we determine that they are similar to services on the existing telehealth list for the roles of,

and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We did not receive any requests from the public for additions to the Medicare Telehealth list for CY 2020. We believe that the vast majority of services under the PFS that can be appropriately furnished as Medicare telehealth services have already been added to the list.

However, there are three HCPCS G-codes describing new services being proposed in section II.H. of this rule for CY 2020 which we believe are sufficiently similar to services currently on the telehealth list to be added on a Category 1 basis. Therefore, we are proposing to add the face-to-face portions of the following services to the telehealth list on a Category 1 basis for CY 2020:

- HCPCS code GYYY1: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code GYYY2: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code GYYY3: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

Similar to our addition of the required face-to-face visit component of TCM services to the Medicare Telehealth list in the CY 2014 PFS final rule with comment period (78 FR 74403), since HCPCS codes GYYY1, GYYY2, and GYYY3 include face-to-face psychotherapy services, we believe that the face-to-face portions of these services are sufficiently similar to services currently on the list of Medicare telehealth services for these services to be added under Category 1. Specifically, we believe that the psychotherapy portions of the bundled codes are similar to the psychotherapy codes described by CPT codes 90832 and 90853, which are currently on the Medicare telehealth services list. We note that like certain other non-face-to-face PFS services, the other components of HCPCS codes GYYY1–3 describing care coordination are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, we do not need to consider whether the non-face-to-face aspects of HCPCS codes GYYY1–3 are similar to other telehealth services. Were these components of HCPCS codes GYYY1–3 separately billable, they would not need to be on the Medicare telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology.

As discussed in the CY 2019 PFS final rule (83 FR 59496), we note that section 2001(a) of the SUPPORT Act (Pub. L. 115–271, October 24, 2018) amended section 1834(m) of the Act, adding a new paragraph (7) that removes the geographic limitations for telehealth services furnished on or after July 1, 2019, for individuals diagnosed with a substance use disorder (SUD) for the purpose of treating the SUD or a co-occurring mental health disorder. Section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. Section 2001(a) of the SUPPORT Act additionally amended section 1834(m) of the Act to require that no originating site facility fee will be paid in instances when the individual's home is the originating site. We believe that adding HCPCS codes GYYY1, GYYY2, and GYYY3 will complement the existing policies related to flexibilities in treating SUDs under Medicare Telehealth.

We note that we welcome public nominations for additions to the Medicare telehealth list. More information on the nomination process is posted under the Telehealth section of the CMS website, which can be accessed at the following web address *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

G. Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Overview

Opioid use disorder (OUD) and deaths from prescription and illegal opioid overdoses have reached alarming levels. The Centers for Disease Control and Prevention (CDC) estimated 47,000 overdose deaths were from opioids in 2017 and 36 percent of those deaths were from prescription opioids.[1] OUD has become a public health crisis. On October 26, 2017, Acting Health and Human Services Secretary, Eric D. Hargan declared a nationwide public health emergency on the opioid crisis as requested by President Donald Trump.[2] This public health emergency was renewed by Secretary Alex M. Azar II on January 24, 2018, April 24, 2018, July 23, 2018, and October 21, 2018, January 17, 2019 and most recently, on April 19, 2019.[3]

The Medicare population, including individuals who are eligible for both Medicare and Medicaid, has the fastest growing prevalence of OUD compared to the general adult population, with more than 300,000 beneficiaries diagnosed with OUD in 2014.[4] An effective treatment for OUD is known as medication-assisted treatment (MAT). The Substance Abuse and Mental Health Services Administration (SAMHSA) defines MAT as the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder (42 CFR 8.2). Currently, Medicare covers medications for MAT, including buprenorphine, buprenorphine-naloxone combination products, and extended-release injectable naltrexone under Part B or Part D, but does not cover methadone. Medicare also covers counseling and behavioral therapy services that are reasonable and necessary and furnished by practitioners that can bill and receive payment under Medicare.

Historically, Medicare has not covered methadone for MAT because of the unique manner in which this drug is dispensed and administered. Medicare Part B covers physician-administered drugs, drugs used in

[1] *https://www.cdc.gov/drugoverdose/data/index.html.*

[2] *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[3] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-19apr2019.aspx.*

[4] *https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238.*

conjunction with durable medical equipment, and certain other statutorily specified drugs. Medicare Part D covers drugs that are dispensed upon a prescription by a pharmacy. Methadone for MAT is not a drug administered by a physician under the incident to benefit like other MAT drugs (that is, implanted buprenorphine or injectable extended-release naltrexone) and therefore has not previously been covered by Medicare Part B. Methadone for MAT is also not a drug dispensed by a pharmacy like certain other MAT drugs (that is buprenorphine or buprenorphine-naloxone combination products) and therefore is not covered under Medicare Part D. Methadone for MAT is a schedule II controlled substance that is highly regulated because it has a high potential for abuse which may lead to severe psychological or physical dependence. As a result, methadone for MAT can only be dispensed and administered by an opioid treatment program (OTP) as provided under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) and 42 CFR part 8. Additionally, OTPs, which are healthcare entities that focus on providing MAT for people diagnosed with OUD, were not previously entities that could bill and receive payment from Medicare for the services they furnish. Therefore, there has historically been a gap in Medicare coverage of MAT for OUD since methadone (one of the three FDA-approved drugs for MAT) has not been covered.

Section 2005 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018) added a new section 1861(jjj) to the Act, establishing a new Part B benefit category for OUD treatment services furnished by an OTP beginning on or after January 1, 2020. Section 1861(jjj)(1) of the Act defines OUD treatment services as items and services furnished by an OTP (as defined in section 1861(jjj)(2)) for treatment of OUD. Section 2005 of the SUPPORT Act also amended the definition of ''medical and other health services'' in section 1861(s) of the Act to provide for coverage of OUD treatment services and added a new section 1834(w) to the Act and amended section 1833(a)(1) of the Act to establish a bundled payment to OTPs for OUD treatment services furnished during an episode of care beginning on or after January 1, 2020.

OTPs must have a current, valid certification from SAMHSA to satisfy the Controlled Substances Act registration requirement under 21 U.S.C. 823(g)(1). To obtain SAMHSA certification, OTPs must have a valid accreditation by an accrediting body approved by SAMHSA, and must be certified by SAMHSA as meeting federal opioid treatment standards in 42 CFR 8.12. There are currently about 1,700 OTPs nationwide.[5] All states except Wyoming have OTPs. Approximately 74 percent of patients receiving services from OTPs receive methadone for MAT, with the vast majority of the remaining patients receiving buprenorphine.[6]

Many payers currently cover MAT services for treatment of OUD. Medicaid [7] is one of the largest payers of medications for substance use disorder (SUD), including methadone for MAT provided in OTPs.[8] OUD treatment services and MAT are also covered by other payers such as TRICARE and private insurers. TRICARE established coverage and payment for MAT and OUD treatment services furnished by OTPs in late 2016 (81 FR 61068). In addition, as discussed in the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020'' proposed rule, many qualified health plans covered MAT medications for plan year 2018 (84 FR 285).

In the CY 2019 PFS final rule (83 FR 59497), we included a Request for Information (RFI) to solicit public comments on the implementation of the new Medicare benefit category for OUD treatment services furnished by OTPs established by section 2005 of the SUPPORT Act. We received 9 public comments. Commenters were generally supportive of the new benefit and expanding access to OUD treatment for Medicare beneficiaries. We received feedback that the bundled payments to OTPs should recognize the intensity of services furnished in the initiation stages, durations of care, the needs of patients with more complex needs, costs of emerging technologies, and use of peer support groups. We also received feedback that costs associated with care coordination among the beneficiary's practitioners should be included in the bundled payment given the myriad of health issues beneficiaries with OUD face. We considered this feedback as we developed our proposals for implementing the new benefit category for OUD treatment services furnished by OTPs and the proposed bundled payments for these services.

To implement section 2005 of the SUPPORT Act, we are proposing to establish rules to govern Medicare coverage of and payment for OUD treatment services furnished in OTPs. In the following discussion, we propose to establish definitions of OUD treatment services and OTP for purposes of the Medicare Program. We also propose a methodology for determining Medicare payment for such services provided by OTPs. We are proposing to codify these policies in a new section of the regulations at § 410.67. For a discussion about Medicare enrollment requirements and the proposed program integrity approach for OTPs, we refer readers to section III.H. Medicare Enrollment of Opioid Treatment Programs, in this proposed rule.

2. Proposed Definitions

a. Opioid Use Disorder Treatment Services

The SUPPORT Act amended section 1861 of the Act by adding a new subsection (jjj)(1) that defines ''opioid use disorder treatment services'' as the items and services that are furnished by an OTP for the treatment of OUD, as set forth in subparagraphs (A) through (F) of section 1861(jjj)(1) of the Act which include:

- Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 355) for use in the treatment of OUD;
- Dispensing and administration of such medications, if applicable;
- Substance use counseling by a professional to the extent authorized under state law to furnish such services;
- Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under state law);
- Toxicology testing; and
- Other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation).

As described previously, section 1861(jjj)(1)(A) of the Act defines covered OUD treatment services to include oral,

[5] *https://dpt2.samhsa.gov/treatment/directory.aspx.*

[6] *https://wwwdasis.samhsa.gov/dasis2/nssats.htm.*

[7] Medicaid provides health care coverage to 65.9 million Americans, including low-income adults, children, pregnant women, elderly adults and people with disabilities. Medicaid is administered by states, according to federal requirements, and is funded jointly by states and the federal government. States have the flexibility to administer the Medicaid program to meet their own state needs within the Medicaid program parameters set forth in federal statute and regulations. As a result, there is variation in how each state implements its programs.

[8] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

injected, and implanted opioid agonist and antagonist medications approved by FDA under section 505 of the FFDCA for use in the treatment of OUD. There are three drugs currently approved by the FDA for the treatment of opioid dependence: Buprenorphine, methadone, and naltrexone.[9] FDA notes that all three of these medications have been demonstrated to be safe and effective in combination with counseling and psychosocial support and that those seeking treatment for an OUD should be offered access to all three options as this allows providers to work with patients to select the medication best suited to an individual's needs.[10] Each of these medications is discussed below in more detail.

Buprenorphine is FDA-approved for acute and chronic pain in addition to opioid dependence. It is listed by the Drug Enforcement Administration (DEA) as a Schedule III controlled substance because of its moderate to low potential for physical and psychological dependence.[11] [12] The medication's partial agonist properties allow for its use in opioid replacement therapy, which is a process of treating OUD by using a substance, for example, buprenorphine or methadone, to substitute for a stronger full agonist opioid.[13] Buprenorphine drug products that are currently FDA-approved and marketed for the treatment of opioid dependence include oral buprenorphine and naloxone [14] films and tablets, an extended-release buprenorphine injection for subcutaneous use, and a buprenorphine implant for subdermal administration.[15] In most patients with opioid dependence, the initial oral dose is 2 to 4 mg per day with a maintenance dose of 8–12 mg per day.[16] Dosing for the extended-release injection is 300 mg monthly for the first 2 months followed by a maintenance dose of 100 mg monthly.[17] The extended-release injection is indicated for patients who have initiated treatment with an oral buprenorphine product for a minimum of 7 days.[18] The buprenorphine implant consists of four rods containing 74.2 mg of buprenorphine each, and provides up to 6 months of treatment for patients who are clinically stable on low-to-moderate doses of an oral buprenorphine-containing product.[19] Currently, federal regulations permit buprenorphine to be prescribed or dispensed by qualifying physicians and qualifying other practitioners at office-based practices and dispensed in OTPs.[20] [21]

Methadone is FDA-approved for management of severe pain in addition to opioid dependence. It is listed by the DEA as a Schedule II controlled substance because of its high potential for abuse, with use potentially leading to severe psychological or physical dependence.[22] [23] Methadone drug products that are FDA-approved for the treatment of opioid dependence include oral methadone concentrate and tablets.[24] In patients with opioid dependence, the total daily dose of methadone on the first day of treatment should not ordinarily exceed 40 mg, unless the program physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence, with clinical stability generally achieved at doses between 80 to 120 mg/day.[25] By law, methadone can only be dispensed through an OTP certified by SAMHSA.[26]

Naltrexone is FDA-approved to treat alcohol dependence in addition to opioid use disorder.[27] Unlike buprenorphine and methadone, which activate opioid receptors, naltrexone binds and blocks opioid receptors and reduces opioid cravings.[28] Therefore, naltrexone is not a scheduled substance; there is no abuse and diversion potential with naltrexone.[29] [30] The naltrexone drug product that is FDA-approved for the treatment of opioid dependence is an extended-release, intramuscular injection.[31] The recommended dose is 380 mg delivered intramuscularly every 4 weeks or once a month after the patient has achieved an opioid-free duration of a minimum of 7–10 days.[32] Naltrexone can be prescribed by any health care provider who is licensed to prescribe medications.[33]

We propose that the OUD treatment services that may be furnished by OTPs include the first five items and services listed in the statutory definition described above, specifically the medications approved by the FDA under section 505 of the FFDCA for use in the treatment of OUD; the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing. We also propose to use our discretion under section 1861(jjj)(1)(F) of the Act to include other items and services that the Secretary determines are appropriate to include the use of telecommunications for certain services, as discussed later in this section. We propose to codify this definition of OUD treatment services furnished by OTPs at § 410.67(b). As part of this definition, we also propose to specify that an OUD treatment service is an item or service that is furnished by an OTP that meets the applicable requirements to participate in the Medicare Program and receive payment.

We seek comment on any other items and services (not including meals or transportation as they are statutorily prohibited) currently covered and paid for under Medicare Part B when furnished by Medicare-enrolled providers/suppliers that the Secretary should consider adding to this definition, including any evidence supporting the impact of the use of such items and services in the treatment of OUD and enumeration of their costs. We are particularly interested in public feedback on whether intake activities, which may include services such as an initial physical examination, initial assessments and preparation of a treatment plan, as well as periodic assessments, should be included in the definition of OUD treatment services. Additionally, we understand that while the current FDA-approved medications under section 505 of the FFDCA for the treatment of OUD are opioid agonists and antagonist medications, other

[9] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[10] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[11] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[12] *https://www.dea.gov/drug-scheduling.*

[13] *https://www.ncbi.nlm.nih.gov/books/NBK459126/.*

[14] Naloxone is added to buprenorphine in order to reduce its abuse potential and limit diversion.

[15] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[16] *https://www.ncbi.nlm.nih.gov/books/NBK459126/.*

[17] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

[18] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

[19] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204442s006lbl.pdf.*

[20] *https://www.fda.gov/Drugs/NewsEvents/ucm611659.htm.*

[21] 21 U.S.C. 823(g)(2).

[22] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[23] *https://www.dea.gov/drug-scheduling.*

[24] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[25] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/017116s032lbl.pdf.*

[26] *https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone.*

[27] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021897s042lbl.pdf.*

[28] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

[29] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[30] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

[31] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[32] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021897s042lbl.pdf.*

[33] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

medications that are not opioid agonist and antagonist medications, including drugs and biologicals, could be developed for the treatment of OUD in the future. We would like public feedback on whether there are any drug development efforts in the pipeline that could result in medications intended for use in the treatment of OUD with a novel mechanism of action that does not involve opioid agonist and antagonist mechanisms (that is, outside of activating and/or blocking opioid receptors). We also welcome comment on how medications that may be approved by the FDA in the future for use in the treatment of OUD with a novel mechanism of action, such as medications approved under section 505 of the FFDCA to treat OUD and biological products licensed under section 351 of the Public Health Service Act to treat OUD, should be considered in the context of OUD treatment services provided by OTPs, and whether CMS should use the discretion afforded under section 1861(jjj)(1)(F) of the Act to include such medications in the definition of OUD treatment services given the possibility that such medications could be approved in the future.

b. Opioid Treatment Program

Section 2005 of the SUPPORT Act also amended section 1861 of the Act by adding a new subsection (jjj)(2) to define an OTP as an entity meeting the definition of OTP in 42 CFR 8.2 or any successor regulation (that is, a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1)), that meets the additional requirements set forth in subparagraphs (A) through (D) of section 1861(jjj)(2) of the Act. Specifically that the OTP:

- Is enrolled under section 1866(j) of the Act;
- Has in effect a certification by SAMHSA for such a program;
- Is accredited by an accrediting body approved by SAMHSA; and
- Meets such additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services.

These requirements are discussed in more detail in this section.

(1) Enrollment

As discussed previously, under section 1861(jjj)(2)(A) of the Act, an OTP must be enrolled in Medicare to receive Medicare payment for covered OUD treatment services under section 1861(jjj)(1) of the Act. We refer the reader to section III.H. of this proposed rule, Medicare Enrollment of Opioid Treatment Programs, for further details on our proposed policies related to enrollment of OTPs.

(2) Certification by SAMHSA

As provided in section 1861(jjj)(2)(B) of the Act, OTPs must be certified by SAMHSA to furnish Medicare-covered OUD treatment services. SAMHSA has created a system to certify and accredit OTPs, which is governed by 42 CFR part 8, subparts B and C. This regulatory framework allows SAMHSA to focus its oversight efforts on improving treatment rather than solely ensuring that OTPs are meeting regulatory criteria, and preserves states' authority to regulate OTPs. To be certified by SAMHSA, OTPs must comply with the federal opioid treatment standards as outlined in § 8.12, be accredited by a SAMHSA-approved accreditation body, and comply with any other conditions for certification established by SAMHSA. Specifically, SAMHSA requires OTPs to provide the following services:

- *General*—OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services.
- *Initial medical examination services*—OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP.
- *Special services for pregnant patients*—OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services for pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.
- *Initial and periodic assessment services*—Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment.
- *Counseling services*—OTPs must provide adequate substance abuse counseling to each patient as clinically necessary by a program counselor, qualified by education, training, or experience to assess the patient's psychological and sociological background.
- *Drug abuse testing services*—OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, defined in 42 CFR 8.2 as detoxification treatment not in excess of 30 days, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

The provisions governing recordkeeping and patient confidentiality at § 8.12(g)(1) require that OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. All records are required to be kept confidential in accordance with all applicable federal and state requirements. The requirements at § 8.12(g)(2) state that OTPs shall document in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances, which is determined by the medical director or program physician of the OTP in which the patient is enrolled (42 CFR 8.12(g)(2)). Additionally, the requirements at § 8.12(h) address medication administration, dispensing, and use.

SAMHSA requires that OTPs shall ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. OTPs shall use only those opioid agonist treatment medications that are approved by the FDA for use in the treatment of OUD. They must maintain current procedures that are adequate to ensure that the dosing requirements are met, and each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling.

At § 8.12(i), regarding unsupervised or ''take-home'' use of opioid agonist treatment medications, SAMHSA has specified that OTPs must follow requirements specified by SAMHSA to limit the potential for diversion of opioid agonist treatment medications to the illicit market when dispensed to patients as take-homes, including maintaining current procedures to identify the theft or diversion of take-

home medications. The requirements at § 8.12(j) for interim maintenance treatment, state that the program sponsor of a public or nonprofit private OTP subject to the approval of SAMHSA and the state, may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. Patients in interim maintenance treatment are permitted to receive daily dosing, but take-homes are not permitted. During interim maintenance treatment, initial treatment plans and periodic treatment plan evaluations are not required and a primary counselor is not required to be assigned to the patient. The OTP must be able to transfer these patients from interim maintenance into comprehensive maintenance treatment within 120 days. Interim maintenance treatment must be provided in a manner consistent with all applicable federal and state laws.

The SAMHSA requirements at § 8.12(b) address administrative and organizational structure, requiring that an OTP's organizational structure and facilities shall be adequate to ensure quality patient care and meet the requirements of all pertinent federal, state, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director who is a physician who is licensed to practice medicine in the jurisdiction in which the OTP is located. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in 42 CFR part 8, subpart C and any regulations regarding the use of opioid agonist treatment medications in the treatment of OUD, which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable federal, state, and local laws and regulations.

The provision governing patient admission criteria at § 8.12(e) requires that an OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual of Mental Disorders, including that the person has an OUD, and that the person has had an OUD at least 1 year before admission for treatment. If under 18 years of age, the patient is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period and have the written consent of a parent, legal guardian or responsible adult designated by the relevant state authority to be eligible for maintenance treatment.

To ensure continuous quality improvement, the requirements at § 8.12(c) state that an OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes and a current Diversion Control Plan as part of its quality assurance program.

The requirements at § 8.12(d) with respect to staff credentials, state that each person engaged in the treatment of OUD must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.

In addition to meeting the criteria described above, OTPs must apply to SAMHSA for certification. As part of the conditions for certification, SAMHSA specifies that OTPs shall:

- Comply with all pertinent state laws and regulations.
- Allow inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, by the DEA, and by authorized employees of any relevant State or federal governmental authority.
- Comply with the provisions of 42 CFR part 2 (regarding confidentiality of substance use disorder patient records).
- Notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.
- Comply with all regulations enforced by the DEA under 21 CFR chapter II, and be registered by the DEA before administering or dispensing opioid agonist treatment medications.
- Operate in accordance with federal opioid treatment standards and approved accreditation elements.

Furthermore, SAMHSA has issued additional guidance for OTPs that describes how programs can achieve and maintain compliance with federal regulations.[34]

[34] *https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf.*

(3) Accreditation of OTPs by a SAMHSA-Approved Accrediting Body

As provided in section 1861(jjj)(2)(C) of the Act, OTPs must be accredited by a SAMHSA-approved accrediting body in order to furnish Medicare-covered OUD treatment services. In 2001, the Department of Health and Human Services (HHS) and SAMHSA issued final regulations to establish a new oversight system for the treatment of substance use disorders with MAT (42 CFR part 8). SAMHSA-approved accrediting bodies evaluate OTPs and perform site visits to ensure SAMHSA's opioid dependency treatment standards are met. SAMHSA also requires OTPs to be accredited by a SAMHSA-approved accrediting body (42 CFR 8.11).

The SAMHSA regulations establish procedures for an entity to apply to become a SAMHSA-approved accrediting body (42 CFR 8.3). When determining whether to approve an applicant as an accreditation body, SAMHSA examines the following:

- Evidence of the nonprofit status of the applicant (that is, of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a state governmental entity or political subdivision;
- The applicant's accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the federal opioid treatment standards set forth in § 8.12;
- A detailed description of the applicant's decision-making process, including:

++ Procedures for initiating and performing onsite accreditation surveys of OTPs;

++ Procedures for assessing OTP personnel qualifications;

++ Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process;

++ Policies and procedures for notifying OTPs and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs; for suspending or revoking an OTP's accreditation; and to ensure processing of applications for accreditation and for renewal of accreditation within a timeframe approved by SAMHSA; and;

++ A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions.

- Policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest;

• A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the applicant's staff;
• A description of the applicant's training policies;
• Fee schedules, with supporting cost data;
• Satisfactory assurances that the applicant will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);
• Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body; and
• Any other information SAMHSA may require.

SAMHSA periodically evaluates the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the federal opioid treatment standards. There are currently six SAMHSA-approved accreditation bodies.[35]

(4) Provider Agreement

Section 2005(d) of the SUPPORT Act amends section 1866(e) of the Act by adding a new paragraph (3) which includes opioid treatment programs (but only with respect to the furnishing of opioid use disorder treatment services) as a ''provider of services'' for purposes of section 1866 of the Act. All providers of services under section 1866 of the Act must enter into a provider agreement with the Secretary and comply with other requirements specified in that section. These requirements are implemented at 42 CFR part 489. Therefore, we are proposing to amend part 489 to include OTPs (but only with respect to the furnishing of opioid use disorder treatment services) as a provider. Specifically, we are proposing to add OTPs (but only with respect to the furnishing of opioid use disorder treatment services) to the list of providers in § 489.2. This addition makes clear that the other requirements specified in Section 1866, and implemented in part 489, which include the limits on charges to beneficiaries, would apply to OTPs (with respect to the furnishing of opioid use disorder treatment services). We are also proposing additional changes to make clear that certain parts of part 489, which implement statutory requirements other than section 1866 of the Act, do not apply to OTPs. For example, since we are not proposing any conditions of participation for OTPs, we are proposing to amend § 489.10(a), which states that providers specified in § 489.2 must meet conditions of participation, to add that OTPs must meet the requirements set forth in part 489 and elsewhere in that chapter. In addition, we are proposing to specify that the effective date of the provider agreement is the date on which CMS accepts a signed agreement (proposed amendment to § 489.13(a)(2)), and is not dependent on surveys or an accrediting organization's determination related to conditions of participation. Finally, as noted earlier in the preamble, OTPs are required to be certified by SAMHSA and accredited by an accrediting body approved by SAMHSA. In § 489.53, we are proposing to create a basis for termination of the provider agreement if the OTP no longer meets the requirements set forth in part 489 or elsewhere in that chapter (including if it no longer has a SAMHSA certification or accreditation by a SAMHSA-approved accrediting body). Finally, we are also proposing to revise 42 CFR part 498 to ensure that OTPs have access to the appeal process in case of an adverse determination concerning continued participation in the Medicare program. Specifically, we are amending the definition of provider in § 498.2 to include OTPs. We are continuing to review the application of the provider agreement requirements to OTPs and may make further amendments to parts 489 and 498 as necessary to ensure that the existing provider agreement regulations are applied to OTPs consistent with our proposals and Section 2005 of the SUPPORT Act.

(5) Additional Conditions

As provided in section 1861(jjj)(2)(D) of the Act, to furnish Medicare-covered OUD treatment services, OTPs must meet any additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services. The comprehensive OTP standards for certification of OTPs address the same topics as would be addressed by CMS supplier standards, such as client assessment and the services required to be provided. Furthermore, the detailed process established by SAMHSA for selecting and overseeing its accreditation organizations is similar to the accrediting organization oversight process that would typically be established by CMS. Thus, we believe the existing SAMHSA certification and accreditation requirements are both appropriate and sufficient to ensure the health and safety of individuals being furnished services by OTPs, as well as the effective and efficient furnishing of such services. We also believe that creating additional conditions at this time for participation in Medicare by OTPs could create unnecessary regulatory duplication and could be potentially burdensome for OTPs. Therefore, CMS is not proposing any additional conditions for participation in Medicare by OTPs at this time. We welcome public comments on this proposed approach, including input on whether there are any additional conditions that should be required for OTPs furnishing Medicare-covered OUD treatment services.

(6) Proposed Definition of Opioid Treatment Program

We propose to define ''opioid treatment program'' at § 410.67(b) as an entity that is an opioid treatment program as defined in 42 CFR 8.2 (or any successor regulation) and meets the applicable requirements for an OTP. We propose to codify this definition at § 410.67(b). In addition, we propose that for an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled under section 1866(j) of the Act, have in effect a certification by SAMHSA for such a program, and be accredited by an accrediting body approved by SAMHSA. We are also proposing that an OTP must have a provider agreement as required by section 1866(a) of the Act. We propose to codify these requirements at § 410.67(c). We welcome public comments on the proposed definition of OTP and the proposed Medicare requirements for OTPs.

3. Proposed Bundled Payments for OUD Treatment Services

Section 1834(w) of the Act, added by section 2005 of the SUPPORT Act, directs the Secretary to pay to the OTP an amount that is equal to 100 percent of a bundled payment for OUD treatment services that are furnished by the OTP to an individual during an episode of care. We are proposing to establish bundled payments for OUD treatment services which, as discussed above, would include the medications approved by the FDA under section 505

[35] *https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-accrediting-bodies/approved.*

of the FFDCA for use in the treatment of OUD; the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing. In calculating the proposed bundled payments, we propose to apply separate payment methodologies for the drug component (which includes the medications approved by the FDA under section 505 of the FFDCA for use in the treatment of OUD) and the non-drug component (which includes the dispensing and administration of such medications, if applicable; substance use counseling; individual and group therapy; and toxicology testing) of the bundled payments. We propose to calculate the full bundled payment rate by combining the drug component and the non-drug components. Below, we discuss our proposals for determining the bundled payments for OUD treatment services. As part of this discussion, we address payment rates for these services under the Medicaid and TRICARE programs, duration of the episode of care for which the bundled payment is made (including partial episodes), methodology for determining bundled payment rates for the drug and non-drug components, site of service, coding and beneficiary cost sharing. We propose to codify the methodology for determining the bundled payment rates for OUD treatment services at § 410.67(d).

a. Review of Medicaid and TRICARE Programs

Section 1834(w)(2) of the Act, added by section 2005(c) of the SUPPORT Act, provides that in developing the bundled payment rates for OUD treatment services furnished by OTPs, the Secretary may consider payment rates paid to the OTPs for comparable services under the state plans under title XIX of the Act (Medicaid) or under the TRICARE program under chapter 55 of title 10 of the United States Code (U.S.C.). The payments for comparable services under TRICARE and Medicaid programs are discussed below. We understand that many private payers cover services furnished by OTPs, and welcome comment on the scope of private payer OTP coverage and the payment rates private payers have established for OTPs furnishing comparable OUD treatment services. We may consider this information as part of the development of the final bundled payment rates for OUD treatment services furnished by OTPs in the final rule.

(1) TRICARE

In the ''TRICARE: Mental Health and Substance Use Disorder Treatment'' final rule, which appeared in the September 2, 2016 **Federal Register** (81 FR 61068) (hereinafter referred to as the 2016 TRICARE final rule), the Department of Defense (DOD) finalized its methodology for determining payments for services furnished to TRICARE beneficiaries by an OTP in the regulations at 32 CFR 199.14(a)(2)(ix). The payments are also described in Chapter 7, Section 5 and Chapter 1, Section 15 of the TRICARE Reimbursement Manual 6010.61–M, April 1, 2015. As discussed in the 2016 TRICARE final rule, a number of commenters indicated that they believed the rates established by DOD are near market rates and acceptable (81 FR 61079).

In the 2016 TRICARE final rule, DOD established separate payment methodologies for treatment in OTPs based on the particular medication being administered. DOD finalized a weekly all-inclusive per diem rate for OTPs when furnishing methadone for MAT. Under 32 CFR 199.14(a)(2)(ix)(A)(3)(i), this weekly rate includes the cost of the drug and the cost of related non-drug services (that is, the costs related to the intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and supportive services), hereafter referred as the non-drug services. We note that the services included in the TRICARE weekly bundle are generally comparable to the definition of OUD treatment services in Section 2005 of the SUPPORT Act. The weekly all-inclusive per diem rate for these services was determined based on preliminary review of industry billing practices (which included Medicaid and other third-party payers) for the dispensing of methadone, including an estimated daily drug cost of $3 and a daily estimated cost of $15 for the non-drug services. These daily costs were converted to an estimated weekly per diem rate of $126 ($18 per day × 7 days) in the 2016 TRICARE final rule. Under 32 CFR 199.14(a)(2)(iv)(C)(S), this rate is updated annually by the Medicare hospital inpatient prospective payment system (IPPS) update factor. The 2019 TRICARE weekly per diem rate for methadone treatment in an OTP is $133.15.[36] Beneficiary cost-sharing consists of a flat copayment that may be applied to this weekly rate.

DOD also established payment rates for other medications used for MAT (buprenorphine and extended-release injectable naltrexone) to allow OTPs to bill for the full range of medications available. Under 32 CFR 199.14(a)(2)(ix)(A)(3)(ii), DOD established a fee-for-service payment methodology for buprenorphine and extended-release injectable naltrexone because they are more likely to be prescribed and administered in an office-based treatment setting but are still available for treatment furnished in an OTP. DOD stated in the 2016 TRICARE final rule (81 FR 61080) that treatment with buprenorphine and naltrexone is more variable in dosage and frequency than with methadone. Therefore, TRICARE pays for these medications and the accompanying non-drug services separately on a fee-for-service basis. Buprenorphine is paid based on 95 percent of average wholesale price (AWP) and the non-drug component is paid on a per visit basis at an estimated cost of $22.50 per visit. Extended-release injectable naltrexone is paid at the average sales price (ASP) plus a drug administration fee while the non-drug services are also paid at an estimated per visit cost of $22.50. DOD also reserved discretion to establish the payment methodology for new drugs and biologicals that may become available for the treatment of SUDs in OTPs.

DOD instructed that OTPs use the ''Alcohol and/or other drug use services, not otherwise specified'' H-code for billing the non-drug services when buprenorphine or naltrexone is used, and required OTPs to also include both the J-code and the National Drug Code (NDC) for the drug used, as well as the dosage and acquisition cost on the claim form.[37] Drugs listed on Medicare's Part B ASP files are paid using the ASP.[38] Drugs not appearing on the Medicare ASP file are paid at the lesser of billed charges or 95 percent of the AWP.[39] Using this methodology, TRICARE estimated a daily drug cost of $10 for buprenorphine and a monthly drug cost of $1,129 for extended-release injectable naltrexone.[40]

[36] *https://health.mil/Military-Health-Topics/Business-Support/Rates-and-Reimbursement/MHSUD-Facility-Rates.*

[37] 81 FR 61080.

[38] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html*; *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

[39] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html*; *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

[40] 81 FR 61080.

(2) Medicaid (Title XIX)

States have the flexibility to administer the Medicaid program to meet their own needs within the Medicaid program parameters set forth in federal statute and regulations. All states cover and pay for some form of medications for medication-assisted treatment of OUD under their Medicaid programs. However, as of 2018, only 42 states covered methadone for MAT for OUD under their Medicaid programs.[41] We note that section 1006(b) of the SUPPORT Act amends sections 1902 and 1905 of the Social Security Act to require that Medicaid State plans cover all drugs approved under section 505 of the FFDCA to treat OUD, including methadone, and all biological products licensed under section 351 of the Public Health Service Act to treat OUD, beginning October 1, 2020. This requirement sunsets on September 30, 2025.

In reviewing Medicaid payments for OUD treatment services furnished by OTPs in a few states, we found significant variation in the MAT coverage, OUD treatment services, and payment structure among the states. Thus, it is difficult to identify a standardized Medicaid payment amount for OTP services. A number of factors such as the unit of payment, types of services bundled within a payment code, and how MAT services are paid varied among the states. For example, for treatment of OUD using methadone for MAT, most OTPs bill under HCPCS code H0020 (Alcohol and/or drug services; methadone administration and/or service (provision of the drug by a licensed program)) under the Medicaid program; however, the unit of payment varies by state from daily, weekly, or monthly. For example, the unit of payment in California is daily for methadone treatment,[42] while the unit of payment in Maryland for methadone maintenance is weekly,[43] and Vermont uses a monthly unit[44] of payment of these OUD treatment items and services.

For the other MAT drugs, all states cover buprenorphine and the buprenorphine-naloxone medications;[45] however, fewer than 70 percent cover the implanted or extended-release injectable versions of buprenorphine.[46] In addition, all states cover the extended-release injectable naltrexone.[47] We also found that many states pay different rates based on the specific type of drug used for MAT.

Non-drug items and services may be included in a bundled payment with the drug or paid separately, depending on the state, and can include dosing, dispensing and administration of the drug, individual and group counseling, and toxicology testing. In some states, certain services such as assessments, individual and group counseling, and toxicology testing can be billed separately. For example, some states (such as Maryland,[48] Texas,[49] and California)[50] separately reimburse for individual and group counseling services, while other states (such as Vermont[51] and New Mexico)[52] included these services in the OUD bundled payment.

b. Aspects of the Bundle

(1) Duration of Bundle

Section 1834(w)(1) of the Act requires the Secretary to pay an OTP an amount that is equal to 100 percent of the bundled payment for OUD treatment services that are furnished by the OTP to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. We are proposing that the duration of an episode of care for OUD treatment services would be a week (that is, a contiguous 7-day period that may start on any day of the week). This is similar to the structure of the TRICARE bundled payment to OTPs for methadone, which is based on a weekly bundled rate (81 FR 61079), as well as the payments by some state Medicaid programs. Given this similarity to existing coding structures, we believe a weekly duration for an episode of care would be most familiar to OTPs and therefore the least disruptive to adopt. We welcome comments on whether we should consider a daily or monthly bundled payment. We are proposing to define an episode of care at § 410.67(b) as a 1 week (contiguous 7-day) period.

We recognize that patients receiving MAT are often on this treatment regimen for an indefinite amount of time and therefore, we are not proposing any maximum number of weeks during an overall course of treatment for OUD.

(a) Requirements for an Episode

We note that SAMHSA requires OTPs to have a treatment plan for each patient that identifies the frequency with which items and services are to be provided (§ 8.12(f)(4)). We recognize that there is a range of service intensity depending on the severity of a patient's OUD and stage of treatment and therefore, a ''full weekly bundle'' may consist of a very different frequency of services for a patient in the initial phase of treatment compared to a patient in the maintenance phase of treatment, but that we would still consider the requirements to bill for the full weekly bundle to be met if the patient is receiving the majority of the services identified in their treatment plan at that time. However, for the purposes of valuation, we assumed one substance use counseling session, one individual therapy session, and one group therapy session per week and one toxicology test per month. Given the anticipated changes in service intensity over time based on the individual patient's needs, we expect that treatment plans would be updated to reflect these changes or noted in the patient's medical record, for example, in a progress note. In cases where the OTP has furnished the majority (51 percent or more) of the services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week, we propose that it could bill for a full weekly bundle. We are proposing to codify the payment methodology for full episodes of care (as well as partial episodes of care and non-drug episodes of care, as discussed below) in § 410.67(d)(2).

(b) Partial Episode of Care

We understand that there may be instances in which a beneficiary does not receive all of the services expected in a given week due to any number of issues, including, for example, an inpatient hospitalization during which a

[41] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[42] *https://www.dhcs.ca.gov/formsandpubs/Documents/MHSUDS%20Information%20Notices/MHSUDS_Information_Notices_2018/MHSUDS_Information_Notice_18_037_SPA_Rates_Exhibit.pdf.*

[43] *https://health.maryland.gov/bhd/Documents/Rebundling%20Initiative%209-6-16.pdf.*

[44] *http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Medicaid%20Rate%20Sheet.pdf.*

[45] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[46] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[47] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[48] *https://health.maryland.gov/bhd/Documents/Rebundling%20Initiative%209-6-16.pdf.*

[49] *http://www.tmhp.com/News_Items/2018/11-Nov/11-16-18%20Substance%20Use%20Disorder%20Benefits%20to%20Change%20for%20Texas%20Medicaid%20January%201,%202019.pdf.*

[50] *https://www.dhcs.ca.gov/formsandpubs/Documents/MHSUDS%20Information%20Notices/MHSUDS_Information_Notices_2018/MHSUDS_Information_Notice_18_037_SPA_Rates_Exhibit.pdf.*

[51] *http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Medicaid%20Rate%20Sheet.pdf.*

[52] *http://www.hsd.state.nm.us/uploads/FileLinks/e7cfb008157f422597cccdc11d2034f0/MAT_Proposed_reimb_MAD_website_pdf.pdf.*

https://stre.samhsa.gov/system/files/medicaidfinancingmatreport.pdfnm.us/uploads/FileLinks/c78b68d063e04ce5adffe29376ff402e/12_10_MAT_OTC_Clinics_Supp_09062012__2_.pdf.

beneficiary would not be able to go to the OTP or inclement weather that impedes access to transportation. To provide more accurate payment to OTPs in cases where a beneficiary is not able to or chooses not to receive all items and services described in their treatment plan or the OTP is unable to furnish services, for example, in the case of a natural disaster, we are proposing to establish separate payment rates for partial episodes that correspond with each of the full weekly bundles. In cases where the OTP has furnished at least one of the items or services (for example, dispensing one day of an oral MAT medication or one counseling session or one toxicology test) but less than 51 percent of the items and services included in OUD treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week, we propose that it could bill for a partial weekly bundle. In cases in which the beneficiary does not receive a drug during the partial episode, we propose that the code describing a non-drug partial weekly bundle must be used. For example, the OTP could bill for a partial episode in instances where the OTP is transitioning the beneficiary from one OUD medication to another and therefore the beneficiary is receiving less than a week of one type of medication. In those cases, two partial episodes could be billed, one for each of the medications, or one partial episode and one full episode, if all requirements for billing are met. We intend to monitor this issue and will consider whether we would need to make changes to this policy in future rulemaking to ensure that the billing for partial episodes is not being abused. We are proposing to define a partial episode of care in § 410.67(b) and to codify the payment methodology for partial episodes in § 410.67(d). We seek comments on our proposed approach to full and partial episodes, including the threshold that should be applied to determine when an OTP may bill for the full weekly bundle versus a partial episode. We also seek comment on the minimum threshold that should be applied to determine when a partial episode could be billed (for example, at least one item or service, or an alternative threshold such as 10 or 25 percent of the items and services included in OUD treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week). We also welcome feedback regarding whether any other payers of OTP services allow for billing partial bundles and what thresholds they use.

(c) Non-Drug Episode of Care

In addition to the bundled payments for full and partial episodes of care that are based on the medication administered for treatment (and include both a drug and non-drug component described in detail below), we are proposing to establish a non-drug episode of care to provide a mechanism for OTPs to bill for non-drug services, including substance use counseling, individual and group therapy, and toxicology testing that are rendered during weeks when a medication is not administered, for example, in cases where a patient is being treated with injectable buprenorphine or naltrexone on a monthly basis or has a buprenorphine implant. We are proposing to codify this non-drug episode of care at § 410.67(d).

(2) Drug and Non-Drug Components

As discussed above, in establishing the bundled payment rates, we propose to develop separate payment methodologies for the drug component and the non-drug (which includes the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing) components of the bundled payment. Each of these components is discussed in this section.

(a) Drug Component

As discussed previously, the cost of medications used by OTPs to treat OUD varies widely. Creating a single bundled payment rate that does not reflect the type of drug used could result in access issues for beneficiaries who might be best served by treatment using a more expensive medication. As a result, we believe that the significant variation in the cost of these drugs needs to be reflected adequately in the bundled payment rates for OTP services to avoid impairing access to appropriate care.

Section 1834(w)(2) of the Act states that the Secretary may implement the bundled payment to OTPs though one or more bundles based on a number of factors, including the type of medication provided (such as buprenorphine, methadone, extended-release injectable naltrexone, or a new innovative drug). Accordingly, consistent with the discretion afforded under section 1834(w)(2) of the Act, and after consideration of payment rates paid to OTPs for comparable services by other payers as discussed above, we propose to base the OTP bundled payment rates, in part, on the type of medication used for treatment. Specifically, we propose the following categories of bundled payments to reflect those drugs currently approved by the FDA under section 505 of the FFDCA for use in treatment of OUD:

- Methadone (oral).
- Buprenorphine (oral).
- Buprenorphine (injection).
- Buprenorphine (implant).
- Naltrexone (injection).

In addition, we propose to create a category of bundled payment describing a drug not otherwise specified to be used for new drugs (as discussed further below). We are also proposing a non-drug bundled payment to be used when medication is not administered (as discussed further below). We believe creating these categories of bundled payments based on the drug used for treatment would strike a reasonable balance between recognizing the variable costs of these medications and the statutory requirement to make a bundled payment for OTP services. We propose to codify this policy of establishing the categories of bundled payments based on the type of opioid agonist and antagonist treatment medication in § 410.67(d)(1).

i. New Drugs

We anticipate that there may be new FDA-approved opioid agonist and antagonist treatment medications to treat OUD in the future. In the scenario where an OTP furnishes MAT using a new FDA-approved opioid agonist or antagonist medication for OUD treatment that is not specified in one of our existing codes, we propose that OTPs would bill for the episode of care using the medication not otherwise specified (NOS) code, HCPCS code GXXX9 (or GXXX19 for a partial episode). In such cases, we propose to use the typical or average maintenance dose to determine the drug cost for the new bundle. Then, we propose that pricing would be determined based on the relevant pricing methodology as described later in this section (section II.G.) of the proposed rule or invoice pricing in the event the information necessary to apply the relevant pricing methodology is not available. For example, in the case of injectable and implantable drugs, which are generally covered and paid for under Medicare Part B, we propose to use the methodology in section 1847A of the Act (which bases most payments on ASP). For oral medications, which are generally covered and paid for under Medicare Part D, we propose to use ASP-based payment when we receive manufacturer-submitted ASP data for

these drugs. In the event that we do not receive manufacturer-submitted ASP pricing data, we are considering several potential pricing mechanisms (as discussed further below) to estimate the payment amounts for oral drugs typically paid for under Medicare Part D but that would become OTP drugs paid under Part B when used as part of MAT furnished in an OTP. We are not proposing a specific pricing mechanism at this time for the situation in which we do not receive manufacturer-submitted ASP pricing data, but are requesting public comment on several potential approaches for estimating the acquisition cost and payment amounts for these drugs. We will consider the comments received in developing our final policy for determining these drug prices. If the information necessary to apply the alternative pricing methodology chosen for the oral drugs is also not available to price the new medication, we propose to use invoice pricing until either ASP pricing data or the information necessary to apply the chosen pricing methodology becomes available to price the medication. We are proposing to codify this approach for determining the amount of the bundled payment for new medications in § 410.67(d)(2).The medication NOS code would be used until CMS has the opportunity to consider through rulemaking establishing a unique bundled payment for episodes of care during which the new drug is furnished. We welcome comments on this proposed approach to the treatment of new drugs used for MAT in OTPs.

As discussed above, we also welcome comments on how new medications that may be approved by the FDA in the future for use in the treatment of OUD with a novel mechanism of action (for example, not an opioid agonist and/or antagonist), such as medications approved under section 505 of the FFDCA to treat OUD and biological products licensed under section 351 of the Public Health Service Act to treat OUD, should be considered in the context of OUD treatment services provided by OTPs. We additionally welcome comments on how such new drugs with a novel mechanism of action should be priced, and specifically whether pricing for these new non-opioid agonist and/or antagonist medications should be determined using the same pricing methodology proposed for new opioid agonist and antagonist treatment medications, described above or whether an alternative pricing methodology should be used.

(b) Non-Drug Component

i. Counseling, Therapy, Toxicology Testing, and Drug Administration

As discussed above, the bundled payment is for OUD treatment services furnished during the episode of care, which we are proposing to define as the FDA-approved opioid agonist and antagonist treatment medications, the dispensing and administration of such medications (if applicable), substance use disorder counseling by a professional to the extent authorized under state law to furnish such services, individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under state law), and toxicology testing. The non-drug component of the OUD treatment services includes all items and services furnished during an episode of care except for the medication.

Under the SAMSHA certification standards at § 8.12(f)(5), OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. We note that section 1861(jjj)(1)(C) of the Act, as added by section 2005(b) of the SUPPORT Act defines OUD treatment services as including ''substance use counseling by a professional to the extent authorized under state law to furnish such services.'' Therefore, professionals furnishing therapy or counseling services for OUD treatment must be operating within state law and scope of practice. These professionals could include licensed professional counselors, licensed clinical alcohol and drug counselors, and certified peer specialists that are permitted to furnish this type of therapy or counseling by state law and scope of practice. To the extent that the individuals furnishing therapy or counseling services are not authorized under state law to furnish such services, the therapy or counseling services would not be covered as OUD treatment services.

Additionally, under SAMSHA certification standards at § 8.12(f)(6), OTPs are required to provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. These drug abuse tests (which are identified as toxicology tests in the definition of OUD treatment services in section 1861(jjj)(1)(E) of the Act) are used for diagnosing, monitoring and evaluating progress in treatment. The testing typically includes tests for opioids and other controlled substances. Urinalysis is primarily used for this testing; however, there are other types of testing such as hair or fluid analysis that could be used. We note that any of these types of toxicology tests would be considered to be OUD treatment services and would be included in the bundled payment for services furnished by an OTP.

The non-drug component of the bundle also includes the cost of drug dispensing and/or administration, as applicable. Additional details regarding our proposed approach for pricing this aspect of the non-drug component of the bundle are included in our discussion of payment rates later in this section.

ii. Other Services

As discussed earlier, we are proposing to define OUD treatment services as those items and services that are specifically enumerated in section 1861(jjj)(1) of the Act, including services that are furnished via telecommunications technology, and are seeking comment on any other items and services we might consider including as OUD treatment services under the discretion given to the Secretary in subparagraph (F) of that section to determine other appropriate items and services. If we were to finalize a definition of OUD treatment services that includes any other items or services, such as intake activities or periodic assessments as discussed above, we would consider whether any changes to the payment rates for the bundled payments are necessary. See below for additional discussion related to how we could price these services.

(3) Adjustment to Bundled Payment Rate for Additional Counseling or Therapy Services

In addition to the items and services already included in the proposed bundles, we recognize that counseling and therapy are important components of MAT and that patients may need to receive counseling and/or therapy more frequently at certain points in their treatment. We seek to ensure that patients have access to these needed services. Accordingly, we are proposing to adjust the bundled payment rates through the use of an add-on code in order to account for instances in which effective treatment requires additional counseling or group or individual therapy to be furnished for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan. As noted previously, we understand that there is variability in the frequency of services a patient might receive in a given week depending on the patient's severity and stage of treatment; however, we assume

that a typical case might include one substance use counseling session, one individual therapy session, and one group therapy session per week. We further understand that the frequency of services will vary among patients and will change over time based on the individual patient's needs. We expect that the patient's treatment plan or the medical record will be updated to reflect when there are changes in the expected frequency of medically necessary services based on the patient's condition and following such an update, the add-on code should no longer be billed if the frequency of the patient's counseling and/or therapy services is consistent with the treatment plan or medical record. In the case of unexpected or unforeseen circumstances that are time-limited, resolve quickly, and do not lead to updates to the treatment plan, we expect that the medical necessity for billing the add-on code would be documented in the medical record. This add-on code (HCPCS code GXX19) would describe each additional 30 minutes of counseling or group or individual therapy furnished in a week of MAT, which could be billed in conjunction with the codes describing the full episode of care or the partial episodes. For example, there may be some weeks when a patient has a relapse or unexpected psychosocial stressors arise that warrant additional reasonable and necessary counseling services that were not foreseen at the time that the treatment plan was developed. Additionally, we note that there may be situations in which the add-on code could be billed in conjunction with the code for a partial episode; for example, if a patient requires prolonged counseling services on the initial day of treatment, but does not return for any of the other services specified in their treatment plan, such as daily medication dispensing, for the remainder of that week. We acknowledge that an unintended consequence of using the treatment plan is a potential incentive for OTPs to document minimal counseling and/or therapy needs for a beneficiary, thereby resulting in increased opportunity for billing the add-on code. We expect that OTPs will ensure that treatment plans reflect the full scope of services expected to be furnished during an episode of care and that they will update treatment plans regularly to reflect changes. We intend to monitor this issue and will consider whether we need to make changes to this policy through future rulemaking to ensure that this adjustment is not being abused. We welcome comments on the proposed add-on code and the threshold for billing. We propose to codify this adjustment to the bundled payment rate for additional counseling or therapy services in § 410.67(d)(3)(i).

(4) Site of Service (Telecommunications)

In recent years, we have sought to decrease barriers to access to care by furthering policies that expand the use of communication technologies. In the CY 2019 PFS final rule (83 FR 59482), we finalized new separate payments for communication technology-based services, including a virtual check-in and a remote evaluation of pre-recorded patient information. SAMHSA's federal guidelines (*https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf*) for OTPs refer to the CMS guidance on telemedicine and also state that OTPs are advised to proceed with full understanding of requirements established by state or health professional licensing boards. SAMHSA's federal guidelines for OTPs state that exceptional attention needs to be paid to data security and privacy in this evolving field. Telemedicine services should, under no circumstances, expand the scope of practice of a healthcare professional or permit practice in a jurisdiction (the location of the patient) where the provider is not licensed.

We are proposing to allow OTPs to furnish the substance use counseling, individual therapy, and group therapy included in the bundle via two-way interactive audio-video communication technology, as clinically appropriate, in order to increase access to care for beneficiaries. We believe this is an appropriate approach because, as discussed previously, we expect the telehealth services that will be furnished by OTPs will be similar to the Medicare telehealth services furnished under section 1834(m) of the Act, and the use of two-way interactive audio-video communication technology is required for these Medicare telehealth services under § 410.78(a)(3). By allowing use of communication technology in furnishing these services, OTPs in rural communities or other health professional shortage areas could facilitate treatment through virtual care coming from an urban or other external site; however, we note that the physicians and other practitioners furnishing these services would be required to comply with all applicable requirements related to professional licensing and scope of practice.

We note that section 1834(m) of the Act applies only to Medicare telehealth services furnished by a physician or other practitioner. Because OUD treatment services furnished by an OTP are not considered to be services furnished by a physician or other practitioner, the restrictions of section 1834(m) of the Act would not apply. Additionally, we note that counseling or therapy furnished via communication technology as part of OUD treatment services furnished by an OTP must not be separately billed by the practitioner furnishing the counseling or therapy because these services would already be paid through the bundled payment made to the OTP.

We are proposing to include language in § 410.67(b) in the definition of opioid use disorder treatment services to allow OTPs to use two-way interactive audio-video communication technology, as clinically appropriate, in furnishing substance use counseling and individual and group therapy services, respectively. We invite comment as to whether this proposal, including whether furnishing these services through communication technology is clinically appropriate. We also invite public comment on other components of the bundle that may be clinically appropriate to be furnished via communication technology, while also considering SAMHSA's guidance that OTPs should pay exceptional attention to data security and privacy.

(5) Coding

We are proposing to adopt a coding structure for OUD treatment services that varies by the medication administered. To operationalize this approach, we are proposing to establish G codes for weekly bundles describing treatment with methadone, buprenorphine oral, buprenorphine injectable, buprenorphine implants (insertion, removal, and insertion/removal), extended-release injectable naltrexone, a non-drug bundle, and one for a medication not otherwise specified. We also propose to establish partial episode G codes to correspond with each of those bundles, respectively. Additionally, we propose to create an add-on code to describe additional counseling that is furnished beyond the amount specified in the patient's treatment plan. As discussed above, we are seeking comment on whether to include intake activities and periodic assessments in the definition of OUD treatment services. Were we to finalize including these activities in the definition of OUD treatment services, we welcome feedback on whether we should consider modifying the payment associated with the bundle or creating add-on codes for services such as the

initial physical examination, initial assessments and preparation of a treatment plan, periodic assessments or additional toxicology testing, and if so, what inputs we might consider in pricing such services, such as payment amounts for similar services under the PFS or Clinical Lab Fee Schedule (CLFS). For example, to price the initial assessment, medical examination, and development of a treatment plan, we could crosswalk to the Medicare payment rate for a level 3 Evaluation and Management (E/M) visit for a new patient and to price the periodic assessments, we could crosswalk to the Medicare payment rate for a level 3 E/M visit for an established patient. To price additional toxicology testing, we could crosswalk to the Medicare payment for presumptive drug testing, such as that described by CPT code 80305. Additionally, we welcome feedback on whether we should consider creating codes to describe bundled payments that include only the cost of the drug and drug administration as applicable in order to account for beneficiaries who are receiving interim maintenance treatment (as described previously in this section) or other situations in which the beneficiary is not receiving all of the services described in the full bundles.

Regarding the non-drug bundle, we note that this code would be billed for services furnished during an episode of care or partial episode of care when a medication is not administered. For example, when a patient receives a buprenorphine injection on a monthly basis, the OTP will only require payment for the medication during the first week of the month when the injection is given, and therefore, would bill the code describing the bundle that includes injectable buprenorphine during the first week of the month and would bill the code describing the non-drug bundle for the remaining weeks in that month for services such as substance use counseling, individual and group therapy, and toxicology testing.

As discussed previously, we propose that the codes describing the bundled payment for an episode of care with a medication not otherwise specified, HCPCS codes GXXX9 and GXX18, should be used when the OTP furnishes MAT with a new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD. OTPs would use these codes until we have the opportunity to propose and finalize a new G code to describe the bundled payment for treatment using that drug and price it accordingly in the next rulemaking cycle. We note that the code describing the weekly bundle for a medication not otherwise specified should not be used when the drug being administered is not a new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD, and therefore, for which Medicare would not have the authority to make payment since section 1861(jjj)(1)(A) of the Act requires that the medication must be an opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD. Given the program integrity concerns regarding the potential for misuse of such a code, we also welcome comments as to whether this code is needed.

The codes and long descriptors for the proposed OTP bundled services are:

- HCPCS code GXXX1: *Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX2: *Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX3: *Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX4: *Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX5: *Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX6: *Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX7: *Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX8: *Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX9: *Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXX10: *Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX1.*
- HCPCS code GXX11: *Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX2.*
- HCPCS code GXX12: *Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX3.*

- HCPCS code GXX13: *Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode (only to be billed once every 6 months). Do not report with GXXX4.*
- HCPCS code GXX14: *Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX5.*
- HCPCS code GXX15: *Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX6.*
- HCPCS code GXX16: *Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX7.*
- HCPCS code GXX17: *Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX8.*
- HCPCS code GXX18: *Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX9.*
- HCPCS code GXX19: *Each additional 30 minutes of counseling or group or individual therapy in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*

See Table 15 for proposed valuations for HCPCS codes GXXX1–GXX19. We propose that only an entity enrolled with Medicare as an OTP could bill these codes. Additionally, we propose that OTPs would be limited to billing only these codes describing bundled payments, and may not bill for other codes, such as those paid under the PFS.

(6) Payment Rates

The codes describing the proposed OTP bundled services (HCPCS codes GXXX1–GXX19) would be assigned flat dollar payment amounts, which are listed in Table 15. As discussed previously, section 2005 of the SUPPORT Act amended the definition of ''medical and other health services'' in section 1861(s) of the Act to provide for coverage of OUD treatment services furnished by an OTP and also added a new section 1834(w) to the Act and amended section 1833(a)(1) of the Act to establish a bundled payment to OTPs for OUD treatment services furnished during an episode of care beginning on or after January 1, 2020. Therefore, OUD treatment services and the payments for such services are wholly separate from physicians' services, as defined under section 1848(j)(3) of the Act, and for which payment is made under the section 1848 of the Act. Because OUD treatment services are not considered physicians' services and are paid outside the PFS, they would not be priced using relative value units (RVUs).

Consistent with section 1834(w) of the Act, which requires the Secretary to make a bundled payment for OUD treatment services furnished by OTPs, we are proposing to build the payment rates for OUD treatment services by combining the cost of the drug and the non-drug components (as applicable) into a single bundled payment as described in more detail below.

(a) Drug Component

As part of determining a payment rate for these proposed bundles for OUD treatment services, a dosage of the applicable medication must be selected in order to calculate the costs of the drug component of the bundle. We propose to use the typical or average maintenance dose, as discussed earlier in this section, to determine the drug costs for each of the proposed bundles. As dosing for some, but not all, of these drugs varies considerably, this approach attempts to strike an appropriate balance between high- and low-dose drug regimens in the context of a bundled payment. Specifically, we propose to calculate payment rates using a 100 mg daily dose for methadone, a 10 mg daily dose for oral buprenorphine, a 100 mg monthly dose for the extended-release buprenorphine injection, four rods each containing 74.2 mg of buprenorphine for the 6-month buprenorphine implant, and a 380 mg monthly dose for extended-release injectable naltrexone. We invite public comments on our proposal to use the typical maintenance dose in order to calculate the drug component of the bundled payment rate for each of the proposed codes. We also seek comment on the specific typical maintenance dosage level that we have identified for each drug, and a process for identifying the typical maintenance dose for new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA when such medications are billed using the medication NOS code, such as using the FDA-approved prescribing information or a review of the published, preferably peer-reviewed, literature. We note that the bundled payment rates are intended to be comprehensive with respect to the drugs provided; therefore, we do not intend to include any other amounts related to drugs, other than for administration, as discussed below. This means, for example, that we would not pay for drug wastage, which we do not anticipate to be significant in the OTP setting.

i. Potential Drug Pricing Data Sources

Payment structures that are closely tailored to the provider's actual acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. We are proposing to estimate an OTP's costs for the drug component of the bundles based on available data regarding drug costs rather than a provider-specific cost-to-charge ratio or another more direct assessment of facility or industry-specific drug costs. OTPs do not currently report costs associated with their services to the Medicare program, and we do not believe that a cost-to-charge ratio based on such reported information could be available for a significant period of time. Furthermore, we are unaware of any industry-specific data that may be used to more accurately assess the prices at which OTPs acquire the medications used for OUD treatment. Therefore, at this time, we are proposing to estimate an OTP's costs for the drugs used in MAT based on other available data sources, rather than applying a cost-to-charge ratio or

another more direct assessment of drug acquisition cost, though we intend to continue to explore alternate ways to gather this information. As described in greater detail below, we propose that the payment amounts for the drug component of the bundles be based on CMS pricing mechanisms currently in place. We request comment on other potential data sources for pricing OUD treatment medications either generally or specifically with respect to acquisition by OTPs. In the case of oral drugs that we are proposing to include in the OTP bundled payments and for which we do not receive manufacturer-submitted ASP data, we are considering several potential approaches for determining the payment amounts for the drug component of the bundles. Although we are not proposing a specific pricing mechanism at this time, we are soliciting comments on several different approaches, and we intend to develop a final policy for determining the payment amount for the drug component of the relevant bundles after considering the comments received.

In considering the payment amount for the drug component of each of the bundled payments that include a drug, we will begin by breaking the drugs into two categories based on their current coverage and payment by Medicare. First, we discuss the injectable and implantable drugs, which are generally covered and paid for under Medicare Part B, and then discuss the oral medications, which are generally covered and paid for under Medicare Part D.[53] Buprenorphine (injection), buprenorphine (implant), and naltrexone (injection) would fall into the former category and methadone and buprenorphine (oral) would fall into the latter category.

ii. Part B Drugs

Part B includes a limited drug benefit that encompasses drugs and biologicals described in section 1861(t) of the Act. Currently, covered Part B drugs fall into three general categories: Drugs furnished incident to a physician's services, drugs administered via a covered item of durable medical equipment, and other drugs specified by statute (generally in section 1861(s)(2) of the Act). Types of providers and suppliers that are paid for all or some of the Medicare-covered Part B drugs that they furnish include physicians, pharmacies, durable medical equipment suppliers, hospital outpatient departments, and end-stage renal disease (ESRD) facilities.

The majority of Part B drug expenditures are for drugs furnished incident to a physician's service. Drugs furnished incident to a physician's service are typically injectable drugs that are administered in a non-facility setting (covered under section 1861(s)(2)(A) of the Act) or in a hospital outpatient setting (covered under section 1861(s)(2)(B) of the Act). The statute (sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act) limits ''incident to'' services to drugs that are not usually self-administered; self-administered drugs, such as orally administered tablets and capsules are not paid for under the ''incident to'' provision. Payment for drugs furnished incident to a physician's service falls under section 1842(o) of the Act. In accordance with section 1842(o)(1)(C) of the Act, ''incident to'' drugs furnished in a non-facility setting are paid under the methodology in section 1847A of the Act. ''Incident to'' drugs furnished in a facility setting also are paid using the methodology in section 1847A of the Act when it has been incorporated under the relevant payment system (for example, the Hospital Outpatient Prospective Payment System (OPPS) [54]).

In most cases, determining payment using the methodology in section 1847A of the Act means payment is based on the ASP plus a statutorily mandated 6 percent add-on. The payment for these drugs does not include costs for administering the drug to the patient (for example, by injection or infusion); payments for these physician and hospital services are made separately, and the payment amounts are determined under the PFS [55] and the OPPS, respectively. The ASP payment amount determined under section 1847A of the Act reflects a volume-weighted ASP for all NDCs that are assigned to a HCPCS code. The ASP is calculated quarterly using manufacturer-submitted data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act such as sales at nominal charge and sales exempt from best price) with manufacturers' rebates, discounts, and price concessions reflected in the manufacturer's determination of ASP.

Although the Part B drug benefit is generally considered to be limited in scope, it includes many categories of drugs and encompasses a variety of care settings and payment methodologies. In addition to the ''incident to'' drugs described above, Part B also covers and pays for certain oral drugs with specific benefit categories defined under section 1861(s) of the Act including certain oral anti-cancer drugs and certain oral antiemetic drugs. In accordance with section 1842(o)(1) of the Act or through incorporation under the relevant payment system as discussed above, most of these oral Part B drugs are also paid based on the ASP methodology described in section 1847A of the Act.

However, at times Part B drugs are paid based on wholesale acquisition cost (WAC) as authorized under section 1847A(c)(4) of the Act [56] or average manufacturer price (AMP)-based price substitutions as authorized under section 1847A(d) of the Act.[57] Also, in accordance with section 1842(o) of the Act, other payment methodologies may be applied to determine the payment amount for certain Part B drugs, for example, AWP-based payments (using current AWP) are made for influenza, pneumococcal pneumonia, and hepatitis B vaccines.[58] We also use current AWP to make payment under the OPPS for very new drugs without an ASP.[59] Contractors may also make independent payment amount determinations in situations where a national price is not available for physician and other supplier claims and for drugs that are specifically excluded from payment based on section 1847A of the Act (for example, radiopharmaceuticals as noted in section 303(h) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003). In such cases, pricing may be determined based on compendia or invoices.[60]

While most Part B drugs are paid based on the ASP methodology, MedPAC has noted that the ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue

[53] Because, by law, methadone used in MAT cannot be dispensed by a pharmacy, it is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug and can be dispensed by a pharmacy.

[54] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

[55] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

[56] See 75 FR 73465–73466, the section titled Partial Quarter ASP data.

[57] See 77 FR 69140.

[58] Section 1842(o)(1)(A)(iv) of the Act.

[59] 80 FR 70426 and 80 FR 70442–3; Medicare Claims Processing Manual 100–04, Chapter 17, Section 20.1.3.

[60] Medicare Claims Processing Manual 100–04, Chapter 17, Section 20.1.3.

for more expensive drugs.[61] The ASP payment amount also does not vary based on the price an individual provider or supplier pays to acquire the drug. The statute does not identify a reason for the additional 6 percent add-on above ASP; however, as noted in the MedPAC report (and by sources cited in the report), the add-on is needed to account for handling and overhead costs and/or for additional mark-up in the distribution channels that are not captured in the manufacturer-reported ASP.[62]

We propose to use the methodology in section 1847A of the Act (which bases most payments on ASP) to set the payment rates for the ''incident to'' drugs. However, we propose to limit the payment amounts for ''incident to'' drugs to 100 percent of the volume-weighted ASP for a HCPCS code instead of 106 percent of the volume-weighted ASP for a HCPCS code. We believe limiting the add-on will incentivize the use of the most clinically appropriate drug for a given patient. In addition, we understand that many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels. We also propose to use the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files in preparing the CY 2020 payment rates for OTPs. Please note that the quarterly ASP Drug Pricing Files include ASP plus 6 percent payment amounts.[63] Accordingly, we would adjust these amounts consistent with our proposal to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a HCPCS code. Proposed payment rates are provided below in this section of this proposed rule. A discussion of the proposed annual payment update methodology is also provided below. We propose to codify the ASP payment methodology for the drug component at § 410.67(d)(2). We solicit public comment on these proposals, as well as on using alternative ASP-based payments to price these drugs, such as a rolling average of the past year's ASP payment rates.

iii. Oral Drugs

We propose to use ASP-based payment, which would be determined based on ASP data that have been calculated consistent with the provisions in 42 CFR part 414, subpart 800, to set the payment rates for the oral product categories when we receive manufacturer-submitted ASP data for these drugs. We believe that using the ASP pricing data for oral OTP drugs currently covered under Part D[64] would facilitate the computation of the estimated costs of these drugs. However, we do not collect ASP pricing information under section 1927(b) of the Act for these drugs. We request public comment on whether manufacturers would be willing to submit ASP pricing data for OTP drugs currently covered under Part D on a voluntary basis.

We also propose to limit the payment amounts for oral drugs to 100 percent of the volume-weighted ASP for a HCPCS code instead of 106 percent of the volume-weighted ASP for a HCPCS code. We believe limiting the add-on will incentivize the use of the most clinically appropriate drug for a given patient. In addition, we understand that many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels. We propose to use the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files in preparing the CY 2020 payment rates for OTPs. Please note that the quarterly ASP Drug Pricing Files include ASP plus 6 percent payment amounts.[65] Accordingly, we would adjust these amounts consistent with our proposal to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a HCPCS code. Proposed payment rates are provided below in this section of this proposed rule. A discussion of the proposed annual payment update methodology is also provided below. We propose to codify the ASP payment methodology for the drug component at § 410.67(d)(2). We solicit public comment on these proposals, as well as on using alternative ASP-based payments to price these drugs, such as a rolling average of the past year's ASP payment rates.

In the event that we do not receive manufacturer-submitted ASP pricing data, we are considering several potential pricing mechanisms to estimate the payment amounts for oral drugs typically paid for under Medicare Part D but that would become OTP drugs paid under Part B when used as part of MAT in an OTP. We are not proposing a specific pricing mechanism for these drugs at this time, but are requesting public comment on the following potential approaches for estimating the acquisition cost and payment amounts for these drugs and on alternative approaches. We will consider the comments received in developing our final policy for determining these drug prices.

Approach 1: The Methodology in Section 1847A of the Act

One approach for estimating the cost of the drugs that are currently covered under Part D and for which ASP data are not available would be to use the methodology in section 1847A of the Act. Please see above for a discussion of the methodology in section 1847A of the Act. Under the methodology in section 1847A of the Act, when ASP data are not available, this option would price drugs using, for example, WAC or invoice pricing.

Approach 2: Medicare's Part D Prescription Drug Plan Finder Data

On January 28, 2005, we issued the ''Medicare Program; Medicare Prescription Drug Benefit'' final rule (70 FR 4194) which implemented the Medicare voluntary prescription drug benefit, as enacted by section 101 of the MMA. Beginning on January 1, 2006, a prescription drug benefit program was available to beneficiaries with much broader drug coverage than was previously provided under Part B to include: Brand-name prescription drugs and biologicals, generic drugs, biosimilars, vaccines, and medical supplies associated with the injection of insulin.[66] This prescription drug benefit is offered to Medicare beneficiaries through Medicare Advantage Drug Plans (MA–PDs) and stand-alone Prescription Drug Plans (PDPs). The prescription drug benefit under Medicare Part D is administered based on the ''negotiated prices'' of covered Part D drugs. Under § 423.100 of the Part D regulations, the negotiated price of a Part D drug equals the amount paid by the Part D sponsor (or its pharmacy benefit manager) to the pharmacy at the point-of-sale for that drug. Typically, these Part D ''negotiated prices'' are based on AWP minus a percentage for brand drugs or either the maximum allowable cost, which is based on proprietary methodologies used to establish the same payment for therapeutically equivalent products marketed by multiple labelers with different AWPs,

[61] See MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, pages 65–72.

[62] Ibid.

[63] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html.*

[64] Please note that methadone is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug.

[65] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html.*

[66] See section 1860D–2(e) of the Act.

or the Generic Effective Rate, which guarantees aggregate minimum reimbursement (for example, AWP–85 percent). The negotiated price under Part D also includes a dispensing fee (for example, $1–$2), which is added to the cost of the drug.

Many of the beneficiaries who choose to enroll in Part D drug plans must pay premiums, deductibles, and copayments/co-insurance. The Medicare Prescription Drug Plan Finder is an online tool available at *http://www.medicare.gov*. This web tool allows beneficiaries to make informed choices about enrolling in Part D plans by comparing the plans' benefit packages, premiums, formularies, pharmacies, and pricing data. PDPs and MA–PDs are required to submit this information to CMS for posting on the Medicare Drug Plan Finder. The database structure provides the drug pricing and pharmacy network information necessary to accurately communicate plan information in a comparative format. The Medicare Prescription Drug Plan Finder displays information on pharmacies that are contracted to participate in the sponsors' network as either retail or mail order pharmacies.

Another approach for estimating the cost of the drugs that are currently covered under Part D and for which ASP data are not available would be to use data retrieved from the online Medicare Prescription Drug Plan Finder. For example, the Part D drug prices for each drug used by an OTP as part of MAT could be estimated based on a national average price charged by all Part D plans and their network pharmacies. However, the prices listed in the Medicare Prescription Drug Plan Finder generally reflect the prices that are negotiated by larger buying groups, as larger pharmacies often have significant buying power and smaller pharmacies generally contract with a pharmacy services administrative organization (PSAO). As a result, our primary concern with this pricing approach is that such prices may fail to reflect the drug prices that smaller OTP facilities may pay in acquiring these drugs and could therefore disadvantage these facilities. If we were to select this pricing approach for oral drugs for which ASP data are not available, we would anticipate setting the pricing for these drugs using the most recent Medicare Drug Plan Finder data available at the drafting of the CY 2020 PFS final rule. We note that, for the Part B ESRD prospective payment system (PPS) outlier calculation, which provides ESRD facilities with additional payment in situations where the costs for treating patients exceed an established threshold under the ESRD PPS, we chose to adopt the ASP methodology in section 1847A of the Act, and the other pricing methodologies under section 1847A of the Act, as appropriate, when ASP data are not available, to price the renal dialysis drugs and biological products that were or would have been separately billable under Part B prior to implementation of the ESRD PPS,[67] and the national average drug prices based on the Medicare Prescription Drug Plan Finder as the data source for pricing the renal dialysis drugs or biological products that were or would have been separately covered under Part D prior to implementation of the ESRD PPS.[68]

We believe that all of the MAT drugs proposed for inclusion in the OTP benefit that are currently covered under Part D have clinical treatment indications beyond MAT such as for the treatment of pain.[69] These drugs will continue to be covered under Part D for these other indications. Buprenorphine will continue to be covered under Part D for MAT as well. Consequently, Part D pricing information should continue to be available for these drugs and could be used in the computation of payment under the approach discussed above.

Because, by law, methadone used in MAT cannot be dispensed by a pharmacy, it is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug and can be dispensed by a pharmacy. Accordingly, we also seek comment on the applicability of Part D payment rates for methadone dispensed by a pharmacy to methadone dispensed by an OTP for MAT.

Approach 3: Wholesale Acquisition Cost (WAC)

Another approach for estimating the cost of the oral drugs that we propose to include as part of the bundled payments but for which ASP data are not available would be to use WAC. Section 1847A(c)(6)(B) of the Act defines WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers in the U.S., not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data. As noted above in the discussion of Part B drugs, WAC is used as the basis for pricing some Part B drugs; for example, it is used when it is less than ASP in the case of single source drugs (section 1847A(b)(4) of the Act) and in cases where ASP is unavailable during the first quarter of sales (section 1847A(c)(4) of the Act).

Because WAC is the manufacturer's list price to wholesalers, we believe that it is more reflective of the price paid by the end user than the AWP. As a result, we believe that this pricing mechanism would be consistent with pricing that currently occurs for drugs that are separately billable under Part B. However, we have concerns about the fact that WAC does not include prompt pay or other discounts, rebates, or reductions in price. If we select this option to estimate the cost of certain drugs, we would develop pricing using the most recent data files available at the drafting of the CY 2020 PFS final rule.

Approach 4: National Average Drug Acquisition Cost (NADAC)

Another approach for estimating the cost of the oral drugs that we propose to include as part of the bundled payments but for which ASP data are not available would be to use Medicaid's NADAC survey. This survey provides another national drug pricing benchmark. CMS conducts surveys of retail community pharmacy prices, including drug ingredient costs, to develop the NADAC pricing benchmark. The NADAC was designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs and is available for consideration by states to assist with their individual pharmacy payment policies.

State Medicaid agencies reimburse pharmacy providers for prescribed covered outpatient drugs dispensed to Medicaid beneficiaries. The reimbursement formula consists of two parts: (1) Drug ingredient costs; and (2) a professional dispensing fee. In a final rule with comment period titled ''Medicaid Program; Covered Outpatient Drugs,'' which appeared in the February 1, 2016 **Federal Register** (81 FR 5169), we revised the methodology that state Medicaid programs use to determine drug ingredient costs, establishing an Actual Acquisition Cost (AAC) based determination, as opposed to a determination based on estimated acquisition costs (EAC). AAC is defined

[67] 82 FR 50742 through 50745.

[68] 75 FR 49142.

[69] For example, while methadone is not covered by Medicare Part D for MAT, methadone dispensed for pain may be considered a Part D drug.

at 42 CFR 447.502 as the agency's determination of the pharmacy providers' actual prices paid to acquire drugs marketed or sold by specific manufacturers. As explained in the Covered Outpatient Drugs final rule with comment period (81 FR 5175), CMS believes shifting from an EAC to an AAC based determination of ingredient costs is more consistent with the dictates of section 1902(a)(30)(A) of the Act. In 2010, a working group within the National Association of State Medicaid Directors (NASMD) recommended the establishment of a single national pricing benchmark based on average drug acquisition costs. Pricing metrics based on actual drug purchase prices provide greater accuracy and transparency in how drug prices are established and are more resistant to manipulation. The NASMD requested that CMS coordinate, develop, and support this benchmark.

Section 1927(f) of the Act provides, in part, that CMS may contract with a vendor to conduct monthly surveys with respect to prices for covered outpatient drugs dispensed by retail community pharmacies. We entered into a contract with Myers & Stauffer, LLC to perform a monthly nationwide retail price survey of retail community pharmacy covered outpatient drug prices (CMS–10241, OMB 0938–1041) and to provide states with weekly updates on pricing files, that is, the NADAC files. The NADAC survey process focuses on drug ingredient costs for retail community pharmacies. The survey collects acquisition costs for covered outpatient drugs purchased by retail pharmacies, which include invoice prices from independent and chain retail community pharmacies. The survey data provide information that CMS uses to assure compliance with federal requirements. We believe NADAC data could be used to set the prices for the oral drugs furnished by OTPs for which ASP data are not available. Survey data on invoice prices provide the closest pricing metric to ASP that we are aware of. However, similar to the other available pricing metrics, we have concerns about the applicability of retail pharmacy prices to the acquisition costs available to OTPs since we have no evidence to suggest that these entities would be able to acquire drugs at a similar price point. If we select this option, we would develop pricing using the most recent data files available at the drafting of the CY 2020 PFS final rule.

Alternative Methadone Pricing: TRICARE

We are also considering an approach for estimating the cost of methadone using the amount calculated by TRICARE. As discussed above in this section of this proposed rule, the TRICARE rates for medications used in OTPs to treat opioid use disorder are spelled out in the 2016 TRICARE final rule (81 FR 61068); in the regulations at § 199.14(a)(2)(ix); and in Chapter 7, Section 5 and Chapter 1, Section 15 of the TRICARE Reimbursement Manual 6010.61–M, April 1, 2015.

In the 2016 TRICARE final rule, DOD established separate payment methodologies for OTPs based on the particular medication being administered for treatment.[70] Based on TRICARE's review of industry billing practices, the initial weekly bundled rate for administration of methadone included a daily drug cost of $3, which is subject to an update factor.[71]

This option would only be applicable for methadone because TRICARE has developed a fee-for-service payment methodology for buprenorphine and naltrexone.[72] In the 2016 TRICARE final rule, the DOD stated that the payments for buprenorphine and naltrexone are more variable in dosage and frequency for both the drug and non-drug services.[73] Accordingly, TRICARE pays for drugs listed on Medicare's Part B ASP files, such as the injectable and implantable versions of buprenorphine using the ASP; drugs not appearing on the Medicare ASP file, such as oral buprenorphine, are priced at the lesser of billed charges or 95 percent of the AWP.[74]

We believe that pricing methadone consistent with the TRICARE payment rate may provide a reasonable payment amount for methadone when ASP data are not available. As DOD noted in the 2016 TRICARE final rule, ''a number of commenters indicated that they believed the rates DOD proposed for OTPs' services are near market rates and are acceptable.'' [75]

We are proposing to codify this proposal to apply an alternative approach for determining the payment rate for oral drugs only if ASP data are not available in § 410.67(d)(2). We request public comment on the potential alternative approaches set forth above for estimating the cost of oral drugs that we propose to include as part of the bundled payments but for which ASP data are not available, including any other alternate sources of data to estimate the cost of these oral MAT drugs. Payment rates based on these different options are set forth in Table 14. We will consider the comments received on these different potential approaches when deciding on the approach that we will use to determine the payment rates for these drugs in the CY 2020 PFS final rule. We also invite public comment on any other potential data sources for estimating the provider acquisition costs of OTP drugs currently paid under either Part B or Part D. As noted previously, we welcome comments on how new drugs with a novel mechanism of action should be priced, and specifically whether pricing for non-opioid agonist and/or antagonist medications should be determined using the same pricing methodology, including the alternatives discussed above, as would be used for medications included in the proposed definition of OUD treatment services.

TABLE 14—ESTIMATED * INITIAL DRUG PAYMENT RATES FOR EACH PRICING APPROACH

Pricing approach (or alternative)	Estimated initial weekly drug payment for methadone	Estimated initial weekly drug payment for oral buprenorphine
Proposal: ASP-Based Payment	ASPs currently not reported	ASPs currently not reported.
Approach 1: The Methodology in Section 1847A of the Act.	$29.61	$117.68.
Approach 2: Medicare's Part D Prescription Drug Plan Finder Data.	22.47	97.65.
Approach 3: WAC	27.93	111.02.
Approach 4: NADAC	11.76	97.02.

[70] 81 FR 61079.

[71] 81 FR 61079.

[72] 81 FR 61080.

[73] 81 FR 61080.

[74] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html*; *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

[75] 81 FR 61080.

TABLE 14—ESTIMATED * INITIAL DRUG PAYMENT RATES FOR EACH PRICING APPROACH—Continued

Pricing approach (or alternative)	Estimated initial weekly drug payment for methadone	Estimated initial weekly drug payment for oral buprenorphine
Alternative Methadone Pricing: TRICARE	22.19	N/A.

* The estimated payment amounts in this table are based on data files posted at the time of the drafting of this proposed rule. We would develop the final pricing for CY 2020 using the most recent data files available at the drafting of the CY 2020 PFS final rule.

(b) Non-Drug Component

To price the non-drug component of the bundled payments, we are proposing to use a crosswalk to the non-drug component of the TRICARE weekly bundled rate for services furnished when a patient is prescribed methadone. As described above, in 2016, TRICARE finalized a weekly bundled rate for administration of methadone that included a daily drug cost of $3, along with a $15 per day cost for non-drug services (that is, the costs related to the intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and supportive services). The daily projected per diem cost ($18/day) was converted to a weekly rate of $126 ($18/day × 7 days) (81 FR 61079). TRICARE updates the weekly bundled methadone rate for OTPs annually using the Medicare update factor used for other mental health care services rendered (that is, the Inpatient Prospective Payment System update factor) under TRICARE (81 FR 61079). The updated amount for CY 2019 to $133.15 (of which $22.19 is the methadone cost and the remainder, $110.96, is for the non-drug services).[76] We believe using the TRICARE weekly bundled rate is a reasonable approach to setting the payment rate for the non-drug component of the bundled payments to OTPs, particularly given the time constraints in developing a payment methodology prior to the January 1, 2020 effective date of this new Medicare benefit category. The TRICARE rate is an established national payment rate that was established through notice and comment rulemaking. As a result, OTPs and other interested parties had an opportunity to present information regarding the costs of these services. Furthermore the TRICARE rate describes a generally similar bundle of services to those services that are included in the definition of OUD treatment services in section 1861(jjj)(1) of the Act. We recognize that there are differences in the patient population for TRICARE compared with the Medicare beneficiary population. However, as OTP services have not previously been covered by Medicare, it is not clear what impact, if any, these differences would have on the cost of the services included in the non-drug component of the proposed bundled payments. We are proposing to codify the methodology for determining the payment rate for the non-drug component of the bundled payments using the TRICARE weekly rate for non-drug services at § 410.67(d)(2). As part of this proposal, we would plan to monitor utilization of non-drug services by Medicare beneficiaries and, if needed, would consider in future rulemaking ways we could tailor the TRICARE payment rate for these non-drug services to the Medicare population, including dually eligible beneficiaries.

Because the TRICARE payment rate for the non-drug services included in its weekly bundled rate for methadone includes daily administration of methadone, as part of our proposed approach we would adjust the TRICARE payment rate for non-drug services for most of the other bundled payments to more accurately reflect the cost of administering the other drugs used in MAT. For the oral buprenorphine bundled payment, we propose to retain the same amount as the rate for the methadone bundled payment based on an assumption that this drug is also being dispensed daily. We understand that patients who have stabilized may be given 7–14 day supplies of oral buprenorphine at a time, but for the purposes of developing the proposed rates, we valued this service to include daily drug dispensing to account for cases where daily drug dispensing is occurring. For the injectable drugs (buprenorphine and naltrexone), we propose to subtract from the non-drug component, an amount that is comparable to the dispensing fees paid by several state Medicaid programs ($10.50) for a week of daily dispensing of methadone. This adjustment accounts for the fact that these injectable drugs are not oral drugs that are dispensed daily; we would then instead add the fee that Medicare pays for the administration of an injection (which is currently $16.94 under the CY 2019 non-facility Medicare payment rate for CPT code 96372). We propose to update the amount of this adjustment annually using the same methodology that we are proposing to use to update the non-drug component of the bundled payments.

Similarly, the payment rates for the non-drug component of the codes for the weekly bundled payments for buprenorphine implants would be adjusted to add an amount for insertion and/or removal based on a direct crosswalk to the non-facility payment rates under the Medicare PFS for the insertion, removal, or insertion and removal of these implants, which describe the physician work, practice expense (PE), and malpractice costs associated with these procedures, and to remove the costs of daily drug dispensing (determined based on the dispensing fees paid by several state Medicaid programs for a week of daily dispensing of methadone, currently $10.50). For HCPCS code GXXX5, we would use a crosswalk to the rate for HCPCS code G0516 (*Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant)*); for HCPCS code GXXX6, we would use a crosswalk to the rate for HCPCS code G0517 (*Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)*); and for HCPCS code GXXX7, we would use a crosswalk to the rate for HCPCS code G0518 (*Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)*). The amounts for HCPCS codes G0516, G0517 and G0518 under the CY 2019 non-facility Medicare payment rate are $111.00, $126.86, and $204.70, respectively.

In order to determine the payment rates for the code describing a non-drug bundled payment, HCPCS code GXXX8, we propose to use a crosswalk to the reimbursement rate for the non-drug services included in the TRICARE weekly bundled rate for administration of methadone, adjusted to subtract the cost of methadone dispensing (using an amount that is comparable to the dispensing fees paid by several state Medicaid programs for a week of daily dispensing of methadone, which is currently $10.50).

We propose that the payment rate for the add-on code, HCPCS code GXX19, would be based on 30 minutes of

[76] *https://health.mil/Military-Health-Topics/Business-Support/Rates-and-Reimbursement/MHSUD-Facility-Rates.*

substance use counseling and valued based on a crosswalk to the rates set by state Medicaid programs for similar services.

i. Medication Not Otherwise Specified

We would expect the non-drug component for medication not otherwise specified bundled payments (HCPCS code GXXX9) to be consistent with the pricing methodology for the other bundled payments and therefore, be based on a crosswalk to the TRICARE rate, adjusted for any applicable administration and dispensing fees. For example, for oral medications, we would use the rate for the non-drug services included in the TRICARE methadone bundle, based on an assumption that the drug is also being dispensed daily. For the injectable medications, we would adjust the TRICARE payment rate for non-drug services using the same methodology we are proposing for injectable medications above (to subtract an amount for daily dispensing and add the non-facility Medicare payment rate for administration of the injection). For implantable medications, we would also use the same methodology we propose above, with the same crosswalked non-facility Medicare payment rates (for insertion, removal, and insertion and removal). We welcome comments on all of the proposed pricing methodologies described in this section. As noted above, we also welcome comments on how new drugs with a novel mechanism of action (that is, drugs that are not opioid agonists and/or antagonists) should be priced. We additionally welcome comments on how the price of the non-drug component of such bundled payments should be determined, in particular the dispensing and/or administration fees, including whether the methodology we propose above for determining the payment rate for the non-drug component of an episodes of are that includes a new opioid agonist and antagonist medication (which is based on whether the drug is oral, injectable, or implantable) would be appropriate to use for these new drugs.

(c) Partial Episode of Care

For HCPCS codes GXX10 and GXX11 (codes describing partial episodes for methadone and oral buprenorphine), we propose that the payment rates for the non-drug component would be calculated by taking one half of the payment rate for the non-drug component for the corresponding weekly bundles. We chose one half as the best approximation of the median cost of the services furnished during a partial episode consistent with our proposal above to make a partial episode bundled payment when the majority of services described in a beneficiary's treatment plan are not furnished during a specific episode of care. However, we welcome comment on other methods that could be used to calculate these payment rates. We propose that the payment rates for the drug component of these partial episode bundles would be calculated by taking one half of the payment rate for the drug component of the corresponding weekly bundles.

For HCPCS codes GXX12 and GXX16 (codes describing partial episodes for injectable buprenorphine and naltrexone), we propose that the payment rates for the drug component would be the same as the payment rate for the drug component of the full weekly bundle so that the OTP would be reimbursed for the cost of the drug that is given at the start of the episode. For the non-drug component, we propose that the payment rate would be calculated as follows: The TRICARE non-drug component payment rate ($110.96), adjusted to remove the cost of daily administration of an oral drug ($10.50), then divided by two; that amount would be added to the fee that Medicare pays for the administration of an injection (which is currently $16.94 under the CY 2019 non-facility Medicare payment rate for CPT code 96372).

For HCPCS codes GXX13, GXX14, GXX15 (codes describing partial episodes for the buprenorphine implant insertion, removal, and insertion and removal, respectively) we propose that the payment rates for drug component would be the same as the payment rate for the corresponding weekly bundle. For the non-drug component, we propose that the payment rate would be calculated as follows: The TRICARE non-drug component payment rate ($110.96), adjusted to remove the cost of daily administration of an oral drug ($10.50), then divided by two; that amount would be added to the Medicare non-facility payment rate for the insertion, removal, or insertion and removal of the implants, respectively (based on the non-facility rates for HCPCS codes G0516, G0517, and G0518, which are currently $111.00, $126.86, and $204.70, respectively).

For HCPCS code GXX17 (code describing a non-drug partial episode of care), we propose that the payment rate would be calculated by taking one half of the payment rate for the corresponding weekly bundle.

We propose that the payment rate for the code describing partial episodes for a medication not otherwise specified (HCPCS code GXX18) would be calculated based on whether the medication is oral, injectable or implantable, following the methodology described above. For oral drugs, we would follow the methodology described for HCPCS codes GXX10 and GXX11. For injectable drugs, we would follow the methodology described for HCPCS codes GXX12 and GXX16. For implantable drugs, we would follow the methodology described for HCPCS codes GXX13, GXX14, and GXX15. We welcome comments on how partial episodes of care using new drugs with a novel mechanism of action (that is, non-opioid agonist and/or antagonist treatment medications) should be priced. For example, we could use the same approach described previously for pricing new opioid agonist and antagonist medications not otherwise specified, which is to follow the methodology based on whether the drug is oral, injectable or implantable.

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TABLE 15: OTP Code Descriptors and Proposed Approximate Payment Amounts

HCPCS	Descriptor	Drug Component Payment Amount**	Non-Drug Component Payment Amount***	Total Payment Amount
	Full weeks			
GXXX1	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$22.19	$110.96	$133.15
GXXX2	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$97.02	$110.96	$207.98
GXXX3	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$1,580.00	$117.40	$1,697.40
GXXX4	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$4,792.10	$211.46	$5,003.56
GXXX5	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$0	$227.32	$227.32
GXXX6	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$4,792.10	$305.16	$5,097.26
GXXX7	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$1,164.38	$117.40	$1,281.78
GXXX8	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	N/A	$100.46	$100.46
GXXX9	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	-	-	-
	Partial episodes			
GXX10	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX1.*	$11.10	$55.48	$66.58

HCPCS	Descriptor	Drug Component Payment Amount**	Non-Drug Component Payment Amount***	Total Payment Amount
GXX11	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX2.*	$48.51	$55.48	$103.99
GXX12	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX3.*	$1,580.00	$67.17	$1,647.17 *
GXX13	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode (only to be billed once every 6 months). *Do not report with GXXX4.*	$4,792.10	$161.23	$4,953.33 *
GXX14	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX5.*	$0	$177.09	$177.09*
GXX15	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX6.*	$4,792.10	$254.93	$5,047.03 *
GXX16	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX7.*	$1,164.38	$67.17	$1,231.55 *
GXX17	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX8.*	N/A	$50.23	$50.23
GXX18	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX9.	-	-	-
Intensity Add-on code				
GXX19	Each additional 30 minutes of counseling or therapy in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	N/A	$26.60	$26.60

* Full drug cost and administration/dispensing fee included.

** Drug pricing subject to change pending additional data. Methadone drug costs are calculated here using TRICARE rates, oral buprenorphine drug costs are calculated here using NADAC data, and the other drug costs are calculated using the ASP data. The estimated payment amounts in this table are based on data files posted at the time of the drafting of this proposed rule. We would develop the final pricing for CY 2020 using the most recent data files available at the drafting of the CY 2020 PFS final rule.

*** The non-drug component of the methadone bundled payment rate (HCPCS code GXXX1) is $110.96 (crosswalked from the TRICARE CY 2019 rate for non-drug services, which is the weekly rate of $133.15 minus the drug cost of $22.19); the non-drug component of the oral buprenorphine bundled payment rate (HCPCS code GXXX2) is also $110.96 (crosswalked from the non-drug component of the methadone bundled payment rate). The non-drug component of both the injectable buprenorphine bundled payment rate (HCPCS code GXXX3) and the injectable naltrexone bundled rate (HCPCS code GXXX7) is $117.40 ($110.96 minus a $10.50 dispensing fee plus a $16.94 administration fee). The non-drug components of the buprenorphine implant bundled payment rates (HCPCS codes GXXX4, GXXX5, and GXXX6 for implant insertion, removal, and insertion and removal, respectively) are $211.46, $227.32, and $305.16, respectively ($110.96 minus a $10.50 dispensing fee plus the corresponding PFS non-facility rate for implant insertion, removal, and insertion and removal, HCPCS codes G0516, G0517, and G0518, which are $111.00, $126.86, and $204.70, respectively). The rate for the no medication bundled payment (HCPCS code GXXX8) is $100.46 ($110.96 minus a $10.50 dispensing fee). As described in further detail above, we are proposing that the codes describing a medication not otherwise specified (HCPCS codes GXXX9 and GXX18) would be priced according to the methodology described above based on whether the medication is oral, injectable or implantable (based on a crosswalk to the TRICARE rate, adjusted for any applicable administration and dispensing fees). The non-drug component of the codes describing partial episodes (HCPCS codes GXX10, GXX11, GXX12, GXX13, GXX14, GXX15, and GXX16) are calculated as described in further detail above, based on a crosswalk to half of the rate for non-drug services included in the TRICARE weekly bundled payment (adjusted to account for administration and dispensing of that drug. Finally, the non-drug component for HCPCS code GXX19 is calculated based on rates set by state Medicaid programs for similar services. All non-drug components of the valuations would be geographically adjusted as discussed in the locality adjustment section of this proposed rule.

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(8) Place of Service (POS) Code for Services Furnished at OTPs

We are creating a new POS code specific to OTPs since there are no existing POS codes that specifically describe OTPs. Claims for OTP services would include this place of service code. We note that POS codes are available for use by all payers. We are not proposing to make any differential payment based on the use of this new POS code. Further guidance will be issued regarding the POS code that should be used by OTPs.

c. Duplicative Payments Under Parts B or D

Section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Part B or Part D for items and services furnished by an OTP. We note that many of the individual items or services provided by OTPs that would be included in the bundled payment rates under our proposal may also be appropriately available to beneficiaries through other Medicare benefits. Although we recognize the potential for significant program integrity concerns when similar items or services are payable under separate Medicare benefits, we also believe that it is important that any efforts to prevent duplicative payments not inadvertently restrict Medicare beneficiaries' access to other Medicare benefits even for the time period they are being treated by an OTP. For example, we believe that a beneficiary receiving counseling or therapy as part of an OTP bundle of services may also be receiving medically reasonable and necessary counseling or therapy as part of a physician's service during the same time period. Similarly, we believe there could be circumstances where Medicare beneficiaries with OUD could receive treatment and/or medication from non-OTP entities that would not result in duplicative payments, presuming that both the OTP and the other entity appropriately furnished separate medically necessary services or items. Consequently, we do not believe that provision of the same kinds of services by both an OTP and a separate provider or supplier would itself constitute a duplicative payment.

We believe that duplicative payments would result from the submission of claims to Medicare leading to payment for drugs furnished to a Medicare beneficiary and the associated dispensing fees on a certain date of service to both an OTP and another provider or supplier under a different benefit. In these circumstances, we would consider only one of the claims to be paid for appropriately. Accordingly, for purposes of implementing section 1834(w)(1) of the Act, we propose to consider payment for medications delivered, administered or dispensed to the beneficiary as part of the OTP bundled payment to be a duplicative payment if delivery, administration or dispensing of the same medications was also separately paid under Medicare Parts B or D. We propose to codify this policy at § 410.67(d)(4). We understand that some OTPs negotiate arrangements whereby community pharmacies supply MAT-related medications to OTPs. If the OTP provides medically necessary MAT-related medications as part of an episode of care, we would expect the OTP to take measures to ensure that there is no claim for payment for these drugs other than as part of the OTP bundled payment. (For example, the MAT drugs billed by an OTP as part of a bundled payment should not be reported to or paid under a Part D plan.) We expect that OTPs will take reasonable steps to ensure that the items and services furnished under their care are not reported or billed under a different Medicare benefit. CMS intends to monitor for duplicative payments, and would take appropriate action as needed when such duplicative payments are identified. Therefore, we are proposing that in cases where a payment for drugs used as part of an OTP's treatment plan is identified as being a duplicative payment because the same costs were paid under a different Medicare benefit, CMS will generally recoup the duplicative payment made to the OTP as the OTP would be in the best position to know whether or not the drug that is included as part of the beneficiary's treatment plan is furnished by the OTP or by another provider or supplier given that the OTP is responsible for managing the beneficiary's overall OUD treatment. We propose to codify this policy at § 410.67(d)(4). CMS notes that this general approach would not preclude CMS or other auditors from conducting appropriate oversight of duplicative payments made to the other provider or suppliers, particularly in cases of fraud and/or abuse.

d. Cost Sharing

Section 2005(c) of the SUPPORT Act amends section 1833(a)(1) of the Act, relating to payment of Part B services, by adding a new subparagraph (CC), which specifies with respect to OUD treatment services furnished by an OTP during an episode of care that the amount paid shall be equal to the amount payable under section 1834(w) of the Act less any copayment required as specified by the Secretary. Section 1834(w) of the Act, which was also added by section 2005(c) of the SUPPORT Act, requires that the Secretary pay an amount that is equal to 100 percent of a bundled payment under this part for OUD treatment services. Given these two provisions, we believe that there is flexibility for CMS to set the copayment amount for OTP services either at zero or at an amount above zero. Therefore, we are proposing to set the copayment at zero for a time-limited duration (for example, for the duration of the national opioid crisis), as we believe this would minimize barriers to patient access to OUD treatment services. Setting the copayment at zero also ensures OTP providers receive the full Medicare payment amount for Medicare beneficiaries if secondary payers are not available or do not pay the copayment, especially for those dually eligible for Medicare and Medicaid.[77] We intend to continue to monitor the opioid crisis in order to determine at what point in the future a copayment may be imposed. At such a time we deem appropriate, we would institute cost sharing through future notice and comment rulemaking. We welcome feedback from the public on our proposal to set the copayment at zero for a time-limited duration, such as for the duration of the national opioid crisis, and any other metrics CMS might consider using to determine when to start requiring a copayment. In developing our proposed approach, we also considered other alternatives, such as setting the copayment at a fixed fee calculated based on 20 percent of the payment rate for the bundle, consistent with the standard copayment requirement for other Part B services, or applying a flat dollar copayment amount similar to TRICARE's copayment; however, we recognize that setting the copayment for OUD services at a non-zero amount could create a barrier to access to treatment for many beneficiaries. We propose to codify the proposed copayment amount of zero at § 410.67(e). We welcome feedback on our proposal to set the copayment amount for OTP services at zero, and on the alternatives considered, including whether we should consider any of these alternatives for CY 2020 or future years.

Separately, we note that the Part B deductible would apply for OUD treatment services, as mandated for all Part B services by section 1833(b) of the Act.

4. Adjustments to Bundled Payment Rates for OUD Treatment Services

The costs of providing OUD treatment services will likely vary over time and depending on the geographic location where the services are furnished. Below we discuss our proposed adjustments to the bundled payment rates to account for these factors.

a. Locality Adjustment

Section 1834(w)(2) of the Act, as added by section 2005(c) of the SUPPORT Act provides that the Secretary may implement the bundled payment for OUD treatment services furnished by OTPs through one or more bundles based on the type of medications, the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determines appropriate. The cost for the provision of OTP treatment services, like many other healthcare services covered by Medicare, will likely vary across the country based upon the differing cost in a given geographic locality. To account for such geographic cost differences in the provision of services, in a number of payment systems, Medicare routinely applies geographic locality adjustments to the payment rates for particular services. As we believe OTP treatment services will also be subject to varying cost based upon the geographic locality where the services are furnished, we propose to apply a geographic locality adjustment to the bundled payment rate for OTP treatment services. Below, we discuss our proposed approach with respect to the drug component (which reflects payment for the drug) and the non-drug component (which reflects payment for all other services furnished to the beneficiary by the OTP, such as drug administration, counseling, toxicology testing, etc.) of the bundled payment.

(1) Drug Component

Because our proposed approaches for pricing the MAT drugs included in the bundles all reflect national pricing, and because there is no geographic adjustment factor applied to the payment of Part B drugs under the ASP methodology, we do not believe that it is necessary to adjust the drug component of the bundled payment rates for OTP services based upon geographic locality. Therefore, we are proposing not to apply a geographic locality adjustment to the drug component of the bundled payment rate for OTP services.

(2) Non-Drug Component

Unlike the national pricing of drugs, the costs for the services included in the non-drug component of the OTP bundled payment for OUD treatments are not constant across all geographic localities. For example, OTPs' costs for rent or employee wages could vary significantly across different localities and could potentially result in disparate costs for the services included in the non-drug component of OUD treatment services. Because the costs of furnishing the services included in the non-drug component of the OTP bundled payment for OUD treatment services will vary based upon the geographic locality in which the services are provided, we believe it would be appropriate to apply a geographic locality adjustment to the non-drug component of the bundled payments. We believe that the geographic variation in cost of the non-drug services provided by OTPs will be similar to the geographic variation in the cost of services furnished in physician offices. Therefore, to account for the differential costs of OUD treatment services across the country, we are proposing to adjust the non-drug component of the bundled payment rates for OUD treatment services using an approach similar to the established methodology used to geographically adjust payments under the PFS based upon the location where the service is furnished. The PFS currently provides for an adjustment to the payment for PFS services based upon the fee schedule area in which the service is provided through the use of Geographic Practice Cost Indices (GPCIs), which measure the relative cost differences among localities compared to the national average for each of the

[77] For those dually eligible individuals in the Qualified Medicare Beneficiary program (7.7 million of the 12 million dually eligible individuals in 2017), state Medicaid programs cover the Medicare Part A and B deductible and coinsurance. However, section 4714 of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides discretion for states to pay Medicare cost-sharing only if the Medicaid payment rate for the service is above the Medicare paid amount for the service. Since most states opt for this discretion, and most Medicaid rates are lower than Medicare's, states often do not pay the provider for the Medicare cost-sharing amount. Providers are further prohibited from collecting the Medicare cost-sharing amount from the beneficiary, effectively having to take a discount compared to the amount received for other Medicare beneficiaries.

three fee schedule components (work, PE, and malpractice).

Although we are proposing to adjust the non-drug component of the OUD treatment services using an approach similar to the established methodology used to adjust PFS payment for geographic locality, because GPCIs provide for the application of geographic locality adjustments to the three distinct components of PFS services, and the OTP bundled payment is a flat rate payment for all OUD treatment services furnished during an episode of care, a single factor would be required to apply the geographic locality adjustment to the non-drug component of the OTP bundled payment rate. Therefore, to apply a geographic locality adjustment to the non-drug component of the OTP bundled payment for OUD treatment services through a single factor, we are proposing to use the Geographic Adjustment Factor (GAF) at § 414.26. Specifically, we are proposing to use the GAF to adjust the payment for the non-drug component of the OTP bundled payment to reflect the costs of furnishing the non-drug component of OUD treatment services in each of the PFS fee schedule areas. The GAF is calculated using the GPCIs under the PFS, and is used to account for cost differences in furnishing physicians' services in differing geographic localities. The GAF is calculated for each fee schedule area as the weighted composite of all three GPCIs (work, PE, and malpractice) for that given locality using the national GPCI cost share weights. In developing this proposal, we also considered geographically adjusting the payment for the non-drug component of the OTP bundled payment using only the PE GPCI value for each fee schedule area. However, because the the non-drug component of OUD treatment services is comprised of work, PE, and malpractice expenses, we ultimately decided to propose using the GAF as we believe the weighted composite of all three GPCIs reflected in the GAF would be the more appropriate geographic adjustment factor to reflect geographic variations in the cost of furnishing these services.

The GAF, which is determined under § 414.26, is further discussed earlier in section II.D.1. of this proposed rule and the specific GAF values for each payment locality are posted in Addendum D to this proposed rule. In developing the proposed geographic locality adjustment for the non-drug component of the OUD treatment services payment rate, we also considered other potential locality adjustments, such as the Inpatient Prospective Payment System (IPPS) hospital wage index. However, we have opted to propose using the GAF as we believe the services provided in an OTP more closely resemble the services provided at a physician office than the services provided in other settings, such as inpatient hospitals. We propose to codify using the GAF to adjust the non-drug component of the OTP bundled payments to reflect the cost differences in furnishing these services in differing geographic localities at § 410.67(d)(3)(ii). We invite public comment on our proposal to adjust the non-drug component of the OTP bundled payments for geographic variations in the costs of furnishing OUD treatment services using the GAF. We also welcome comments on any factors, other than the GAF, that could be used to make this payment adjustment.

Additionally, we note that the majority of OTPs operate in urban localities. In light of this fact, we are interested in receiving information on whether rural areas have appropriate access to treatment for OUD. We are particularly interested in any potential limitations on access to care for OUD in rural areas and whether there are additional adjustments to the proposed bundled payments that should be made to account for the costs incurred by OTPs in furnishing OUD treatment services in rural areas. We invite public comment on this issue and potential solutions we could consider adopting to address this potential issue through future rulemaking.

b. Annual Update

Section 1834(w)(3) of the Act, as added by section 2005(c) of the SUPPORT Act, requires that the Secretary provide an update each year to the OTP bundled payment rates. To fulfill this statutory requirement, we are proposing to apply a blended annual update, comprised of distinct updates for the drug and non-drug components of the bundled payment rates, to account for the differing rate of growth in the prices of drugs relative to other services. We propose that this blended annual update for the OTP bundled payment rates would first apply for determining the CY 2021 OTP bundled payment rates. The specific details of the proposed updates for the drug and non-drug components respectively are discussed in this section.

(1) Drug Component

As stated above, we are proposing to establish the pricing of the drug component of the OTP bundled payment rates for OUD treatment services based on CMS pricing mechanisms currently in place. To recognize the potential change in costs of the drugs used in MAT from year to year and to fulfill the requirement to provide an annual update to the OTP bundled payment rates, we are proposing to update the payment for the drug component based upon the changes in drug costs reported under the pricing mechanism used to establish the pricing of the drug component of the applicable bundled payment rate, as discussed earlier. As an example, if we were to finalize our proposal to price the drug component of the bundled payment rate for episodes of care that include injectable and implantable drugs generally covered and paid under Medicare Part B using ASP data, the pricing of the drug component for these OTP bundled payments, would be updated using the most recently available ASP data at the time of ratesetting for the applicable calendar year. Similarly, if we finalize our proposal to price the drug component of the bundled payment rate for episodes of care that include oral drugs using ASP data, if such data are available, we would also update the pricing of the drug component using the most recently available ASP data at the time of ratesetting for the applicable calendar year. Previously, we also discussed a number of alternative data sources that could be used to price oral drugs in the drug component of OTP bundled payments in cases when we do not receive manufacturer-submitted ASP pricing data. As an example, if we were to use NADAC data as discussed as one of the alternatives, to determine the payment for the drug component of the bundled payment for oral drugs in cases when we do not have manufacturer-submitted ASP pricing data, this payment rate would also be updated using the most recently available NADAC data at the time of ratesetting for the applicable calendar year. We propose to codify this methodology for determining the annual update to the payment rate for the drug component at § 410.67(d)(3)(i).

In developing the proposal to annually update the pricing of the drug component of the OUD treatment services payment rate, we also considered other methodologies, including applying a single uniform update factor to the drug and non-drug components of the proposed payment rates. We ultimately determined not to propose the use of a single uniform update factor, because we believe that it is important to apply an annual update to the payment rates that recognizes the differing rate of growth of drug costs

compared to the rate of growth in the cost of the other services. In addition, we also considered annually updating the pricing of the drug component of the OUD treatment services payment rate via an established update factor such as the Producer Price Index (PPI) for chemicals and allied products, analgesics (WPU06380202). The PPI for chemicals and allied products, analgesics is a subset of the PPI produced by the Bureau of Labor Statistics, which measures the average change over time in the selling prices received by domestic producers for their output. Ultimately we decided against updating the pricing of the drug component of the OUD treatment services payment rate via an established update factor such as the PPI in favor of our proposed approach because we believe the proposed approach updated the pricing of the drug component of the OUD treatment services payment rate in the manner most familiar to stakeholders. We invite public comment on our proposed approach to updating the drug component of the bundled payment rates. We also seek comment on possible alternate methodologies for updating the drug component of the payment rate for OUD treatment services, such as use of the PPI for chemicals and allied products, analgesics.

(2) Non-Drug Component

To account for the potential changing costs of the services included in the non-drug component of the bundled payment rates for OUD treatment services, we are proposing to update the non-drug component of the bundled payment for OUD treatment services based upon the Medicare Economic Index (MEI). The MEI is defined in section 1842(i)(3) of the Act and the methodology for computing the MEI is described in § 405.504(d). The MEI is used to update the payment rates for physician services under section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973, may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such a higher level is justified by year-to-year economic changes. The MEI is a fixed-weight input price index that reflects the physicians' own time and the physicians' practice expenses, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity. The MEI was last revised in the CY 2014 PFS final rule with comment period (78 FR 74264). In developing the proposed update factor for the non-drug component of the OUD treatment services payment rate, we considered other potential update factors, such as the Bureau of Labor Statistics Consumer Price Index for All Items for Urban Consumers (Bureau of Labor Statistics #CUUR0000SA0 (*https://www.bls.gov/cpi/data.htm*) and the IPPS hospital market basket reduced by the multifactor productivity adjustment. The Consumer Price Index for All Items (CPI–U) is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. However, we concluded that a healthcare-specific update factor, such as the MEI, would be more appropriate for OTPs than the CPI–U, which measures general inflation, as the MEI would more accurately reflect the change in the prices of goods and services included in the non-drug component of the OTP bundled payments.

Similarly, we believe the MEI would be more appropriate than the IPPS market basket to update the non-drug component of the bundled payment rates as the services provided by an OTP more closely resemble the services provided at a physician office than the services provided by an inpatient hospital. Accordingly, we propose to update the payment amount for the non-drug component of each of the bundled payment rates for OUD treatment services furnished by OTPs based upon the most recently available historical annual growth in the MEI available at the time of rulemaking. We propose to codify this proposal at § 410.67(d)(3)(iii). We invite public comment on this proposal.

H. Bundled Payments Under the PFS for Substance Use Disorders

1. Background and Proposal

In the CY 2019 PFS proposed rule (83 FR 35730), we solicited comment on creating a bundled episode of care payment for management and counseling treatment for substance use disorders. We received approximately 50 comments on this topic, most of which were supportive of creating a separate bundled payment for these services. Some commenters recommended focusing the bundle on services related to medication assisted treatment (MAT) used in treatment for opioid use disorder (OUD). Several commenters also recommended that we establish higher payment amounts for patients with more complex needs who require more intensive services and management, and also expressed concern that an episode of care that limited the duration of treatment would not be conducive to treating OUD, given the chronic nature of this disorder. Other commenters recommended that we establish separate bundled payments for treatment of substance use disorders that does, and does not, involve MAT.

In response to the public comments, we are proposing to establish bundled payments for the overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities. We note that, if a patient's treatment involves MAT, this proposed bundled payment would not include payment for the medication itself. Billing and payment for medications under Medicare Part B or Part D would remain unchanged. Additionally, payment for medically necessary toxicology testing would not be included in the proposed OUD bundle, and would continue to be billed separately under the Clinical Lab Fee Schedule. We are also proposing in this proposed rule to implement the new Medicare Part B benefit added by section 2005 of the SUPPORT Act for coverage of certain services furnished by Opioid Treatment Programs (OTPs) beginning in CY 2020. We believe the proposed bundled payment under the PFS for OUD treatment described below will create an avenue for physicians and other health professionals to bill for a bundle of services that is similar to the new bundled OUD treatment services benefit, but not furnished by an OTP. By creating a separate bundled payment for these services under the PFS, we hope to incentivize increased provision of counseling and care coordination for patients with OUD in the office setting, thereby expanding access to OUD care.

To implement this new bundled payment, we are proposing to create two HCPCS G-codes to describe monthly bundles of services that include overall management, care coordination, individual and group psychotherapy and counseling for office-based OUD treatment. Although we considered proposing weekly-reported codes to describe a bundle of services that would align with the proposed OTP bundle, we believe that monthly-reported codes will better align with the practice and billing of other types of care management services furnished in office settings and billed under the PFS (for example, behavioral health integration (BHI) services). We believe monthly-reported codes would be less administratively burdensome for practitioners, and more likely to be consistent with care management and prescribing patterns in the office setting (as compared with an OTP) given the increased use of long-acting MAT drugs (such as injectable naltrexone or

implanted buprenorphine) in the office setting compared to the OTP setting. Based on feedback we received through the comment solicitation, we are proposing to create a code to describe the initial month of treatment, which would include intake activities and development of a treatment plan, as well as assessments to aid in development of the treatment plan in addition to care coordination, individual therapy, group therapy, and counseling; a code to describe subsequent months of treatment including care coordination, individual therapy, group therapy, and counseling; and an add-on code that could be billed in circumstances when effective treatment requires additional resources for a particular patient that substantially exceed the resources included in the base codes. In other words, the add-on code would address extraordinary circumstances that are not contemplated by the bundled code. We acknowledge that the course of treatment for OUD is variable, and in some instances, the first several months of treatment may be more resource intensive. We welcome comments on whether we should consider creating a separately billable code or codes to describe additional resources involved in furnishing OUD treatment-related services after the first month, for example, when substantial revisions to the treatment plan are needed, and what resource inputs we might consider in setting values for such codes.

We believe that, in general, bundled payments create incentives to provide efficient care by mitigating incentives tied to volume of services furnished, and that these incentives can be undermined by creating separate billing mechanisms to account for higher resource costs for particular patients. However, we share some of the concerns raised by commenters that an OUD bundle should not inadvertently limit the appropriate amount of OUD care furnished to patients with varying medical needs. In consideration of this concern, we are proposing to create an add-on code to make appropriate payment for additional resource costs in order to mitigate the risks that the bundled OUD payment might limit clinically-indicated patient care for patients that require significantly more care than is in the range of what is typical for the kinds of care described by the base codes. However, we are also interested in comments regarding ways we might better stratify the coding for OUD treatment to reflect the varying needs of patients (based on complexity or frequency of services, for example) while maintaining the full advantage of the bundled payment, including increased efficiency and flexibility in furnishing care.

We anticipate that these services would often be billed by addiction specialty practitioners, but note that these codes are not limited to any particular physician or non-physician practitioner specialty. Additionally, unlike the codes that describe care furnished using the psychiatric collaborative care model (CPT codes 99492, 99493, and 99494), which require consultation with a psychiatric consultant, we are not proposing to require consultation with a specialist as a condition of payment for these codes.

The codes and descriptors for the proposed services are:

- HCPCS code GYYY1: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code GYYY2: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code GYYY3: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

For the purposes of valuation for HCPCS codes GYYY1 and GYYY2, we are assuming two individual psychotherapy sessions per month and four group psychotherapy sessions per month; however, we understand that the number of therapy and counseling sessions furnished per month will vary among patients and also fluctuate over time based on the individual patient's needs. Consistent with the methodology for pricing other services under the PFS, HCPCS codes GYYY1, GYYY2, and GYYY3 are valued based on what we believe to be a typical case, and we understand that based on variability in patient needs, some patients will require more resources, and some fewer. In order to maintain the advantages inherent in developing a payment bundle, we are proposing that the add-on code (HCPCS code GYYY3) can only be billed when the total time spent by the billing professional and the clinical staff furnishing the OUD treatment services described by the base code exceeds double the minimum amount of service time required to bill the base code for the month. We believe it is appropriate to limit billing of the add-on code to situations where medically necessary OUD treatment services for a particular patient exceed twice the minimum service time for the base code because, as noted above, the add-on code is intended to address extraordinary situations where effective treatment requires additional resources that substantially exceed the resources included in the base codes. For example, the needs of a particular patient in a month may be unusually acute, well beyond the needs of the typical patient; or there may be some months when psychosocial stressors arise that were unforeseen at the time the treatment plan was developed, but warrant additional or more intensive therapy services for the patient. We are proposing that when the time requirement is met, HCPCS code GYYY3 could be billed as an add-on code during the initial month or subsequent months of OUD treatment. Practitioners should document the medical necessity for the use of the add-on code in the patient's medical record. We welcome comments on this proposal.

We are proposing to value HCPCS codes GYYY1, GYYY2, and GYYY3 using a building block methodology that sums the work RVUs and direct PE inputs from codes that describe the component services we believe would be typical, consistent with the approach we have previously used in valuing monthly care management services that include face-to-face services within the payment. For HCPCS code GYYY1, we developed proposed inputs using a crosswalk to CPT code 99492 (*Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric*

consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.), which is assigned a work RVU of 1.70, plus CPT code 90832 (*Psychotherapy, 30 minutes with patient*), which is assigned a work RVU of 1.50 (assuming two over the course of the month), and CPT code 90853 (*Group psychotherapy (other than of a multiple-family group)*), which is assigned a work RVU of 0.59 (assuming four over the course of a month), for a work RVU of 7.06. The required minimum number of minutes described in HCPCS code GYYY1 is also based on a crosswalk to CPT codes 99492. Additionally, for HCPCS code GYYY1, we are proposing to use a crosswalk to the direct PE inputs associated with CPT code 99492, CPT code 90832 (times two), and CPT code 90853 (times four). We believe that the work and practice expense described by these crosswalk codes is analogous to the services described in HCPCS code GYYY1 because HCPCS code GYYY1 includes similar care coordination activities as described in CPT code 99492 and bundles in the psychotherapy services described in CPT codes 90832 and 90853.

We are proposing to value HCPCS code GYYY2 using a crosswalk to CPT code 99493 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: Tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment*), which is assigned a work RVU of 1.53, plus CPT code 90832, which is assigned a work RVU of 1.50 (assuming two over the course of the month), and CPT code 90853, which is assigned a work RVU of 0.59 (assuming four over the course of a month), for a work RVU of 6.89. The required minimum number of minutes described in HCPCS code GYYY2 is also based on a crosswalk to CPT codes 99493. For HCPCS code GYYY2, we are proposing to use a crosswalk to the direct PE inputs associated with CPT code 99493, CPT code 90832 (times two), and CPT code 90853 (times four). We believe that the work and practice expense described by these crosswalk codes is analogous to the services described in HCPCS code GYYY2 because HCPCS code GYYY2 includes similar care coordination activities as described in CPT code 99493 and bundles in the psychotherapy services described in CPT codes 90832 and 90853.

We are proposing to value HCPCS code GYYY3 using a crosswalk to CPT code 99494 (*Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (List separately in addition to code for primary procedure)*), which is assigned a work RVU of 0.82. The required minimum number of minutes described in HCPCS code GYYY2 is also based on a crosswalk to CPT codes 99493. For HCPCS code GYYY3, we are proposing to use a crosswalk to the direct PE inputs associated with CPT code 99494. We believe that the work and practice expense described by this crosswalk code is analogous to the services described in HCPCS code GYYY3 because HCPCS code GYYY3 includes similar care coordination activities as described in CPT code 99494.

For additional details on the proposed direct PE inputs for HCPCS codes GYYY1–GYYY3, *see* Table 22.

We understand that many beneficiaries with OUD have comorbidities and may require medically-necessary psychotherapy services for other behavioral health conditions. In order to avoid duplicative billing, we are proposing that, when furnished to treat OUD, CPT codes 90832, 90834, 90837, and 90853 may not be reported by the same practitioner for the same beneficiary in the same month as HCPCS codes GYYY1, GYYY2, and GYYY3. We welcome comments on this proposal.

We are proposing that practitioners reporting the OUD bundle must furnish a separately reportable initiating visit in association with the onset of OUD treatment, since the bundle requires a level of care coordination that cannot be effective without appropriate evaluation of the patient's needs. This is similar to the requirements for chronic care management (CCM) services (CPT codes 99487, 99489, 99490, and 99491) and BHI services (CPT codes 99484, 99492, 99493, and 99494) finalized in the CY 2017 PFS final rule (81 FR 80239) The initiating visit would establish the beneficiary's relationship with the billing practitioner, ensure the billing practitioner assesses the beneficiary to determine clinical appropriateness of MAT in cases where MAT is being furnished, and provide an opportunity to obtain beneficiary consent to receive care management services (as discussed further below). We propose that the same services that can serve as the initiating visit for CCM services and BHI services can serve as the initiating visit for the proposed services described by HCPCS codes GYYY1–GYYY3. For new patients or patients not seen by the practitioner within a year prior to the commencement of CCM services and BHI services, the billing practitioner must initiate the service during a ''comprehensive'' E/M visit (levels 2 through 5 E/M visits), annual wellness visit (AWV) or initial preventive physical exam (IPPE). The face-to-face visit included in transitional care management (TCM) services (CPT codes 99495 and 99496) also qualifies as a ''comprehensive'' visit for CCM and BHI initiation. We propose that these visits could similarly serve as the initiating visit for OUD services.

We are proposing that the counseling, therapy, and care coordination described in the proposed OUD treatment codes could be provided by professionals who are qualified to provide the services under state law and within their scope of practice ''incident to'' the services of the billing physician or other practitioner. We are also proposing that the billing clinician would manage the patient's overall care, as well as supervise any other individuals participating in the treatment, similar to the structure of the BHI codes describing the psychiatric collaborative care model finalized in the CY 2017 PFS final rule (81 FR 80229), in which services are reported by a treating physician or other qualified health care professional and include the services of the treating physician or other qualified health care professional,

as well as the services of other professionals who furnish services incident to the services of the treating physician or other qualified health care professional. Additionally, we are proposing to add these codes to the list of designated care management services for which we allow general supervision of the non-face-to-face portion of the required services. Consistent with policies for other separately billable care management services under the PFS, because these proposed OUD treatment bundles include non-face-to-face care management components, we are proposing that the billing practitioner or clinical staff must document in the beneficiary's medical record that they obtained the beneficiary's consent to receive the services, and that, as part of the consent, they informed the beneficiary that there is cost sharing associated with these services, including potential deductible and coinsurance amounts, for both in-person and non-face-to-face services that are provided.

We are also proposing to allow any of the individual therapy, group therapy and counseling services included in HCPCS codes GYYY1, GYYY2, and GYYY3 to be furnished via telehealth, as clinically appropriate, in order to increase access to care for beneficiaries. As discussed in section II.F. of this proposed rule regarding Telehealth Services, like certain other non-face-to-face PFS services, the components of HCPCS codes GYYY1 through GYYY3 describing care coordination are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, these services are not considered telehealth services for purposes of Medicare, and we do not need to consider whether the non-face-to-face aspects of HCPCS codes GYYY1 through GYYY3 are similar to other telehealth services. If the non-face-to-face components of HCPCS codes GYYY1 through GYYY3 were separately billable, they would not need to be on the Medicare telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology.

Section 2001(a) of the SUPPORT Act amended section 1834(m) of the Act, adding a new paragraph (7) that removes the geographic limitations for telehealth services furnished on or after July 1, 2019, to an individual with a substance use disorder (SUD) diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder. The new paragraph at section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. As discussed in section II.F. of this proposed rule, Telehealth Services, we are proposing to add HCPCS codes GYYY1, GYYY2, and GYYY3 to the list of Medicare Telehealth services. Because certain required services (such as individual psychotherapy or group psychotherapy services) that are included in the proposed OUD bundled payment codes would be furnished to treat a diagnosed SUD, and would ordinarily require a face-to-face encounter, they could be furnished more broadly as telehealth services as permitted under section 1834(m)(7) of the Act.

For these proposed services described above (HCPCS codes GYYY1, GYYY2, and GYYY3), we seek comment on how these potential codes, descriptors, and payment rates align with state Medicaid coding and payment rates for the purposes of state payment of cost sharing for Medicare-Medicaid dually eligible individuals. Additionally, we understand that treatment for OUD can vary, and that MAT alone has demonstrated efficacy. In cases where a medication such as buprenorphine or naltrexone is used to treat OUD alone, without therapy or counseling, we note that existing applicable codes can be used to furnishing and bill for that care (for example, using E/M visits, in lieu of billing the bundled OUD codes proposed here).

As discussed in section II.G. of this proposed rule, Medicare Coverage for Certain Services Furnished by Opioid Treatment Programs, we are proposing to set the copayment at zero for OUD services furnished by an OTP, given the flexibility in section 1834(w)(1) of the Act for us to set the copayment amount for OTP services either at zero or at an amount above zero. We note that we do not have the statutory authority to eliminate the deductible and coinsurance requirements for the bundled OUD treatment services under the PFS. We acknowledge the potential impact of coinsurance on patient health care decisions and intend to monitor its impact if these proposals were to be finalized.

Finally, we recognize that historically, the CPT Editorial Panel has frequently created CPT codes describing services that we originally established using G-codes and adopted them through the CPT Editorial Panel process. We note that we would consider new using any available CPT coding to describe services similar to those described here in future rulemaking, as early as CY 2021. We would consider and adopt any such CPT codes through subsequent rulemaking.

Additionally, we understand that in some cases, OUD can first become apparent to practitioners in the emergency department setting. We recognize that there is not specific coding that describes diagnosis of OUD or the initiation of, or referral for, MAT in the emergency department setting. We are seeking comment on the use of MAT in the emergency department setting, including initiation of MAT and the potential for either referral or follow-up care, as well as the potential for administration of long-acting MAT agents in this setting, in order to better understand typical practice patterns to help inform whether we should consider making separate payment for such services in future rulemaking. We welcome feedback from stakeholders and the public on other potential bundles describing services for other substance use disorders for our consideration in future rulemaking.

2. Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

In the CY 2018 PFS final rule (82 FR 53169 through 53180), we established payment for General Care Management (CCM) services using HCPCS G0511 which is an RHC and FQHC-specific G code for at least 20 minutes of CCM, complex CCM, or general behavioral health services. Payment for this code is currently set at the average of the non-facility, non-geographically adjusted payment rates for CPT codes 99490, 99487, 99491, and 99484. The types of chronic conditions that are eligible for care management services include mental health or behavioral health conditions, including substance use disorders.

In the CY 2018 PFS final rule with comment period (82 FR 53169 through 53180), we also established payment for psychiatric Collaborative Care Services (CoCM) using HCPCS code G0512, which is an RHC and FQHC specific G-code for at least 70 minutes in the first calendar month, and at least 60 minutes in subsequent calendar months of psychiatric CoCM services. Payment for this code is set at the average of the non-facility, non-geographically adjusted rates for CPT codes 99492 and 99493. The psychiatric CoCM model of care may be used to treat patients with any behavioral health condition that is being treated by the billing practitioner, including substance use disorders.

RHCs and FQHCs can also bill for individual psychotherapy services using CPT codes 90791, 90792, 90832, 90834, 90837, 90839, or 90845, which are billable visits under the RHC all-inclusive rate (AIR) and FQHC Prospective Payment System (PPS) when furnished by an RHC or FQHC practitioner. If a qualified mental health service is furnished on the same day as a qualified primary care service, the RHC or FQHC can bill for 2 visits.

RHCs and FQHCs are engaged primarily in providing services that are furnished typically in a physician's office or an outpatient clinic. As a result of the proposed bundled payment under the PFS for OUD treatment furnished by physicians, we reviewed the applicability of RHCs and FQHCs furnishing and billing for similar services. Specifically, we considered establishing a new RHC and FQHC specific G code for OUD treatment with the payment rate set at the average of the non-facility, non-geographically adjusted payment rates for GYYY1 and GYYY2, beginning on January 1, 2020. The requirements to bill the services would be similar to the requirements under the PFS for GYYY1 and GYYY2, including that an initiating visit with a primary care practitioner must occur within one year before OUD services begin, and that consent be obtained before services are furnished.

However, because RHCs and FQHCs that choose to furnish OUD services can continue to report these individual codes when treating OUD, and can also offer their patients comprehensive care coordination services using HCPCS codes G0511 and G0512, we do not believe that adding a new and separate code to report a bundle of OUD services is necessary. Therefore, we are not proposing to add a new G code for a bundle of OUD service.

I. Physician Supervision for Physician Assistant (PA) Services

1. Background

Section 4072(e) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509, October 21, 1986), added section 1861(s)(2)(K)(i) of the Act to establish a benefit for services furnished by a physician assistant (PA) under the supervision of a physician. We have interpreted this physician supervision requirement in the regulation at § 410.74(a)(2)(iv) to require PA services to be furnished under the general supervision of a physician. This general supervision requirement was based upon another longstanding regulation at § 410.32(b)(3)(i) that defines three levels of supervision for diagnostic tests, which are general, direct and personal supervision. Of these three supervision levels, general supervision is the most lenient. Specifically, the general supervision requirement means that PA services must be furnished under a physician's overall direction and control, but the physician's presence is not required during the performance of PA services.

In the CY 2018 PFS proposed rule (82 FR 34172 through 34173), we published a request for information (RFI) on CMS flexibilities and efficiencies. In response to this RFI, commenters including PA stakeholders informed us about recent changes in the practice of medicine for PAs, particularly regarding physician supervision. These commenters also reached out separately to CMS with their concerns. They stated that PAs are now practicing more autonomously, like nurse practitioners (NPs) and clinical nurse specialists (CNSs), as members of medical teams that often consist of physicians, nonphysician practitioners and other allied health professionals. This changed approach to the delivery of health care services involving PAs has resulted in changes to scope of practice laws for PAs regarding physician supervision across some states. According to these commenters, some states have already relaxed their requirements for PAs related to physician supervision, some states have made changes and are now silent about their physician supervision requirements, while other states have not yet changed their PA scope of practice in terms of their physician supervision requirements. Overall, these commenters believe that as states continue to make changes to their physician supervision requirements for PAs, the Medicare requirement for general supervision of PA services may become increasingly out of step with current medical practice, imposing a more stringent standard than state laws governing physician supervision of PA services. Furthermore, as currently defined, stakeholders have suggested that the supervision requirement is often misinterpreted or misunderstood in a manner that restricts PAs' ability to practice to the full extent of their education and expertise. The stakeholders have suggested that the current regulatory definition of physician supervision as it applies to PAs could inappropriately restrict the practice of PAs in delivering their professional services to the Medicare population.

We note that we have understood our current policy to require general physician supervision for PA services to fulfill the statutory physician supervision requirement; and we believe that general physician supervision gives PAs flexibility to furnish their professional services without the need for a physician's physical presence or availability. Nonetheless, we appreciate the concerns articulated by stakeholders. To more fully understand the current landscape for medical practice involving PA services and how the current regulatory definition may be problematic, we invite public comments on specific examples of changes in state law and state scope of practice rules that enable PAs to practice more broadly such that those rules are in tension with the Medicare requirement for general physician supervision of PA services that has been in place since the inception of the PA benefit category under Medicare law.

Given the commenters' understanding of ongoing changes underway to the state scope of practice laws regarding physician supervision of PA services, commenters on our CY 2018 RFI have requested that CMS reconsider its interpretation of the statutory requirement that PA services must be furnished under the supervision of a physician to allow PAs to operate similarly to NPs and CNSs, who are required by section 1861(s)(2)(K)(ii) of the Act to furnish their services ''in collaboration'' with a physician. In general, we have interpreted collaboration for this purpose at §§ 410.75(c)(3) and 410.76(c)(3) of our regulations to mean a process in which an NP or CNS (respectively) works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided by state law in which the services are performed. The commenters stated that allowing PA services to be furnished using such a collaborative process would offer PAs the flexibility necessary to deliver services more effectively under today's health care system in accordance with the scope of practice in the state(s) where they practice, rather than being limited by the system that was in place when PA services were first covered under Medicare Part B over 30 years ago.

2. Proposal

After considering the comments we received on the RFI, as well as information we received regarding the scope of practice laws in some states regarding supervision requirements for PAs, we are proposing to revise the regulation at § 410.74 that establishes physician supervision requirements for PAs. Specifically, we are proposing to

revise § 410.74(a)(2) to provide that the statutory physician supervision requirement for PA services at section 1861(s)(2)(K)(i) of the Act would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services. Consistent with current rules, such documentation would need to be available to CMS, upon request. This proposed change would substantially align the regulation on physician supervision for PA services at § 410.74(a)(2) with our current regulations on physician collaboration for NP and CNS services at §§ 410.75(c)(3) and 410.76(c)(3). We continue to engage with key stakeholders on this issue and receive information on the expanded role of nonphysician practitioners as members of the medical team. As we are informed about transitions in state law and state scope of practice governing physician supervision, as well as changes in the way that PAs practice, we acknowledge the state's role and autonomy to establish, uphold, and enforce their state laws and PA scope of practice requirements to ensure that an appropriate level of physician oversight occurs when PAs furnish their professional services to Medicare Part B patients. Our policy proposal on this issue largely defers to state law and state scope of practice and enables states the flexibility to develop requirements for PA services that are unique and appropriate for their respective state, allowing the states to be accountable for the safety and quality of health care services that PAs furnish.

J. Review and Verification of Medical Record Documentation

1. Background

In an effort to reduce mandatory and duplicative medical record evaluation and management (E/M) documentation requirements, we finalized an amended regulatory provision at 42 CFR part 415, subpart D, in the CY 2019 PFS final rule (83 FR 59653 through 59654). Specifically, § 415.172(a) requires as a condition of payment under the PFS that the teaching physician (as defined in § 415.152) must be present during certain portions of services that are furnished with the involvement of residents (individuals who are training in a graduate medical education program). Section 415.174(a) provides for an exception to the teaching physician presence requirements in the case of certain E/M services under certain conditions, but requires that the teaching physician must direct and review the care provided by no more than four residents at a time. Sections 415.172(b) and 415.174(a)(6), respectively require that the teaching physician's presence and participation in services involving residents must be documented in the medical record. We amended these regulations to provide that a physician, resident, or nurse may document in the patient's medical record that the teaching physician presence and participation requirements were met. As a result, for E/M visits furnished beginning January 1, 2019, the extent of the teaching physician's participation in services involving residents may be demonstrated by notes in the medical records made by a physician, resident, or nurse.

For the same burden reduction purposes, we issued CR 10412, Transmittal 3971 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R3971CP.pdf* on February 2, 2018, which revised a paragraph in our manual instructions on ''Teaching Physician Services'' at Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100.1.1B., to reduce duplicative documentation requirements by allowing a teaching physician to review and verify (sign/date) notes made by a student in a patient's medical record for E/M services, rather than having to re-document the information, largely duplicating the student's notes. We issued corrections to CR 10412 through Transmittal 4068 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4068CP.pdf* and re-issued the CR on May 31, 2018. Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100 contains a list of definitions pertinent to teaching physician services. Following these amendments to our regulations and manual, certain stakeholders raised concerns about the definitions in this section, particularly those for teaching physician, student, and documentation; and when considered in conjunction with the interpretation of the manual provision at Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100.1.1B., which addresses documentation of E/M services involving students. While there is no regulatory definition of student, the manual instruction defines a student as an individual who participates in an accredited educational program (for example, a medical school) that is not an approved graduate medical education (GME) program. The manual instructions also specify that a student is never considered to be an intern or a resident, and that Medicare does not pay for services furnished by a student (*see* Section 100.1.1B. for a discussion concerning E/M service documentation performed by students).

We are aware that nonphysician practitioners who are authorized under Medicare Part B to furnish and be paid for all levels of E/M services are seeking similar relief from burdensome E/M documentation requirements that would allow them to review and verify medical record notes made by their students, rather than having to re-document the information. These nonphysician practitioners include nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse-midwives (CNMs), collectively referred to hereafter for purposes of this discussion as advanced practice registered nurses (APRNs), as well as physician assistants (PAs). Subsequent to the publication of the CY 2019 PFS final rule (83 FR 59653 through 59654), through feedback from listening sessions hosted by CMS' Documentation Requirements Simplification workgroup, we began to hear concerns from a variety of stakeholders about the requirements for teaching physician review and verification of documentation added to the medical record by other individuals. Physician and nonphysician practitioner stakeholders expressed concern about the scope of the changes to §§ 415.172(b) and 415.174(a)(6) which authorize only a physician, resident, or nurse to include notes in the medical record to document E/M services furnished by teaching physicians, because they believed that students and other members of the medical team should be similarly permitted to provide E/M medical record documentation. In addition to students, these stakeholders indicated that ''other members of the medical team'' could include individuals who the teaching physician, other physicians, PA and APRN preceptors designate as being appropriate to document services in the medical record, which the billing practitioner would then review and verify, and rely upon for billing purposes.

Subsequent to the publication of the student documentation manual

instruction change at section 100.1.1B of the Medicare Claims Processing Manual, representatives of PAs and APRNs requested clarification about whether PA and APRN preceptors and their students were subject to the same E/M documentation requirements as teaching physicians and their medical students. These stakeholders suggested that the reference to ''student'' in the manual instruction on E/M documentation provided by students is ambiguous because it does not specify ''medical student''. These stakeholders also suggested that the definition of ''student'' in section 100 of this manual instruction is ambiguous because PA and APRN preceptors also educate students who are individuals who participate in an accredited educational program that is not an approved GME program. Accordingly, these stakeholders expressed concern that the uncertainty throughout the health care industry, including among our contractors, concerning the student E/M documentation review and verification policy under these manual guidelines results in unequal treatment as compared to teaching physicians. The stakeholders stated that depending on how the manual instruction is interpreted, PA and APRN preceptors may be required to re-document E/M services in full when their students include notes in the medical records, without having the same option that teaching physicians do to simply review and verify medical student documentation.

2. Proposal

After considering the concerns expressed by these stakeholders, we believe it would be appropriate to provide broad flexibility to the physicians, PAs and APRNs (regardless of whether they are acting in a teaching capacity) who document and who are paid under the PFS for their professional services. Therefore, we propose to establish a general principle to allow the physician, the PA, or the APRN who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team. This principle would apply across the spectrum of all Medicare-covered services paid under the PFS. Because this proposal is intended to apply broadly, we propose to amend regulations for teaching physicians, physicians, PAs, and APRNs to add this new flexibility for medical record documentation requirements for professional services furnished by physicians, PAs and APRNs in all settings. We invite comments on this proposal.

Specifically, to reflect our simplified and standardized approach to medical record documentation for all professional services furnished by physicians, PAs and APRNs paid under the PFS, we are proposing to amend §§ 410.20 (Physicians' services), 410.74 (PA services), 410.75 (NP services), 410.76 (CNS services) and 410.77 (CNM services) to add a new paragraph entitled, ''Medical record documentation.'' This paragraph would specify that, when furnishing their professional services, the clinician may review and verify (sign/date) notes in a patient's medical record made by other physicians, residents, nurses, students, or other members of the medical team, including notes documenting the practitioner's presence and participation in the services, rather than fully re-documenting the information. We note that, while the proposed change addresses who may document services in the medical record, subject to review and verification by the furnishing and billing clinician, it does not modify the scope of, or standards for, the documentation that is needed in the medical record to demonstrate medical necessity of services, or otherwise for purposes of appropriate medical recordkeeping.

We are also proposing to make conforming amendments to §§ 415.172(b) and 415.174(a)(6) to also allow physicians, residents, nurses, students, or other members of the medical team to enter information in the medical record that can then be reviewed and verified by a teaching physician without the need for re-documentation. We invite comments on these proposed amendments to our regulations.

K. Care Management Services

1. Background

In recent years, we have updated PFS payment policies to improve payment for care management and care coordination. Working with the CPT Editorial Panel and other clinicians, we have expanded the suite of codes describing these services. New CPT codes were created that distinguish between services that are face-to-face; represent a single encounter, monthly service or both; are timed services; represent primary care versus specialty care; address specific conditions; and represent the work of the billing practitioner, their clinical staff, or both (*see* Table 16). Additional information regarding recent new codes and associated PFS payment rules is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html.*

TABLE 16—SUMMARY OF SPECIAL CARE MANAGEMENT CODES

Service	Summary
Care Plan Oversight (CPO) (also referred to as Home Health Supervision, Hospice Supervision) (HCPCS Codes G0181, G0182).	Supervision of home health, hospice, per month.
ESRD Monthly Services (CPT Codes 90951–70)	ESRD management, with and without face-to-face visits, by age, per month.
Transitional Care Management (TCM) (adopted in 2013) (CPT Codes 99495, 99496).	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit, once per patient within 30 days post-discharge.
Chronic Care Management (CCM) (adopted in 2015, 2017, 2019) (CPT Codes 99487, 99489, 99490, 99491).	Management of all care for patients with two or more serious chronic conditions, timed, per month.
Advance Care Planning (ACP) (adopted in 2016) (CPT Codes 99497, 99498).	Counseling/discussing advance directives, face-to-face, timed.
Behavioral Health Integration (BHI) (adopted in 2017) (CPT Codes 99484, 99492, 99493, 99494).	Management of behavioral health conditions(s), timed, per month.
Assessment/Care Planning for Cognitive Impairment (adopted in 2017) (CPT Code 99483).	Assessment and care planning of cognitive impairment, face-to-face visit.
Prolonged Evaluation & Management (E/M) Without Direct Patient Contact (adopted in 2017) (CPT Codes 99358, 99359).	Non-face-to-face E&M work related to a face-to-face visit, timed.

TABLE 16—SUMMARY OF SPECIAL CARE MANAGEMENT CODES—Continued

Service	Summary
Remote Patient Monitoring (adopted in 2019) (CPT Code 99091)	Review and analysis of patient-generated health data, timed, per 30 days.
Interprofessional Consultation (adopted in 2019) (CPT Codes 99446, 99447, 99448, 99449, 99451, 99452).	Inter-practitioner consultation.

Based on our review of the Medicare claims data we estimate that approximately 3 million unique beneficiaries (9 percent of the Medicare fee-for-service (FFS) population) receive these services annually, with higher use of chronic care management (CCM), transitional care management (TCM), and advance care planning (ACP) services. We believe gaps remain in coding and payment, such as for care management of patients having a single, serious, or complex chronic condition. In this proposed rule, we continue our ongoing work in this area through code set refinement related to TCM services and CCM services, in addition to proposing new coding for principal care management (PCM) services, and addressing chronic care remote physiologic monitoring (RPM) services.

2. Transitional Care Management (TCM) Services

Utilization of TCM services has increased each year since CMS established coding and began paying separately for TCM services. Specifically, there were almost 300,000 TCM professional claims during 2013, the first year of TCM services, and almost 1.3 million professional claims during 2018, the most recent year of complete claims data. However, based upon an analysis of claims data by Bindman and Cox,[78] utilization of TCM services is low when compared to the number of Medicare beneficiaries with eligible discharges. Additionally, Bindman and Cox noted that the beneficiaries who received TCM services demonstrated reduced readmission rates, lower mortality, and decreased health care costs. Based upon these findings, we believe that increasing utilization of TCM services could positively affect patient outcomes.

In developing a proposal designed to increase utilization of TCM services, we considered possible factors contributing to low utilization. Bindman and Cox identified two likely contributing factors: The administrative burdens associated with billing TCM services and the payment amount to physicians for services.

We focused initially on the requirements for billing TCM services. In reviewing the TCM billing requirements, we noted that we had established in the CY 2013 PFS final rule with comment period a list of 57 HCPCS codes that cannot be billed during the 30-day period covered by TCM services by the same practitioner reporting TCM (77 FR 68990). This list mirrored reporting restrictions put in place by the CPT Editorial Panel for the TCM codes upon their creation. At the time we established separate payment for the TCM CPT codes, we agreed with the CPT Editorial Panel that the services described by the 57 codes could be overlapping and duplicative with TCM in their definition and scope; although, many of these codes were not separately payable or covered under the PFS so even if they were reported for PFS payment, they would not be have been separately paid (*see,* for example, 77 FR 68985). In response to those concerns, we adopted billing restrictions to avoid duplicative billing and payment for covered services. In our recent analysis of the services associated with the 57 codes, we found that the majority of codes on the list remain either bundled, noncovered by Medicare, or invalid for Medicare payment purposes. Table 17 provides detailed information regarding the subset of these codes that would be separately payable under the PFS (Status Indicator ''A'') and, as such, are the focus of this year's CY 2020 proposed policy for TCM. Fourteen (14) codes on the list represent active codes that are paid separately under the PFS and that upon reconsideration, we believe may not substantially overlap with TCM services and should be separately payable alongside TCM. For example, CPT code 99358 (*Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service*) would allow the physician or other qualified healthcare professional extra time to review records and manage patient support services after the face-to-face visit required as part of TCM services. CPT code 99091 (*Collection & interpretation of physiologic data, requiring a minimum of 30 minutes each 30 days*) would permit the physician or other qualified healthcare professional to collect and analyze physiologic parameters associated with the patient's chronic disease.

Thus, after review of the services described by these 14 HCPCS codes, we believe these codes, when medically necessary, may complement TCM services rather than substantially overlap or duplicate services. We also believe removing the billing restrictions associated with these codes may increase utilization of TCM services.

TABLE 17—14 HCPCS CODES THAT CURRENTLY CANNOT BE BILLED CONCURRENTLY WITH TCM BY THE SAME PRACTITIONER AND ARE ACTIVE CODES PAYABLE BY MEDICARE PFS

Code family	HCPCS code	Descriptor
Prolonged Services without Direct Patient Contact.	99358	Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service.
	99359	Prolonged E/M service before and/or after direct patient care; each additional 30 minutes beyond the first hour of prolonged services.

[78] Bindman, AB, Cox DF. Changes in health care costs and mortality associated with transitional care management services after a discharge among Medicare beneficiaries [published online July 30, 2018]. *JAMA Intern Med,* doi:10.1001/jamainternmed.2018.2572.

TABLE 17—14 HCPCS CODES THAT CURRENTLY CANNOT BE BILLED CONCURRENTLY WITH TCM BY THE SAME PRACTITIONER AND ARE ACTIVE CODES PAYABLE BY MEDICARE PFS—Continued

Code family	HCPCS code	Descriptor
Home and Outpatient International Normalized Ratio (INR) Monitoring Services.	93792	Patient/caregiver training for initiation of home INR monitoring.
	93793	Anticoagulant management for a patient taking warfarin; includes review and interpretation of a new home, office, or lab INR test result, patient instructions, dosage adjustment and scheduling of additional test(s).
End Stage Renal Disease Services (patients who are 20+ years).	90960	ESRD related services monthly with 4 or more face-to-face visits per month; for patients 20 years and older.
	90961	ESRD related services monthly with 2–3 face-to-face visits per month; for patients 20 years and older.
	90962	ESRD related services with 1 face-to-face visit per month; for patients 20 years and older.
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older.
	90970	ESRD related services for dialysis less than a full month of service; per day; for patient 20 years and older.
Interpretation of Physiological Data	99091	Collection & interpretation of physiologic data, requiring a minimum of 30 minutes each 30 days.
Complex Chronic Care Management Services.	99487	Complex Chronic Care with 60 minutes of clinical staff time per calendar month.
	99489	Complex Chronic Care; additional 30 minutes of clinical staff time per month.
Care Plan Oversight Services	G0181	Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities within a calendar month; 30+ minutes.
	G0182	Physician supervision of a patient receiving Medicare-covered hospice services (Pt not present) requiring complex and multidisciplinary care modalities; within a calendar month; 30+ minutes.

Thus, with the goal of increasing medically appropriate use of TCM services, we are proposing to revise our billing requirements for TCM by allowing TCM codes to be billed concurrently with any of these codes. Before we finalize such a rule, however, we seek comment on whether overlap of services exists, and if so, which services should be restricted from being billed concurrently with TCM. We also seek comment on whether any overlap would depend upon whether the same or a different practitioner reports the services. We note that CPT reporting rules generally apply at the practitioner level, and we are seeking input from stakeholders as to whether our policy should differ based on whether it is the same or a different practitioner reporting the services. We are seeking comment on whether the newest CPT code in the chronic care management services family (CPT code 99491 for CCM by a physician or other qualified health professional, established in 2019) overlaps with TCM or should be reportable and separately payable in the same service period.

As part of our analysis of the utilization data for TCM services, we also examined how current payment rates for TCM might negatively affect the appropriate utilization of TCM services, an idea proposed by Bindman and Cox. CPT code 99495 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*) and CPT code 99496 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge*) were resurveyed during 2018 as part of a regular RUC review of new technologies or services. For this RUC resurvey, several years of claims data were available and clinicians had more experience to inform their views about the work required to furnish TCM services. Based upon the results of the 2018 RUC survey of the two TCM codes, the RUC recommended a slight increase in work RVUs for both codes. We believe the results from the new survey will better reflect the work involved in furnishing TCM services as care management services. Thus, also for CY 2020, we are proposing the RUC-recommended work RVU of 2.36 for CPT code 99495 and the RUC-recommended work RVU of 3.10 for CPT code 99496. We are not proposing any direct PE refinements to the RUC's recommendations for this code family.

3. Chronic Care Management (CCM) Services

CCM services are comprehensive care coordination services per calendar month, furnished by a physician or non-physician practitioner (NPP) managing overall care and their clinical staff, for patients with two or more serious chronic conditions. There are currently two subsets of codes: One for non-complex chronic care management (starting in 2015, with a new code for 2019) and a set of codes for complex chronic care management (starting in 2017). Table 17 provides a high-level summary of the CCM service elements.

Early data show that, in general, CCM services are increasing patient and practitioner satisfaction, saving costs and enabling solo practitioners to remain in independent practice.[79] Utilization has reached approximately 75 percent of the level we initially assumed under the PFS when we began paying for CCM services separately under the PFS. While these are positive results, we believe that CCM services (especially complex CCM services) continue to be underutilized. In addition, we note that, at the February 2019 CPT Editorial Panel meeting, certain specialty associations requested refinements to the existing CCM codes, and consideration of their proposal was postponed. Also, we have heard from some stakeholders suggesting that the

[79] *https://innovation.cms.gov/Files/reports/chronic-care-mngmt-finalevalrpt.pdf.*

time increments for non-complex CCM performed by clinical staff should be changed to recognize finer increments of time, and that certain requirements related to care planning are unclear. Based on our consideration of this ongoing feedback, we believe some of the refinements requested by specialty associations and other stakeholders may be necessary to improve payment accuracy, reduce unnecessary burden and help ensure that beneficiaries who need CCM services have access to them. Accordingly, we are proposing the following changes to the CCM code set for CY 2020.

a. Non-Complex CCM Services by Clinical Staff (CPT Code 99490, HCPCS Codes GCCC1 and GCCC2)

Currently, the clinical staff CPT code for non-complex CCM, CPT code 99490 *(Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.)* describes 20 or more minutes of clinical staff time spent performing chronic care management activities under the direction of a physician/qualified health care professional. When we initially adopted this code for payment and, in feedback we have since received, a number of stakeholders suggested that CMS undervalued the PE RVU because we assumed that the minimum time for the code (20 minutes of clinical staff time) would be typical (see, for example, 79 FR 67717 through 67718). In the CY 2017 PFS final rule with comment period, we continued to consider whether the payment amount for CPT code 99490 is appropriate, given the amount of time typically spent furnishing CCM services (81 FR 80243 through 80244). We adopted the complex CCM codes for payment beginning in CY 2017, in part, to pay more appropriately for services furnished to beneficiaries requiring longer service times.

There are two CPT codes for complex CCM:

- CPT code 99487 *(Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately);* and
- CPT code 99489 *(each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).*

Complex CCM describes care management for patients who require not only more clinical staff time, but also complex medical decision-making. Some stakeholders continue to recommend that, in addition to separate payment for the complex CCM codes, we should create an add-on code for non-complex CCM, such that non-complex CCM would be defined and valued in 20-minute increments of time with additional payment for each additional 20 minutes, or extra payment for 20 to 40 minutes of clinical staff time spent performing care management activities.

We agree that coding changes that identify additional time increments would improve payment accuracy for non-complex CCM. Accordingly, we propose to adopt two new G codes with new increments of clinical staff time instead of the existing single CPT code (CPT code 99490). The first G code would describe the initial 20 minutes of clinical staff time, and the second G code would describe each additional 20 minutes thereafter. We intend these would be temporary G codes, to be used for PFS payment instead of CPT code 99490 until the CPT Editorial Panel can consider revisions to the current CPT code set. We would consider adopting any CPT code(s) once the CPT Editorial Panel completes its work. We acknowledge that imposing a transitional period during which G codes would be used under the PFS in lieu of the CPT codes is potentially disruptive, and are seeking comment on whether the benefit of proceeding with the proposed G codes outweighs the burden of transitioning to their use in the intervening year(s) before a decision by the CPT Editorial Panel.

We are proposing that the base code would be HCPCS code GCCC1 *(Chronic care management services, initial 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and comprehensive care plan established, implemented, revised, or monitored. (Chronic care management services of less than 20 minutes duration, in a calendar month, are not reported separately)).* We propose a work RVU of 0.61 for HCPCS code GCCC1, which we crosswalked from CPT code 99490. We believe these codes have a similar amount of work since they would have the same intra-service time of 15 minutes.

We propose an add-on HCPCS code GCCC2 *(Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Use GCCC2 in conjunction with GCCC1). (Do not report GCCC1, GCCC2 in the same calendar month as GCCC3, GCCC4, 99491)).* We are proposing a work RVU of 0.54 for HCPCS code GCCC2 based on a crosswalk to CPT code 11107 (*Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)*), which has a work RVU of 0.54, which we believe accurately reflects the work associated with each additional 20 minutes of CCM services. Both codes have the same intraservice time of 15 minutes. We note that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, codes need not share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. In this case, CPT code 11107 shares a similar work intensity to proposed HCPCS code GCCC2. Furthermore, although HCPCS codes GCCC1 and GCCC2 share the same intraservice time, add-on codes often have lower intensity than the base codes because they describe the continuation of an already initiated service.

We are soliciting public comment on whether we should limit the number of times this add-on code (HCPCS code GCCC2) can be reported in a given service period for a given beneficiary. It

is not clear how often more than 40 minutes of clinical staff time is currently spent or is medically necessary. In addition, once 60 minutes of clinical staff time is spent, many or most patients might also require complex medical decision-making, and such patients would be already described under existing coding for complex CCM. A limit (such as allowing the add-on code to be reported only once per service period per beneficiary) may be appropriate in order to maintain distinctions between complex and non-complex CCM, as well as appropriately limit beneficiary cost sharing and program spending to medically necessary services. We note that complex CCM already describes (in part) 60 or more minutes of clinical staff time in a service period. We are seeking comment on whether and how often beneficiaries who do not require complex CCM (for example, do not require the complex medical decision making that is part of complex CCM) would need 60 or more minutes of non-complex CCM clinical staff time and thereby warrant more than one use of HCPCS code GCCC2 within a service period.

b. Complex CCM Services (CPT Codes 99487 and 99489, and HCPCS Codes GCCC3 and GCCC4)

Currently, the CPT codes for complex CCM include in the code descriptors a requirement for establishment or substantial revision of the comprehensive care plan (see above). The code descriptors for complex CCM also include moderate to high complexity medical decision-making (moderate to high complexity medical decision-making is an explicit part of the services). We propose to adopt two new G codes that would be used for billing under the PFS instead of CPT codes 99487 and 99489, and that would not include the service component of substantial care plan revision. We believe it is not necessary to explicitly include substantial care plan revision because patients requiring moderate to high complexity medical decision making implicitly need and receive substantial care plan revision. The service component of substantial care plan revision is potentially duplicative with the medical decision making service component and, therefore, we believe it is unnecessary as a means of distinguishing eligible patients. Instead of CPT code 99487, we propose to adopt HCPCS code GCCC3 *(Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately)).* We are proposing a work RVU of 1.00 for HCPCS code GCCC3, which is a crosswalk to CPT code 99487.

Instead of CPT code 99489, we propose to adopt HCPCS code GCCC4 (*each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3). (Do not report GCCC4 for care management services of less than 30 minutes additional to the first 60 minutes of complex chronic care management services during a calendar month)).* We are proposing a work RVU of 0.50 for HCPCS code GCCC4, which is a crosswalk to CPT code 99489.

We intend these would be temporary G codes to remain in place until the CPT Editorial Panel can consider revising the current code descriptors for complex CCM services. We would consider adopting any new or revised complex CCM CPT code(s) once the CPT Editorial Panel completes its work. We acknowledge that imposing a transitional period during which G codes would be used under the PFS in lieu of the CPT codes is potentially disruptive. We are seeking comment on whether the benefit of proceeding with the proposed G codes outweighs the burden of transitioning to their use in the intervening year(s) before a decision by the CPT Editorial Panel.

c. Typical Care Plan

In 2013, in working with the physician community to develop and propose the CCM codes for PFS payment, the medical community recommended and CMS agreed that adequate care planning is integral to managing patients with multiple chronic conditions. We stated our belief that furnishing care management to beneficiaries with multiple chronic conditions requires complex and multidisciplinary care modalities that involve, among other things, regular physician development and/or revision of care plans and integration of new information into the care plan (78 FR 43337). In the CY 2014 PFS final rule with comment period (78 FR 74416 through 74418), consistent with recommendations CMS received in 2013 from the AMA's Complex Chronic Care Coordination Workgroup, we finalized a CCM scope of service element for a patient-centered plan of care with the following characteristics: It is a comprehensive plan of care for all health problems and typically includes, but is not limited to, the following elements: Problem list; expected outcome and prognosis; measurable treatment goals; cognitive and functional assessment; symptom management; planned interventions; medical management; environmental evaluation; caregiver assessment; community/social services ordered; how the services of agencies and specialists unconnected to the practice will be directed/coordinated; identify the individuals responsible for each intervention, requirements for periodic review; and when applicable, revisions of the care plan.

The CPT Editorial Panel also incorporated and adopted this language in the prefatory language for Care Management Services codes (page 49 of the 2019 CPT Codebook) including CCM services.

As we continue to consider the need for potential refinements to the CCM code set, we have heard that there is still some confusion in the medical community regarding what a care plan typically includes. We have re-reviewed this language for CCM, and we believe there may be aspects of the typical care plan language we adopted for CCM that are redundant or potentially unduly burdensome. We note that because these are ''typical'' care plan elements, these elements do not comprise a set of strict requirements that must be included in a care plan for purposes of billing for CCM services; the elements are intended to reflect those that are typically, but perhaps not always, included in a care plan as medically appropriate for a particular beneficiary. Nevertheless, we are proposing to eliminate the phrase ''community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention'' and insert the phrase ''interaction and coordination with outside resources and practitioners and providers.'' We believe simpler language would describe the important work of interacting and coordinating with resources external to the practice. While it is preferable, when feasible, to identify who is responsible for

interventions, it may be difficult to maintain an up-to-date listing of responsible individuals especially when they are outside of the practice, for example, when there is staff turnover or assignment changes.

Our proposed new language would read: The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements:

- Problem list.
- Expected outcome and prognosis.
- Measurable treatment goals.
- Cognitive and functional assessment.
- Symptom management.
- Planned interventions.
- Medical management.
- Environmental evaluation.
- Caregiver assessment.
- Interaction and coordination with outside resources and practitioners and providers.
- Requirements for periodic review.
- When applicable, revision of the care plan.

We welcome feedback on our proposal, including language that would best guide practitioners as they decide what to include in their comprehensive care plan for CCM recipients.

Additional information regarding the existing requirements for billing CCM, including links to prior rules, is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html*.

4. Principal Care Management (PCM) Services

A gap we identified in coding and payment for care management services is care management for patients with only one chronic condition. The current CCM codes require patients to have two or more chronic conditions. These codes are primarily billed by practitioners who are managing a patient's total care over a month, including primary care practitioners and some specialists such as cardiologists or nephrologists. We have heard from a number of stakeholders, especially those in specialties that use the office/outpatient E/M code set to report the majority of their services, that there can be significant resources involved in care management for a single high risk disease or complex chronic condition that is not well accounted for in existing coding (FR 78 74415). This issue has also been raised by the stakeholder community in proposal submissions to the Physician-Focused Payment Model Technical Advisory Committee (PTAC), which are available at *https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee*. Therefore, we are proposing separate coding and payment for Principal Care Management (PCM) services, which describe care management services for one serious chronic condition. A qualifying condition would typically be expected to last between three months and a year, or until the death of the patient, may have led to a recent hospitalization, and/or place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

While we are not proposing any restrictions on the specialties that could bill for PCM, we expect that most of these services would be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. We expect that, in most instances, initiation of PCM would be triggered by an exacerbation of the patient's complex chronic condition or recent hospitalization such that disease-specific care management is warranted. We anticipate that in the majority of instances, PCM services would be billed when a single condition is of such complexity that it could not be managed as effectively in the primary care setting, and instead requires management by another, more specialized, practitioner. For example, a typical patient may present to their primary care practitioner with an exacerbation of an existing chronic condition. While the primary care practitioner may be able to provide care management services for this one complex chronic condition, it is also possible that the primary care practitioner and/or the patient could instead decide that another clinician should provide relevant care management services. In this case, the primary care practitioner would still oversee the overall care for the patient while the practitioner billing for PCM services would provide care management services for the specific complex chronic condition. The treating clinician may need to provide a disease-specific care plan or may need to make frequent adjustments to the patient's medication regimen. The expected outcome of PCM is for the patient's condition to be stabilized by the treating clinician so that overall care management for the patient's condition can be returned to the patient's primary care practitioner. If the beneficiary only has one complex chronic condition that is overseen by the primary care practitioner, then the primary care practitioner would also be able to bill for PCM services. We are proposing that PCM services include coordination of medical and/or psychosocial care related to the single complex chronic condition, provided by a physician or clinical staff under the direction of a physician or other qualified health care professional.

We anticipate that many patients will have more than one complex chronic condition. If a clinician is providing PCM services for one complex chronic condition, management of the patient's other conditions would continue to be managed by the primary care practitioner while the patient is receiving PCM services for a single complex condition. It is also possible that the patient could receive PCM services from more than one clinician if the patient experiences an exacerbation of more than one complex chronic condition simultaneously.

For CY 2020, we are proposing to make separate payment for PCM services via two new G codes: HCPCS code GPPP1 (*Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities*) and HCPCS code GPPP2 (*Comprehensive care management for a single high-risk disease services, e.g., Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities*). HCPCS code GPPP1 would be reported when, during the calendar month, at least 30 minutes of physician or other qualified health care provider time is spent on comprehensive care management for a

single high risk disease or complex chronic condition. HCPCS code GPPP2 would be reported when, during the calendar month, at least 30 minutes of clinical staff time is spent on comprehensive management for a single high risk disease or complex chronic condition.

For HCPCS code GPPP1, we are proposing a crosswalk to the work value associated with CPT code 99217 (*Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital* ''*observation status*'' *if the discharge is on other than the initial date of* ''*observation status.*'' *To report services to a patient designated as* ''*observation status*'' *or* ''*inpatient status*'' *and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234–99236 as appropriate]*) as we believe these values most accurately reflect the resource costs associated when the billing practitioner performs PCM services. CPT code 99217 has the same intraservice time as HCPCS code GPPP1 and the physician work is of similar intensity. Therefore, we are proposing a work RVU of 1.28 for HCPCS code GPPP1.

For HCPCS code GPPP2 we are proposing a crosswalk to the work and PE inputs associated with CPT code 99490 (clinical staff non-complex CCM) as we believe these values reflect the resource costs associated with the clinician's direction of clinical staff who are performing the PCM services, and the intraservice times and intensity of the work for the two codes would be the same. Therefore, we are proposing a work RVU of 0.61 for HCPCS code GPPP2.

While we are proposing separate coding and payment for PCM services performed by clinical staff with the oversight of the billing professional and services furnished directly by the billing professional, we are seeking comment on whether both codes are necessary to appropriately describe and bill for PCM services. We note that we are basing this coding structure on the codes for CCM services with CPT code 99491 reflecting care management by the billing professional and CPT code 99490 reflecting care management by clinical staff directed by a physician or other qualified health care professional.

We acknowledge that we are concurrently proposing revisions for both complex and non-complex CCM services. Were we not to finalize the proposed changes for both complex and non-complex CCM services, we believe that the overall structure and description of the CCM services remain close enough to serve as a model for the coding structure and description of services for the proposed PCM services. We are seeking public comment on whether it would be appropriate to create an add-on code for additional time spent each month (similar to HCPCS code GCCC2 discussed above) when PCM services are furnished by clinical staff under the direction of the billing practitioner.

While we believe that PCM services describe a situation where a patient's condition is severe enough to require care management for a single complex chronic condition beyond what is described by CCM or performed in the primary care setting, we are concerned that a possible unintended consequence of making separate payment for care management for a single chronic condition is that a patient with multiple chronic conditions could have their care managed by multiple practitioners, each only billing for PCM, which could potentially result in fragmented patient care, overlaps in services, and duplicative services. While we are not proposing additional requirements for the proposed PCM services, we did consider alternatives such as requiring that the practitioner billing PCM must document ongoing communication with the patient's primary care practitioner to demonstrate that there is continuity of care between the specialist and primary care settings, or requiring that the patient have had a face-to-face visit with the practitioner billing PCM within the prior 30 days to demonstrate that they have an ongoing relationship. We are seeking comment on whether requirements such as these are necessary or appropriate, and whether there should be additional requirements to prevent potential care fragmentation or service duplication.

Due to the similarity between the description of the PCM and CCM services, both of which involve non-face-to-face care management services, we are proposing that the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record. We are seeking comment on whether there are required elements of CCM services that the public and stakeholders believe should not be applicable to PCM, and should be removed or altered. A high level summary of these requirements is available in Table 18 and available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf*. Both the initiating visit and the patient's verbal consent are necessary as not all patients who meet the criteria to receive separately billable PCM services may want to receive these services. The beneficiary should be educated as to what PCM services are and any cost sharing that may apply. Additionally, as practitioners have informed us that beneficiary cost sharing is a significant barrier to provision of other care management services, we are seeking comment on how best to educate practitioners and beneficiaries on the benefits of PCM services.

Additionally, we are proposing to add GPPP2 to the list of designated care management services for which we allow general supervision as described in our regulation at § 410.26(b)(5). Due to the potential for duplicative payment, we are proposing that PCM could not be billed by the same practitioner for the same patient concurrent with certain other care management services, such as CCM, behavioral health integration services, and monthly capitated ESRD payments. We are also proposing that PCM would not be billable by the same practitioner for the same patient during a surgical global period, as we believe those resource costs would already be included in the valuation of the global surgical code.

TABLE 18—CHRONIC CARE MANAGEMENT SERVICES SUMMARY

CCM Service Summary*
Verbal Consent: • Inform regarding availability of the service; that only one practitioner can bill per month; the right to stop services effective at the end of any service period; and that cost sharing applies (if no supplemental insurance). • Document that consent was obtained.
Initiating Visit for New Patients (separately paid).
Certified Electronic Health Record (EHR) Use: • Structured Recording of Core Patient Information Using Certified EHR (demographics, problem list, medications, allergies).

TABLE 18—CHRONIC CARE MANAGEMENT SERVICES SUMMARY—Continued

CCM Service Summary *
24/7 Access (“On Call” Service).
Designated Care Team Member.
Comprehensive Care Management:
• Systematic needs assessment (medical and psychosocial).
• Ensure receipt of preventive services.
• Medication reconciliation, management and oversight of self-management.
Comprehensive Electronic Care Plan:
• Plan is available timely within and outside the practice (can include fax).
• Copy of care plan to patient/caregiver (format not prescribed).
• Establish, implement, revise or monitor the plan.
Management of Care Transitions/Referrals (e.g., discharges, ED visit follow up, referrals):
• Create/exchange continuity of care document(s) timely (format not prescribed).
Home- and Community-Based Care Coordination:
• Coordinate with any home- and community-based clinical service providers, and document communication with them regarding psychosocial needs and functional deficits.
Enhanced Communication Opportunities:
• Offer asynchronous non-face-to-face methods other than telephone, such as secure email.

* All elements that are medically reasonable and necessary must be furnished during the month, but all elements do not necessarily apply every month. Consent need only be obtained once, and initiating visits are only for new patients or patients not seen within a year prior to initiation of CCM.

We are also seeking comment on any potential for duplicative payment between the proposed PCM services and other services, such as interprofessional consultation services (CPT codes 99446–99449 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional*), CPT code 99451 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time*), and CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes*)) or remote patient monitoring (CPT code 99091 (*Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days*), CPT code 99453 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*), and CPT code 99457 (*Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month*)).

5. Chronic Care Remote Physiologic Monitoring Services

Chronic Care remote physiologic monitoring (RPM) services involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan. The current CPT code 99457 is a treatment management code, billable after 20 minutes or more of clinical staff/physician/other qualified professional time with a patient in a calendar month.

In September 2018, the CPT Editorial Panel revised the CPT code structure for CPT code 99457 effective beginning in CY 2020. The new code structure retains CPT code 99457 as a base code that describes the first 20 minutes of the treatment management services, and uses a new add-on code to describe subsequent 20 minute intervals of the service. The new code descriptors for CY 2020 are: CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; initial 20 minutes*) and CPT code 994X0 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes*).

In considering the work RVUs for the new add-on CPT code 994X0, we first considered the value of its base code. We previously valued the base code at 0.61 work RVUs. Given the value of the base code, we do not agree with the RUC-recommended work RVU of 0.61 for the add-on code. Instead, we are proposing a work RVU of 0.50 for the add-on code. This value is supported by CPT code 88381 (*Microdissection (i.e., sample preparation of microscopically identified target); manual*), which has the same intraservice and total times of 20 minutes with an XXX global period and work RVU of 0.53, as well as the survey value at the 25th percentile. We are proposing the RUC-recommended direct PE inputs for CPT code 994X0.

Finally, we are proposing that RPM services reported with CPT codes 99457 and 994X0 may be furnished under general supervision rather than the currently required direct supervision. Because care management services include establishing, implementing, revising, or monitoring treatment plans, as well as providing support services, and because RPM services (that is, CPT codes 99457 and 994X0) include establishing, implementing, revising, and monitoring a specific treatment plan for a patient related to one or more chronic conditions that are monitored remotely, we believe that CPT codes 99457 and 994X0 should be included as designated care management services. Designated care management services can be furnished under general

supervision. Section 410.26(b)(5) of our regulations states that designated care management services can be furnished under the general supervision of the ''physician or other qualified health care professional (who is qualified by education, training, licensure/regulation and facility privileging)'' (see also 2019 CPT Codebook, page xii) when these services or supplies are provided incident to the services of a physician or other qualified healthcare professional. The physician or other qualified healthcare professional supervising the auxiliary personnel need not be the same individual treating the patient more broadly. However, only the supervising physician or other qualified healthcare professional may bill Medicare for incident to services.

6. Comment Solicitation on Consent for Communication Technology-Based Services

In the CY 2019 PFS Final Rule, CMS finalized separate payment for a number of services that could be furnished via telecommunications technology. Specifically, CMS finalized HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*)), HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*)), CPT codes 99446–99449 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional*), CPT code 99451 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time*), and CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes*).

As discussed in that rule, (83 FR 59490–59491), while a few commenters suggested that it would be less burdensome to obtain a general consent for multiple services at once, we stipulated that verbal consent must be documented in the medical record for each service furnished so that the beneficiary is aware of any applicable cost sharing. This is similar to the requirements for other non-face-to-face care management services under the PFS.

We have continued to hear from stakeholders that requiring advance beneficiary consent for each of these services is burdensome. For HCPCS codes G2010 and G2012, stakeholders have stated that it is difficult and burdensome to obtain consent at the outset of each of what are meant to be brief check-in services. For CPT codes 99446–99449, 99451 and 99452, practitioners have informed us that it is particularly difficult for the consulting practitioner to obtain consent from a patient they have never seen. Given our longstanding goals to reduce burden and promote the use of communication technology-based services, we are seeking comment on whether a single advance beneficiary consent could be obtained for a number of communication technology-based services. During the consent process, the practitioner would make sure the beneficiary is aware that utilization of these services will result in a cost sharing obligation. We are seeking comment on the appropriate interval of time or number of services for which consent could be obtained, for example, for all these services furnished within a 6 month or one year period, or for a set number of services, after which a new consent would need to be obtained. We are also seeking comment on the potential program integrity concerns associated with allowing advance consent and how best to minimize those concerns.

7. Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

RHCs and FQHCs are paid for general care management services using HCPCS code G0511, which is an RHC and FQHC-specific G-code for 20 minutes or more of CCM services, complex CCM services, or general behavioral health services. Payment for this service is set at the average of the national, non-facility payment rates for CPT codes 99490, 99487, and 99484. We are proposing to use the non-facility payment rates for HCPCS codes GCCC1 and GCCC3 instead of the non-facility payment rates for CPT codes 99490 and 99487, respectively, if these changes are finalized for practitioners billing under the PFS. We note that we are not proposing any changes in the valuation of these codes. Upon finalization, the payment for HCPCS code G0511 would be set at the average of the national, non-facility payment rates for HCPCS codes GCCC1 and GCCC3 and CPT code 99484.

L. Coinsurance for Colorectal Cancer Screening Tests

Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and, under sections 1861(pp)(1)(B) and (C) of the Act, ''screening flexible sigmoidoscopy'' and ''screening colonoscopy'' are two of the recognized procedures. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to include other tests or procedures in the definition, and modifications to the tests and procedures described under this subsection, ''with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.'' Section 1861(s)(2)(R) of the Act includes these colorectal cancer screening tests in the definition of the medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(ddd)(3) of the Act includes these colorectal cancer screening services within the definition of ''preventive services.'' In addition, section 1833(a)(1)(Y) of the Act provides for payment for preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B under the PFS at 100 percent of the lesser of the actual charge or the fee schedule amount for these colorectal cancer screening tests, and under the OPPS at 100 percent of the OPPS payment amount. As such, there is no beneficiary responsibility for coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act.

Under these statutory provisions, we have issued regulations governing payment for colorectal cancer screening tests at 42 CFR 410.152(l)(5). We pay 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance.

In addition to screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness or injury, Medicare also covers various diagnostic tests (§ 410.32). In general, diagnostic tests must be ordered by the physician or practitioner who is treating the beneficiary, and who uses the results of the diagnostic test in the management of the patient's specific medical problem. Under Part B, Medicare may cover flexible sigmoidoscopies and colonoscopies as diagnostic tests when those tests are reasonable and necessary as specified in section 1862(a)(1)(A) of the Act. When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the Part B coinsurance (normally 20 percent) associated with these services.

We define ''colorectal cancer screening tests'' in our regulation at § 410.37(a)(1) to include ''flexible screening sigmoidoscopies'' and ''screening colonoscopies, including anesthesia furnished in conjunction with the service.'' Under our current policies, we exclude from the definition of colorectal screening services colonoscopies and sigmoidoscopies that begin as a screening service, but where a polyp or other growth is found and removed as part of the procedure. The exclusion of these services from the definition of colorectal cancer screening services is based upon separate provisions of the statute dealing with the detection of lesions or growths during procedures (62 FR 59048, 59082, October 31, 1997). Section 1834(d)(2)(D) of the Act provides that if, during the course of a screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. Similarly, section 1834(d)(3)(D) of the Act that provides if, during the course of a screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

Because we interpret sections 1834(d)(2)(C)(ii) and 1834(d)(3)(C)(ii) of the Act to require us to pay for these tests as diagnostic tests, rather than as screening tests, the 100 percent payment rate for recommended preventive services under section 1833(a)(1)(Y) of the Act, as codified in our regulation at § 410.152(l)(5), would not apply to those diagnostic procedures. As such, beneficiaries are responsible for the usual coinsurance that applies to the services (20 or 25 percent of the cost of the services depending on the setting).

Under section 1833(b) of the Act, before making payment under Medicare Part B for expenses incurred by a beneficiary for covered Part B services, beneficiaries must first meet the applicable deductible for the year. Section 4104 of the Affordable Care Act (that is, the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010), collectively referred to as the ''Affordable Care Act'') amended section 1833(b)(1) of the Act to make the deductible inapplicable to expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF, including colorectal cancer screening tests as defined in section 1861(pp) of the Act. Section 4104 of the Affordable Care Act also added a sentence at the end of section 1833(b)(1) of the Act specifying that the exception to the deductible shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. Although the Affordable Care Act addressed the applicability of the deductible in the case of a colorectal cancer screening test that involves biopsy or tissue removal, it did not alter the coinsurance provision in section 1833(a) of the Act for such procedures. Although public commenters encouraged the agency to also eliminate the coinsurance in these circumstances, the agency found that the statute did not provide for elimination of the coinsurance (75 FR 73170, 73431, November 29, 2010).

Beneficiaries have continued to contact us noting their ''surprise'' that a coinsurance (20 or 25 percent depending on the setting) applies when they expected to receive a colorectal screening procedure to which coinsurance does not apply, but instead received what Medicare considers to be a diagnostic procedure because polyps were discovered and removed. Similarly, physicians have also expressed concerns about the reactions of beneficiaries when they are informed that they will be responsible for coinsurance if polyps are discovered and removed during what they expected to be a screening procedure to which coinsurance does not apply. Other stakeholders and some members of Congress have regularly expressed to us that they consider the agency's policy on coinsurance for colorectal screening procedures during which tissue is removed to be a misinterpretation of the law.

Over the years, we have released a wide variety of publicly available educational materials that explain the Medicare preventive services benefits as part of our overall outreach activities to Medicare beneficiaries. These materials contain a complete description of the Medicare preventive services benefits, including information on colorectal cancer screening, and also provide relevant details on the applicability of cost sharing. These materials can be found at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1243319.html.* We believe that the information in these materials can be instrumental in continuing to educate physicians and beneficiaries about cost sharing obligations in order to mitigate instances of ''surprise'' billing. We invite comment on whether we should consider establishing a requirement that the physician who plans to furnish a colorectal cancer screening notify the patient in advance that a screening procedure could result in a diagnostic procedure if polyps are discovered and removed, and that coinsurance may apply. We specifically invite comment on whether we should require the physician, or their staff, to provide a verbal notice with a notation in the medical record, or whether we should consider a different approach to informing patients of the copay implications, such as a written notice with standard language that we would require the physician, or their staff, to provide to patients prior to a colorectal cancer screening. We note that we would consider adopting such a requirement in the final rule in accordance with public comments. We also invite comment on what mechanism, if any, we should consider using to monitor compliance with a notification requirement if we decide to finalize one for CY 2020 or through future rulemaking.

M. Therapy Services

1. Repeal of the Therapy Caps and Limitation To Ensure Appropriate Therapy

a. Background

In the CY 2019 PFS proposed and final rules (83 FR 34850; 83 FR 59654 and 59661), we discussed the statutory requirements of section 50202 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018). Beginning January 1, 2018, section 50202 of the BBA of 2018 repealed the Medicare outpatient therapy caps and the therapy cap exceptions process, while retaining the cap amounts as limitations and requiring medical review to ensure that therapy services are furnished when appropriate. Section 50202 of the BBA of 2018 amended section 1833(g) of the Act by adding a new paragraph (7)(A) requiring that after expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the previous therapy cap amounts, all therapy suppliers and providers must continue to use an appropriate modifier on claims. We implemented this provision by continuing to require use of the existing KX modifier. By using the KX modifier on the claim, the therapy supplier or provider is attesting that the services are medically necessary and that supportive justification is documented in the medical record. As with the incurred expenses for the prior therapy cap amounts, there is one amount for physical therapy (PT) and speech language pathology (SLP) services combined, and a separate amount for occupational therapy (OT) services. These KX modifier threshold amounts are indexed annually by the Medicare Economic Index (MEI). After the beneficiary's incurred expenditures for outpatient therapy services exceed the KX modifier threshold amount for the year, claims for outpatient therapy services without the KX modifier are denied.

Section 50202 of the BBA of 2018 also added a new paragraph 7(B) to section 1833(g) of the Act which retained the targeted medical review (MR) process for 2018 and subsequent years, but established a lower threshold amount of $3,000 rather than the $3,700 threshold amount that had applied for the original manual MR process established by section 3005(g) of the Middle Class Tax Relief and Jobs Creation Act of 2012 (MCTRJCA) (Pub. L. 112–96, February 22, 2012). The manual MR process with a threshold amount of $3,700 was replaced by the targeted MR process with the same threshold amount through amendments made by section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015).

With the latest amendments made by the BBA of 2018, for CY 2018 (and each successive calendar year until 2028, at which time it is indexed annually by the MEI), the MR threshold is $3,000 for PT and SLP services and $3,000 for OT services. For purposes of applying the targeted MR process, we use a criteria-based process for selecting providers and suppliers that includes factors such as a high percentage of patients receiving therapy beyond the medical review threshold as compared to peers. For information on the targeted medical review process, please visit *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html.*

In the CY 2019 PFS final rule (83 FR 59661), when discussing our tracking and accrual process for outpatient therapy services in the section on the KX Threshold Amounts, we noted that we track each beneficiary's incurred expenses for therapy services annually by applying the PFS-based payment amount for each service less any applicable multiple procedure reduction for CMS-designated ''always therapy'' services. We also stated that we use the PFS rates to accrue expenses for therapy services provided in critical access hospitals (CAHs) as required by section 1833(g)(6)(B) of the Act, added by section 603(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, January 2, 2013). As discussed below, we mistakenly indicated that this statutory requirement was extended by subsequent legislation, including section 50202 of the BBA of 2018.

b. Proposed Regulatory Revisions

While we explained and implemented the changes required by section 50202 of the BBA of 2018 in CY 2019 PFS rulemaking (83 FR 34850; 83 FR 59654 and 59661), we did not codify those changes in regulation text. We are now proposing to revise the regulations at §§ 410.59 (outpatient occupational therapy) and 410.60 (physical therapy and speech-language pathology) to incorporate the changes made by section 50202 of the BBA of 2018. We propose to add a new paragraph (e)(1)(v) to §§ 410.59 and 410.60 to clarify that the specified amounts of annual per-beneficiary incurred expenses are no longer applied as limitations but as threshold amounts above which services require, as a condition of payment, inclusion of the KX modifier; and that use of the KX modifier confirms that the services are medically necessary as justified by appropriate documentation in the patient's medical record. We propose to amend paragraph (e)(2) in §§ 410.59 and 410.60 to specify the therapy services and amounts that are accrued for purposes of applying the KX modifier threshold, including the continued accrual of therapy services furnished by CAHs directly or under arrangements at the PFS-based payment rates. We are also proposing to amend paragraph (e)(3) in §§ 410.59 and 410.60 for the purpose of applying the medical review threshold to clarify the threshold amounts and the applicable years for both the manual MR process originally established through section 3005(g) of MCTRJCA and the targeted MR process established by the MACRA, and including the changes made through section 50202 of the BBA of 2018 as discussed previously.

In the CY 2019 PFS final rule (83 FR 59661), we incorrectly stated that section 1833(g)(6)(B) of the Act continues to require that we accrue expenses for therapy services furnished by CAHs at the PFS rate because the provision, originally added by section 603(b) of the ATRA, was extended by subsequent legislation, including section 50202 of the BBA of 2018. The requirement in section 1833(g)(6)(B) of the Act was actually time-limited to services furnished in CY 2013. To apply the therapy caps (and now the KX modifier thresholds) after the expiration of the requirement in 1833(g)(6)(B) of the Act, we needed a process to accrue the annual expenses for therapy services furnished by CAHs and, in the CY 2014 PFS final rule with comment period, we elected to continue the process prescribed in section 1833(g)(6)(B) of the Act (78 FR 74405 through 74410).

2. Proposed Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

a. Background

Section 53107 of the BBA of 2018 added a new subsection 1834(v) to the Act to require in paragraph (1) that, for services furnished on or after January 1, 2022, payment for outpatient physical and occupational therapy services for which payment is made under sections 1848 or 1834(k) of the Act which are furnished in whole or in part by a therapy assistant must be paid at 85 percent of the amount that is otherwise applicable. Section 1834(v)(2) of the Act further required that we establish a modifier to identify these services by January 1, 2019, and that claims for outpatient therapy services furnished in

whole or in part by a therapy assistant must include the modifier effective for dates of service beginning on January 1, 2020. Section 1834(v)(3) of the Act required that we implement the subsection through notice and comment rulemaking.

In the CY 2019 PFS proposed and final rules (83 FR 35850 through 35852 and 83 FR 59654 through 50660, respectively), we established two modifiers—one to identify services furnished in whole or in part by a physical therapist assistant (PTA) and the other to identify services furnished in whole or in part by an occupational therapy assistant (OTA). The modifiers are defined as follows:

- *CQ Modifier:* Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant.
- *CO Modifier:* Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant.

In the CY 2019 PFS final rule, we clarified that the CQ and CO modifiers are required to be used when applicable for services furnished on or after January 1, 2020, on the claim line of the service alongside the respective GP or GO therapy modifier to identify services furnished under a PT or OT plan of care. The GP and GO therapy modifiers, along with the GN modifier for speech-language pathology (SLP) services, have been used since 1998 to track and accrue the per-beneficiary incurred expenses amounts to different therapy caps, now KX modifier thresholds, one amount for PT and SLP services combined and a separate amount for OT services. We also clarified in the CY 2019 PFS final rule that the CQ and CO modifiers will trigger application of the reduced payment rate for outpatient therapy services furnished in whole or in part by a PTA or OTA, beginning for services furnished in CY 2022.

In response to public comments on the CY 2019 PFS proposed rule, we did not finalize our proposed definition of ''furnished in whole or in part by a PTA or OTA'' as a service for which any minute of a therapeutic service is furnished by a PTA or OTA. Instead, we finalized a *de minimis* standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA.

We also explained in the CY 2019 PFS proposed and final rules (83 FR 35850 through 35852 and 83 FR 59654 through 59660, respectively) that the CQ and CO modifiers would not apply to claims for outpatient therapy services that are furnished by, or incident to the services of, physicians or nonphysician practitioners (NPPs) including nurse practitioners, physician assistants, and clinical nurse specialists. This is because our regulations for outpatient physical and occupational therapy services require that an individual furnishing outpatient therapy services incident to the services of a physician or NPP must meet the qualifications and standards for a therapist. As such, only therapists and not therapy assistants can furnish outpatient therapy services incident to the services of a physician or NPP (83 FR 59655 through 59656); and, the new PTA and OTA modifiers cannot be used on the line of service of the professional claim when the rendering NPI identified on the claim is a physician or an NPP. We also intend to revise our manual provisions at Pub. 100–02, Medicare Benefit Policy Manual (MBPM), Chapter 15, section 230, as appropriate, to reflect requirements for the new CQ and CO modifiers that will be used to identify services furnished in whole or in part by a PTA or OTA starting in CY 2020. We anticipate amending these manual provisions for CY 2020 to reflect the policies we adopt through the CY 2020 PFS notice and comment rulemaking process.

In PFS rulemaking for CY 2019, we identified certain situations when the therapy assistant modifiers do apply. The modifiers are applicable to:

- Therapeutic portions of outpatient therapy services furnished by PTAs/OTAs, as opposed to administrative or other non-therapeutic services that can be performed by others without the education and training of OTAs and PTAs.
- Services wholly furnished by PTAs or OTAs without physical or occupational therapists.
- Evaluative services that are furnished in part by PTAs/OTAs (keeping in mind that PTAs/OTAs are not recognized to wholly furnish PT and OT evaluation or re-evaluations).

We also identified some situations when the therapy assistant modifiers do not apply. They do not apply when:

- PTAs/OTAs furnish services that can be done by a technician or aide who does not have the training and education of a PTA/OTA.
- Therapists exclusively furnish services without the involvement of PTAs/OTAs.

Finally, we noted that we would be further addressing application of the modifiers for therapy assistant services and the 10 percent *de minimis* standard more specifically in PFS rulemaking for CY 2020, including how the modifiers are applied in different scenarios for different types of services.

b. Applying the CQ and CO Modifiers

CMS interprets the references in section 1834(v)(1) and (2) of the Act to outpatient physical therapy ''service'' and outpatient occupational therapy ''service'' to mean a specific procedure code that describes a PT or OT service. This interpretation makes sense because section 1834(v)(2) of the Act requires the use of a modifier to identify on each request for payment, or bill submitted for an outpatient therapy service furnished in whole or in part by a PTA/OTA. For purposes of billing, each outpatient therapy service is identified by a procedure code.

To apply the *de minimis* standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA, we propose to make the 10 percent calculation based on the respective therapeutic minutes of time spent by the therapist and the PTA/OTA, rounded to the nearest whole minute. The minutes of time spent by a PTA/OTA furnishing a therapeutic service can overlap partially or completely with the time spent by a physical or occupational therapist furnishing the service. We propose that the total time for a service would be the total time spent by the therapist (whether independent of, or concurrent with, a PTA/OTA) plus any additional time spent by the PTA/OTA independently furnishing the therapeutic service. When deciding whether the therapy assistant modifiers apply, we propose that if the PTA/OTA participates in the service concurrently with the therapist for only a portion of the total time that the therapist delivers a service, the CQ/CO modifiers apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes spent by the therapist furnishing the service. If the PTA/OTA and the therapist each separately furnish portions of the same service, we propose that the CQ/CO modifiers would apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes—the sum of the minutes spent by the therapist and therapy assistant—for that service. We propose to apply the CQ/CO modifier policies to all services that would be billed with the respective GP or GO therapy modifier. We believe this is appropriate because it is the same way that CMS currently identifies physical therapy or occupational therapy services for purposes of accruing incurred expenses for the thresholds and targeted review process.

For purposes of deciding whether the 10 percent *de minimis* standard is exceeded, we offer two different ways to compute this. The first is to divide the PTA/OTA minutes by the total minutes for the service—which is (a) the therapist's total time when PTA/OTA minutes are furnished concurrently with the therapist, or (b) the sum of the PTA/OTA and therapist minutes when the PTA/OTA's services are furnished separately from the therapist; and then to multiply this number by 100 to calculate the percentage of the service that involves the PTA/OTA. We propose to round to the nearest whole number so that when this percentage is 11 percent or greater, the 10 percent *de minimis* standard is exceeded and the CQ/CO modifier is applied. The other method is simply to divide the total time for the service (as described above) by 10 to identify the 10 percent *de minimis* standard, and then to add one minute to identify the number of minutes of service by the PTA/OTA that would be needed to exceed the 10 percent standard. For example, where the total time of a service is 60 minutes, the 10 percent standard is six (6) minutes, and adding one minute yields seven (7) minutes. Once the PTA/OTA furnishes at least 7 minutes of the service, the CQ/CO modifier is required to be added to the claim for that service. As noted above, we propose to round the minutes and percentages of the service to the nearest whole integer. For example, when the total time for the service is 45 minutes, the 10 percent calculation would be 4.5 which would be rounded up to 5, and the PTA/OTA's contribution would need to meet or exceed 6 minutes before the CQ/CO modifier is required to be reported on the claim. See Table 19 for minutes needed to meet or exceed using the ''simple'' method with typical times for the total time of a therapy service.

TABLE 19—SIMPLE METHOD FOR DETERMINING WHEN CQ/CO MODIFIERS APPLY

Method Two: simple method to apply 10 percent de minimis standard			
Total Time * examples using typical service total times	Determine the 10 percent standard by dividing service Total Time by 10	Round 10 percent standard to next whole integer	PTA/OTA Minutes needed to exceed—apply CQ/CO
10	1.0	1.0	2.0
15	1.5	2.0	3.0
20	2.0	2.0	3.0
30	3.0	3.0	4.0
45	4.5	5.0	6.0
60	6.0	6.0	7.0
75	7.5	8.0	9.0

Total Time equals total therapist minutes plus any PTA/OTA independent minutes. Concurrent minutes: When PTA/OTA's minutes are furnished concurrently with the therapist, total time equals the total minutes of the therapist's service. Separate minutes: When PTA/OTA's minutes are furnished separately from the minutes furnished by the therapist, total time equals the sum of the minutes of the service furnished by the PT/OT plus the minutes of the service furnished separately by the PTA/OTA.

We want to clarify that the 10 percent *de minimis* standard, and therefore the CQ/CO modifiers, are not applicable to services in which the PTA/OTA did not participate. To the extent that the PTA/OTA and the physical therapist/occupational therapist (PT/OT) separately furnish different services that are described by procedure codes defined in 15-minute increments, billing examples and proposed policies are included below in Scenario Two.

As we indicated in the CY 2019 PFS final rule, we are addressing more specifically in this proposed rule the application of the 10 percent *de minimis* standard in various clinical scenarios to decide when the CQ/CO modifiers apply. We acknowledge that application of the 10 percent *de minimis* standard can work differently depending on the types of services and scenarios involving both the PTA/OTA and the PT/OT. Therapy services are typically furnished in multiple units of the same or different services on a given treatment day, which can include untimed services (not billable in multiple units) and timed services that are defined by codes described in 15-minute intervals. The majority of the untimed services that therapists bill for fall into three categories: (1) Evaluative procedures, (2) group therapy, and (3) supervised modalities. We discuss each of these in greater detail below. Only one (1) unit can be reported in the claim field labeled ''units'' for each procedure code representing an untimed service. The preponderance of therapy services, though, are billed using codes that are described in 15-minute increments. These services are typically furnished to a patient on a single day in multiple units of the same and/or different services. Under our current policy, the total number of units of one or more timed services that can be added to a claim depends on the total time for all the 15-minute timed codes that were delivered to a patient on a single date of service. We address our proposals for applying the CQ/CO modifiers using the 10 percent *de minimis* standard, along with applicable billing scenarios, by category below. In each of these scenarios, we assume that the PTA/OTA minutes are for therapeutic services.

- *Evaluations and re-evaluations: CPT codes 97161 through 97163 for physical therapy evaluations for low, moderate, and high complexity level, and CPT code 97164 for physical therapy re-evaluation; and CPT codes 97165 through 97167 for occupational therapy evaluations for low, moderate, and high complexity level, and CPT 97168 for occupational therapy re-evaluation.* These PT and OT evaluative procedures are untimed codes and cannot be billed in multiple units—one unit is billed on the claim. As discussed in CY 2019 PFS rulemaking (83 FR 35852 and 83 FR 59656) and noted above, PTAs/OTAs are not recognized to furnish evaluative or assessment services, but to the extent that they furnish a portion of an evaluation or re-evaluation (such as completing clinical labor tasks for each code) that exceeds the 10 percent *de minimis* standard, the appropriate therapy assistant modifier (CQ or CO) must be used on the claim. We note that it is possible for the PTA/OTA to furnish these minutes either concurrently or separately from the therapist. For example, when the PTA/OTA assists the PT/OT concurrently for a 5-minute portion of the 30 minutes that a PT or OT spent furnishing an evaluation (for example, CPT code 97162 for moderate complexity PT evaluation or CPT code 97165 for a low complexity OT evaluation—each have a typical therapist face-to-face time of 30

minutes), the respective CQ or CO modifier is applied to the service because the 5 minutes surpasses the 10 percent *de minimis* standard. In other words, 10 percent of 30 minutes is 3 minutes, and the CQ or CO modifier applies if the PTA/OTA furnishes more than 3 minutes, meaning at least 4 minutes, of the service. If the PTA/OTA separately furnishes a portion of the service that takes 5 minutes (for example, performing clinical labor tasks such as obtaining vital signs, providing self-assessment tool to the patient and verifying its completion), and then the PT/OT separately (without the PTA/OTA) furnishes a 30 minute face-to-face evaluative procedure—bringing the total time of the service to 35 minutes (the sum of the separate PTA/OTA minutes, that is, 5 minutes, plus the 30-minute therapist service), the CQ or CO modifier would be applied to the service because the 5 minutes of OTA/PTA time exceeds 10 percent of the 35 total minutes for the service. In other words, 10 percent of 35 minutes is 3.5 minutes which is rounded up to 4 minutes. The CQ or CO modifier would apply when the PTA/OTA furnishes 5 or more minutes of the service, as discussed above and referenced in Table 19.

• *Group Therapy: CPT code 97150 (requires constant attendance of therapist or assistant, or both).* CPT code 97150 describes a service furnished to a group of 2 or more patients. Like evaluative services, this code is an untimed service and cannot be billed in multiple units on the claim, so one unit of the service is billed for each patient in the group. For the group service, the CQ/CO modifier would apply when the PTA/OTA wholly furnishes the service without the therapist. The CQ/CO modifier would also apply when the total minutes of the service furnished by the PTA/OTA (whether concurrently with, or separately from, the therapist), exceed 10 percent of the total time, in minutes, of the group therapy service (that is, the total minutes of service spent by the therapist (with or without the PTA/OTA) plus any minutes spent by the PTA/OTA separately from the therapist). For example, the modifiers would apply when the PTA/OTA participates concurrently with the therapist for 5 minutes of a total group therapy service time of 40-minutes (based on the time of the therapist); or when the PTA/OTA separately furnishes 5 minutes of a total group time of 40 minutes (based on the sum of minutes of the PTA/OTA (5) and therapist (35)).

• *Supervised Modalities: CPT codes 97010 through 97028, and HCPCS codes G0281, G0183, and G0329.* Modalities, in general, are physical agents that are applied to body tissue in order to produce a therapeutic change through various forms of energy, including but not limited to thermal, acoustic, light, mechanical or electric. Supervised modalities, for example vasopneumatic devices, paraffin bath, and electrical stimulation (unattended), do not require the constant attendance of the therapist or supervised therapy assistant, unlike the modalities defined in 15-minute increments that are discussed in the below category. When a supervised modality, such as whirlpool (CPT code 97022), is provided without the direct contact of a PT/OT and/or PTA/OTA, that is, it is furnished entirely by a technician or aide, the service is not covered and cannot be billed to Medicare. Supervised modality services are untimed, so only one unit of the service can be billed regardless of the number of body areas that are treated. For example, when paraffin bath treatment is provided to both of the patient's hands, one unit of CPT code 97018 can be billed, not two. For supervised modalities, the CQ or CO modifier would apply to the service when the PTA/OTA fully furnishes all the minutes of the service, or when the minutes provided by the PTA or OTA exceed 10 percent of total minutes of the service. For example, the CQ/CO modifiers would apply when either (1) the PTA/OTA concurrently furnishes 2 minutes of a total 8-minute service by the therapist furnishing paraffin bath treatment (HCPCS code 97018) because 2 minutes is greater than 10 percent of 8 minutes (0.8 minute, or 1 minute after rounding); or (2) the PTA/OTA furnishes 3 minutes of the service separately from the therapist who furnishes 5 minutes of treatment for a total time of 8 minutes (total time equals the sum of the PT/OT minutes plus the separate PTA/OTA minutes) because 3 minutes is greater than 10 percent of 8 total minutes (0.8 minute rounded to 1 minute).

• *Services defined by 15-minute increments/units: These timed codes are included in the following current CPT code ranges: CPT codes 97032 through 97542—including the subset of codes for modalities in the series CPT codes 97032 through 97036; and, codes for procedures in the series CPT codes 97110–97542; CPT codes 97750–97755 for tests and measurements; and CPT codes: 97760–97763 for orthotic management and training and prosthetic training.* Based on CPT instructions for these codes, the therapist (or their supervised therapy assistant, as appropriate) is required to furnish the service directly in a one-on-one encounter with the patient, meaning they are treating only one patient during that time. Examples of modalities requiring one-on-one patient contact include electrical stimulation (attended), CPT code 97032, and ultrasound, CPT code 97035. Examples of procedures include therapeutic exercise, CPT code 97110, neuromuscular reeducation, CPT 97112, and gait training, CPT code 97116.

Our policy for reporting of service units with HCPCS codes for both untimed services and timed services (that is, only those therapy services defined in 15-minute increments) is explained in section 20.2 of Chapter 5 of the Medicare Claims Processing Manual (MCPM). To bill for services described by the timed codes (hereafter, those codes described per each 15-minutes) furnished to a patient on a date of service, the therapist or therapy assistant needs to first identify all timed services furnished to a patient on that day, and then total all the minutes of all those timed codes. Next, the therapist or therapy assistant needs to identify the total number of units of timed codes that can be reported on the claim for the physical or occupational therapy services for a patient in one treatment day. Once the number of billable units is identified, the therapist or therapy assistant assigns the appropriate number of unit(s) to each timed service code according to the total time spent furnishing each service. For example, to bill for one 15-minute unit of a timed code, the qualified professional (the therapist or therapy assistant) must furnish at least 8 minutes and up to 22 minutes of the service; to bill for 2 units, at least 23 minutes and up to 37 minutes, and to bill for 3 units, at least 38 minutes and up to 52 minutes. We note that these minute ranges are applicable when one service, or multiple services, defined by timed codes are furnished by the qualified professional on a treatment day. We understand that the therapy industry often refers to these billing conventions as the ''eight-minute rule.'' The idea is that when a therapist or therapy provider bills for one or more units of services that are described by timed codes, the therapist's direct, one-on-one patient contact time would average 15 minutes per unit. This idea is also the basis for the work values we have established for these timed codes. Our current policies for billing of timed codes and related documentation do not take into consideration whether a service is furnished ''in whole or in

part'' by a PTA/OTA, or otherwise address the application of the CQ/CO modifier when the 10 percent *de minimis* standard is exceeded, for those services in which both the PTA/OTA and the PT/OT work together to furnish a service or services.

To support the number of 15-minute timed units billed on a claim for each treatment day, we require that the total timed-code treatment time be documented in the medical record, and that the treatment note must document each timed service, whether or not it is billed, because the unbilled timed service(s) can impact billing. The minutes that each service is furnished can be, but are not required to be, documented. We also require that each untimed service be documented in the treatment note in order to support these services billed on the claim; and, that the total treatment time for each treatment day be documented—including minutes spent providing services represented by the timed codes (the total timed-code treatment time) and the untimed codes. To minimize burden, we are not proposing changes to these documentation requirements in this proposed rule.

Beginning January 1, 2020, in order to provide support for application of the CQ/CO modifier(s) to the claim as required by section 1834(v)(2)(B) of the Act and our proposed regulations at §§ 410.59(a)(4) and 410.60(a)(4), we propose to add a requirement that the treatment notes explain, via a short phrase or statement, the application or non-application of the CQ/CO modifier for each service furnished that day. We would include this documentation requirement in subsection in Chapter 15, MBPM, section 220.3.E on treatment notes. Because the CQ/CO modifiers also apply to untimed services, our proposal to revise our documentation requirement for the daily treatment note extends to those codes and services as well. For example, when PTAs/OTAs assist PTs/OTs to furnish services, the treatment note could state one of the following, as applicable: (a) ''Code 97110: CQ/CO modifier applied—PTA/OTA wholly furnished''; or, (b) ''Code 97150: CQ/CO modifier applied—PTA/OTA minutes = 15%''; or ''Code 97530: CQ/CP modifier not applied—PTA/OTA minutes less than 10% standard.'' For those therapy services furnished exclusively by therapists without the use of PTAs/OTA, the PT/OT could note one of the following: ''CQ/CO modifier NA'', or ''CQ/CO modifier NA—PT/OT fully furnished all services.'' Given that the minutes of service furnished by or with the PTA/OTA and the total time in minutes for each service (timed and untimed) are used to decide whether the CQ/CO modifier is applied to a service, we seek comment on whether it would be appropriate to require documentation of the minutes as part of the CQ/CO modifier explanation as a means to avoid possible additional burden associated with a contractor's medical review process conducted for these services. We are also interested in hearing from therapists and therapy providers about current burden associated with the medical review process based on our current policy that does not require the times for individual services to be documented. Based on comments received, if we were to adopt a policy to include documentation of the PTA/OTA minutes and total time (TT) minutes, the CQ/CO modifier explanation could read similar to the following: ''Code 97162 (TT = 30 minutes): CQ/CO modifier not applied—PTA/OTA minutes (3) did not exceed the 10 percent standard.''

To recap, under our proposed policy, therapists or therapy assistants would apply the therapy assistant modifiers to the timed codes by first following the usual process to identify all procedure codes for the 15-minute timed services furnished to a beneficiary on the date of service, add up all the minutes of the timed codes furnished to the beneficiary on the date of service, decide how many total units of timed services are billable for the beneficiary on the date of service (based on time ranges in the chart in the manual), and assign billable units to each billable procedure code. The therapist or therapy assistant would then need to decide for each billed procedure code whether or not the therapy assistant modifiers apply.

As previously explained, the CQ/CO modifier does not apply if all units of a procedure code were furnished entirely by the therapist; and, where all units of the procedure code were furnished entirely by the PTA/OTA, the appropriate CQ/CO modifier would apply. When some portion of the billed procedure code is furnished by the PTA/OTA, the therapist or therapy assistant would need to look at the total minutes for all the billed units of the service, and compare it to the minutes of the service furnished by the PTA/OTA as described above in order to decide whether the 10 percent *de minimis* standard is exceeded. If the minutes of the service furnished by the PTA/OTA are more than 10 percent of the total minutes of the service, the therapist or therapy assistant would assign the appropriate CQ or CO modifier. We would make clarifying technical changes to chapter 5, section 20.2 of the MCPM to reflect the policies adopted through in this rulemaking related to the application or non-application of the therapy assistant modifiers. We anticipate that we will add examples to illustrate when the applicable therapy assistant modifiers must be applied, similar to the examples provided below.

We are providing the following examples of clinical scenarios to illustrate how the 10 percent *de minimis* standard would be applied under our proposals when therapists and their assistants work together concurrently or separately to treat the same patient on the same day. These examples reflect how the therapist or therapy provider would decide whether the CQ or CO therapy assistant modifier should be included when billing for one or more service units of the 15-minute timed codes. In the following scenarios, ''PT'' is used to represent physical therapist and ''OT'' is used to refer to an occupational therapist for ease of reference; and, the services of the PTA/OTA are assumed to be therapeutic in nature, and not services that a technician or aide without the education and training of a PTA/OTA could provide.

- *Scenario One:* Where only one service, described by a single HCPCS code defined in 15-minute increments, is furnished in a treatment day:

(1) The PT/OT and PTA/OTA each separately, that is individually and exclusively, furnish minutes of the same therapeutic exercise service (HCPCS code 97110) in different time frames: The PT/OT furnishes 7 minutes and the PTA furnishes 7 minutes for a total of 14 minutes, one unit can be billed using the total time minute range of at least 8 minutes and up to 22 minutes.

Billing Example: One 15-minute unit of HCPCS code 97110 is reported on the claim with the CQ/CO modifier to signal that the time of the service furnished by the PTA/OTA (7 minutes) exceeded 10 percent of the 14-minute total service time (1.4 minutes rounded to 1 minute, so the modifier would apply if the PTA/OTA had furnished 2 or more minutes of the service).

(2) The PT/OT and PTA/OTA each separately, exclusive of the other, furnish minutes of the same therapeutic exercise service (HCPCS code 97110) in different time frames: The PT/OT furnishes 20 minutes and the PTA/OTA furnishes 25 minutes for a total of 45 minutes, three units can be billed using the total time minute range of at least 38 minutes and up to 52 minutes.

Billing Example: All three units of CPT code 97110 are reported on the claim with the corresponding CQ/CO modifier because the 25 minutes

furnished by the PTA/OTA exceeds 10 percent of the 45-minute total service time (4.5 minutes rounded to 5 minutes, so the modifier would apply if the PTA/OTA had furnished 6 or more minutes of the service).

(3) The PTA/OTA works concurrently with the respective PT/OT as a team to furnish the same neuromuscular reeducation service (HCPCS code 97112) for a 30-minute session, resulting in 2 billable units of the service (at least 23 minutes and up to 37 minutes).

Billing Example: Both units of HCPCS code 97112 are reported with the appropriate CQ or CO modifier because the service time furnished by the PTA/OTA (30 minutes) exceeded 10 percent of the 30-minute total service time (3 minutes, so the modifier would apply if the PTA/OTA had furnished 4 or more minutes of the service).

- *Scenario Two:* When services that are represented by different procedure codes are furnished. Follow our current policy to identify the procedure codes to bill and the units to bill for the service(s) provided for the most time. We propose that when the PT/OT and the PTA/OTA each independently furnish a service defined by a different procedure code for the same number of minutes, for example 10 minutes, for a total time of 20 minutes, qualifying for 1 unit to be billed (at least 8 minutes up to 23 minutes), the code for the service furnished by the PT/OT is selected to break the tie—one unit of that service would be billed without the CQ/CO modifier.

(1) When only one unit of a service can be billed (requires a minimum of 8 minutes but less than 23 minutes):

(a) The PT/OT independently furnishes 15 minutes of manual therapy (HCPCS code 97140) and the PTA/OTA independently furnishes 7 minutes of therapeutic exercise (HCPCS code 97110). One unit of HCPCS code 97140 can be billed (at least 8 minutes and up to 22 minutes).

Billing Example: One unit of HCPCS code 97140 is billed without the CQ/CO modifier because the PT/OT exclusively (without the PTA/OTA) furnished a full unit of a service defined by 15-minute time interval (current instructions require ''1'' unit to be reported). The 7 minutes of a different service delivered solely by the PTA/OTA do not result in a billable service. Both services, though, are documented in the medical record, noting which services were furnished by the PT/OT or PTA/OTA; and, the 7 minutes of HCPCS code 97110 would be included in the total minutes of timed codes that are considered when identifying the procedure codes and units of each that can be billed on the claim.

(b) If instead, the PT/OT independently furnished 7 minutes of CPT code 97140 and the PTA/OTA independently furnished a full 15-minutes of CPT code 97110, one unit of CPT code 97110 is billed and the CQ/CO modifier is applied; the 7 minutes of the PT/OT service (CPT code 97140) do not result in billable service, but all the minutes are documented and included in the total minutes of the timed codes that are considered when identifying the procedure codes and units of each that can be billed on the claim.

(c) If the PT/OT and PTA/OTA each independently furnish an equal number of minutes of CPT codes 97140 and 97110, respectively, that is less than the full 15-minute mark, and the total minutes of the timed codes qualify for billing one unit of a service, the code furnished by the PT/OT would be selected to break the tie and billed without a CQ/CO modifier because the PT/OT furnished that service independently of the PTA/OTA.

If instead the PT/OT furnishes an 8-minute service (CPT code 97140) and the PTA/OTA delivers a 13-minute service (CPT code 97110), one unit of the 13-minute PTA/OTA-delivered service (CPT code 97110) would be billed consistent with our current policy to bill the service with the greater time; and the service would be billed with a CQ/CO modifier because the PTA/OTA furnished the service independently.

(2) When two or more units can be billed (requires a minimum of 23 minutes), follow current instructions for billing procedure codes and units for each timed code.

(a) The PT/OT furnishes 20 minutes of neuromuscular reeducation (CPT code 97112) and the PTA/OTA furnishes 8 minutes of therapeutic exercise (CPT code 97110) for a total of 28 minutes, which permits two units of the timed codes to be billed (at least 23 minutes and up to 37 minutes).

Billing Example: Following our usual process for billing for the procedure codes and units based on services furnished with the most minutes, one unit of each procedure code would be billed—one unit of CPT code 97112 is billed without a CQ/CO modifier and one unit of CPT code 97110 is billed with a CQ/CO modifier. This is because, under our current policy, the two billable units of timed codes are allocated among procedure codes by assigning the first 15 minutes of service to code 97112 (the code with the highest number of minutes), which leaves another 13 minutes of timed services: 5 minutes of code 97112 (20 minus 15) and 8 minutes of code 97110. Since the 8 minutes of code 97110 is greater than the remaining 5 minutes of code 97112, the second billable unit of service would be assigned to 97110. The CQ/CO modifier would not apply to CPT code 97112 because the therapist furnished all minutes of that service independently. The CQ/CO modifier would apply to CPT code 97110 because the PTA/OTA furnished all minutes of that service independently.

(b) The PT/OT furnishes 32 minutes of neuromuscular reeducation (CPT code 97112), the PT/OT and the PTA/OTA each separately furnish 12 minutes and 14 minutes, respectively, of therapeutic exercise (CPT code 97110) for a total of 26 minutes, and the PTA/OTA independently furnishes 12 minutes of self-care (CPT code 97535) for a total of 70 minutes of timed code services, permitting five units to be billed (68–82 minutes). Under our current policy, the five billable units would be assigned as follows: Two units to CPT code 97112, two units to CPT code 97110, and one unit to CPT code 97535.

Billing Example: The two units of CPT code 97112 would be billed without a CQ/CO modifier because all 32 minutes of that service were furnished independently by the PT/OT. The two units of CPT code 97110 would be billed with the CQ/CO modifier because the PTA/OTA's 14 minutes of the service are greater than 10 percent of the 26 total minutes of the service (2.6 minutes which is rounded to 3 minutes, so the modifiers would apply if the PTA/OTA furnished 4 or more minutes of the service), and the one unit of CPT code 97535 would be billed with a CQ/CO modifier because the PTA/OTA independently furnished all minutes of that service.

(c) The PT/OT independently furnishes 12 minutes of neuromuscular reeducation activities (CPT code 97112) and the PTA/OTA independently furnishes 8 minutes of self-care activities (CPT code 97535) and 7 minutes of therapeutic exercise (CPT code 97110)—the total treatment time of 27 minutes allows for two units of service to be billed (at least 23 minutes and up to 37 minutes). Under our current policy, the two billable units would be assigned as follows: One unit of CPT code 97112 and one unit of CPT code 97535.

Billing Example: The one unit of HCPCS code 97112 would be billed without the CQ/CO modifier because it was furnished independently by the PT/OT; and, the one unit of CPT code 97535 is billed with the CQ/CO modifier because it was independently furnished

by the PTA/OTA. In this example, CPT code 97110 is not billable; however, the minutes for all three codes are documented and counted toward the total time of the timed code services furnished to the patient on the date of service.

(d) The PT/OT furnishes 15 minutes of each of two services described by CPT codes 97112 and 97535, and is assisted by the PTA/OTA who furnishes 3 minutes of each service concurrently with the PT/OT. The total time of 30 minutes allows two 15-minute units to be billed—one unit each of CPT code 97112 and CPT code 97535.

Billing Example: Both CPT codes 97112 and 97535 are billed with the applicable CQ/CO modifier because the time the PTA/OTA spent assisting the PT/OT for each service exceeds 10 percent of the 15-minute total time for each service (1.5 minutes which is rounded to 2 minutes, so that the modifiers apply if the PTA/OTA furnishes 3 or more minutes of the service).

c. Proposed Regulatory Provisions

In accordance with section 1834(v)(2)(B) of the Act, we are proposing to amend §§ 410.59(a)(4) and 410.60(a)(4) for outpatient physical and occupational therapy services, respectively, and § 410.105(d) for physical and occupational therapy services furnished by comprehensive outpatient rehabilitation facilities (CORFs) as authorized under section 1861(cc) of the Act, to establish as a condition of payment that claims for services furnished in whole or in part by an OTA or PTA must include a prescribed modifier; and that services will not be considered furnished in part by an OTA or PTA unless they exceed 10 percent of the total minutes for that service, beginning for services furnished on and after January 1, 2020. To implement section 1834(v)(1) of the Act, we are proposing to amend §§ 410.59(a)(4) and 410.60(a)(4) for outpatient physical and occupational therapy services, respectively, and at § 410.105(d) for physical and occupational therapy services furnished by CORFs to specify that claims from physical and occupational therapists in private practice paid under section 1848 of the Act and from providers paid under section 1834(k) of the Act for physical therapy and occupational therapy services that contain a therapy assistant modifier, are paid at 85 percent of the otherwise applicable payment amount for the service for dates of service on and after January 1, 2022. As specified in the CY 2019 PFS final rule, we also note that the CQ or CO modifier is to be applied alongside the corresponding GP or GO therapy modifier that is required on each claim line of service for physical therapy or occupational therapy services. Beginning for dates of service and after January 1, 2020, claims missing the corresponding GP or GO therapy modifier will be rejected/returned to the therapist or therapy provider so they can be corrected and resubmitted for processing.

As discussed in the CY 2019 PFS proposed and final rules (*see* 83 FR 35850 and 83 FR 59654), we established that the reduced payment rate under section 1834(v)(1) of the Act for the outpatient therapy services furnished in whole or in part by therapy assistants is not applicable to outpatient therapy services furnished by CAHs, for which payment is made under section 1834(g) of the Act. We would like to take this opportunity to clarify that we do not interpret section 1834(v) of the Act to apply to outpatient physical therapy or occupational therapy services furnished by CAHs, or by other providers for which payment for outpatient therapy services is not made under section 1834(k) of the Act based on the PFS rates.

N. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010 and CY 2015. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.E. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and reproposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes

within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the federal government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we propose those values as recommended. Additionally, we continually engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that included the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (*see* the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for

a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time. In response to comments in the CY 2019 PFS final rule (83 FR 59515), we clarify that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate stakeholder feedback, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the proposed valuation considered for specific codes. Table 20 contains a list of codes and descriptors for which we are proposing work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2019. The proposed work RVUs, work time and other payment information for all CY 2020 payable codes are available on the CMS website under downloads for the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 21 details our proposed refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain proposed refinements that would be common across codes. Proposed refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note

that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also note that approximately half of the refinements listed in Table 21 result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

We also note that the proposed direct PE inputs for CY 2020 are displayed in the CY 2020 direct PE input files, available on the CMS website under the downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the proposed CY 2020 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2020, we received invoices for several new supply and equipment items. Tables 22 and 23 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encouraged stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encouraged stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 22 and 23 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address proposed code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the public use files for the PFS proposed and final rules for each year display the services subject to the MPPR for diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services. We also include a list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2020 are available on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

4. Proposed Valuation of Specific Codes for CY 2020

(1) Tissue Grafting Procedures (CPT Codes 15X00, 15X01, 15X02, 15X03, and 15X04)

CPT code 20926 (*Tissue grafts, other (e.g., paratenon, fat, dermis)*), was identified through a review of services with anomalous sites of service when compared to Medicare utilization data. The CPT Editorial Panel subsequently replaced CPT code 20926 with five codes in the Integumentary section to better describe tissue grafting procedures.

We are proposing the RUC-recommended work RVUs of 6.68 for CPT code 15X00 (*Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)*), 6.73 for CPT code 15X01 (*grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50cc or less injectate*), 2.50 for CPT code 15X02 (*grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50cc injectate, or part thereof (list separately in addition to code for primary procedure)*), 6.83 for CPT code 15X03 (*grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25cc or less injectate*), and 2.41 for CPT code 15X04 (*grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25cc injectate, or part thereof (list separately in addition to code for primary procedure)*).

We are proposing the RUC-recommended direct PE inputs for this code family without refinement.

(2) Drug Delivery Implant Procedures (CPT Codes 11981, 11982, 11983, 206X0, 206X1, 206X2, 206X3, 206X4, and 206X5)

CPT codes 11980–11983 were identified as potentially misvalued since the majority specialty found in recent claims data differs from the two specialties that originally surveyed the codes. The current valuation of CPT code 11980 (*Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)*) was reaffirmed by the RUC as the physician work had not changed since the last review. The CPT Editorial Panel revised the other three existing codes in the family and created six additional add-on codes to describe orthopaedic drug delivery. These codes were surveyed and reviewed for the October 2018 RUC meeting.

CPT code 11980 (*Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)*) with the current work value of 1.10 RVUs and 12 minutes of intraservice time, and 27 minutes of total time, was determined to be unchanged since last reviewed and was recommended by the RUC to be maintained. We concur. We also are not proposing any direct PE refinements to CPT code 11980. CPT code 11981 (*Insertion, non-biodegradable drug delivery implant*) has a current work RVU of 1.48, with 39 minutes of total physician time. The specialty society survey recommended a work RVU of 1.30, with 31 minutes of total physician time and 5 minutes of intraservice time. The RUC recommended a work RVU of 1.30 (25th percentile), with 30 minutes of total physician time and 5 minutes of intraservice time. For comparable reference CPT codes to CPT code 11981, the RUC and the survey respondents had selected CPT code 55876 (*Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple (work RVU = 1.73, 20 minutes intraservice time and 59 total minutes)*) and CPT code 57500 (*Biopsy of cervix,*

single or multiple, or local excision of lesion, with or without fulguration (separate procedure) (work RVU = 1.20, 15 minutes intraservice time and 29 total minutes)). The RUC further offers for comparison, CPT code 67515 (*Injection of medication or other substance into Tenon's capsule (work RVU = 1.40 (from CY 2018), 5 minutes intraservice time and 21 minutes total time*)), CPT code 12013 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm (work RVU = 1.22 and 27 total minutes)*) and CPT code 12004 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm) (work RVU = 1.44 and 29 total minutes)*). In addition, we offer CPT code 67500 (*Injection of medication into cavity behind eye) (work RVU = 1.18 and 5 minutes intraservice time and 33 total minutes*) for reference. Given that the CPT code 11981 incurs a 23 percent reduction in the new total physician time and with reference to CPT code 67500, we are proposing a work RVU of 1.14, and accept the survey recommended 5 minutes for intraservice time and 30 minutes of total time. We are not proposing any direct PE refinements to CPT code 11981.

CPT code 11982 (*Removal, non-biodegradable drug delivery implant*) has a current work RVU of 1.78, with 44 minutes of total physician time. The specialty society survey recommended a work RVU of 1.70 RVU, with 10 minutes of intraservice time and 34 minutes of total physician time. The RUC also recommended a work RVU of 1.70, with 10 minutes of intraservice time and 33 minutes of total physician time. The RUC confirmed that removal (CPT code 11982), requires more intraservice time to perform than the insertion (CPT code 11981). For comparable reference codes to CPT code 11982, the RUC and the survey respondents had selected CPT code 54150 (*Circumcision, using clamp or other device with regional dorsal penile or ring block) (work RVU = 1.90, 15 minutes intraservice time and 45 total minutes)*) and CPT code 12004 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm) (work RVU = 1.44, with 17 minutes intraservice time and 29 minutes total time)*). We offer CPT code 64486 (*Injections of local anesthetic for pain control and abdominal wall analgesia on one side) (work RVU = 1.27, 10 minutes intraservice time and 35 total minutes)*) for reference. Given that the CPT code 11982 incurs a 25 percent reduction in the new total physician time and with reference to CPT code 64486, we are proposing a work RVU of 1.34, and accept the RUC-recommended 10 minutes for intraservice time and 33 minutes of total time. We are not proposing any direct PE refinements to CPT code 11982.

CPT code 11983 (*Removal with reinsertion, non-biodegradable drug delivery implant*) has a current work RVU of 3.30, with 69 minutes of total physician time. The specialty society survey recommended a work RVU of 2.50 RVU, with 15 minutes of intraservice time and 41 minutes of total physician time. The RUC also recommended a work RVU of 2.10, with 15 minutes of intraservice time and 40 minutes of total physician time. The RUC confirmed that CPT code 11983 requires more intraservice time to perform than the insertion CPT code 11981. For comparable reference codes to CPT code 11983, the RUC and the survey respondents had selected CPT code 55700 (*Biopsy, prostate; needle or punch, single or multiple, any approach) (work RVU = 2.50, 15 minutes intraservice time and 35 total minutes)*), CPT code 54150 (*Circumcision, using clamp or other device with regional dorsal penile or ring block) (work RVU = 1.90, 15 minutes intraservice time and 45 total minutes)*) and CPT code 52281 (*Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female) (work RVU = 2.75 and 20 minutes intraservice time and 46 minutes total time)*). We offer CPT code 62324 (*Insertion of indwelling catheter and administration of substance into spinal canal of upper or middle back) (work RVU = 1.89, 15 minutes intraservice time and 43 total minutes)*) for reference. Given that the CPT code 11983 incurs a 42 percent reduction in new total physician time and with reference to CPT code 62324, we are proposing a work RVU of 1.91, and accept the RUC-recommended 15 minutes for intraservice time and 40 minutes of total time. We are not proposing any direct PE refinements to CPT code 11983.

The new proposed add-on CPT codes 206X0–206X5 are intended to be typically reported with CPT codes 11981–11983, with debridement or arthrotomy procedures done primarily by orthopedic surgeons. The specialty society's survey for CPT code 206X0 (*Manual preparation and insertion of drug delivery device(s), deep (e.g., subfascial)*) found a 2.00 work RVU value at the median and a 1.50 work RVU value at the 25th percentile, with 20 minutes of intraservice time and 30 minutes of total physician time, for the preparation of the antibiotic powder and cement, rolled into beads and threaded onto suture for insertion into the infected bone. The RUC recommended a work RVU of 1.50, with 20 minutes of intraservice time and 27 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof) (work RVU = 1.80, and 30 minutes intraservice time)*), CPT codes 64484 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level) (work RVU = 1.00 and 10 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation) (work RVU = 2.09 and 20 minutes intraservice time)*). Our review of similar add-on CPT codes yielded CPT code 64634 (*Destruction of upper or middle spinal facet joint nerves with imaging guidance) (work RVU = 1.32 and 20 minutes intraservice time)*). We are proposing for CPT code 206X0, a work RVU of 1.32, and accept the RUC-recommended 20 minutes of intraservice time and 20 minutes of total time.

The specialty society's survey for CPT code 206X1 (*Manual preparation and insertion of drug delivery device(s), intramedullary*) found a 3.25 work RVU value at the median and a 2.50 work RVU value at the 25th percentile, with 25 minutes of intraservice time and 38 minutes of total physician time, for the preparation of the ''antibiotic nail'' ready for insertion into the intramedullary canal with fluoroscopic guidance. The RUC recommended a work RVU of 2.50, with 25 minutes of intraservice time and 32 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof) (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (work*

RVU = 4.88 and 45 minutes intraservice time)), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We find that the reference CPT code 11047, with 30 minutes of intraservice time, is suitable, but we adjust our proposed work RVU of 1.70 to account for the 25 minutes, instead of our reference code's 30 minutes of intraservice time (and the 32 minutes of total time), for CPT code 206X1.

The specialty society's survey for CPT code 206X2 (*Manual preparation and insertion of drug delivery device(s), intra-articular*) found a 4.00 work RVU value at the median and a 2.60 work RVU value at the 25th percentile, with 30 minutes of intraservice time and 45 minutes of total physician time, for the preparation of the antibiotic cement inserted into a pre-fabricated silicone mold, when after setting up, will be cemented to the end of the bone (with the joint). The RUC recommended a work RVU of 2.60, with 30 minutes of intraservice time and 37 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (work RVU = 4.88 and 45 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 20 minutes intraservice time)*). We find that the reference CPT code 11047, with 30 minutes of intraservice time, is a suitable guide and we are proposing the work RVU of 1.80 with the RUC-recommended 30 minutes of intraservice time and 37 minutes of total time, for CPT code 206X2.

The specialty society's survey for CPT code 206X3 (*Removal of drug delivery device(s), deep (e.g., subfascial)*) found a 1.75 work RVU value at the median and a 1.13 work RVU value at the 25th percentile, with 15 minutes of intraservice time and 18 minutes of total physician time. The work includes a marginal dissection to expose the drug delivery device and to remove it. The RUC recommended a work RVU of 1.13, with 18 minutes of total physician time and 15 minutes of intraservice time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 64484 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (work RVU = 1.00 and 10 minutes intraservice time)*), and CPT code 64480 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional level (work RVU = 1.20 and 15 minutes intraservice time)*). We are proposing the RUC-recommended work RVU of 1.13 with 15 minutes of intraservice time and 18 minutes of total time for 206X3.

The specialty society's survey for CPT code 206X4 (*Removal of drug delivery device(s), intramedullary*) found a 2.50 work RVU value at the median and a 1.80 work RVU value at the 25th percentile, with 20 minutes of intraservice time and 28 minutes of total physician time. The work includes a marginal dissection, in addition to what was in the base procedure, to loosen and expose the drug delivery device and to remove it, any remaining drug delivery device shards that may have broken off. The RUC recommended a work RVU of 1.80, with 20 minutes of intraservice time and 23 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT codes 37253 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (work RVU = 1.44 and 20 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We are proposing the RUC-recommended work RVU of 1.80 with 20 minutes of intraservice time and 23 minutes of total time for 206X4.

The specialty society's survey for CPT code 206X5 (*Removal of drug delivery device(s), intra-articular*) found a 3.30 work RVU value at the median and a 2.15 work RVU value at the 25th percentile, with 25 minutes of intraservice time and 28 minutes of total physician time. The work includes the removal of the intra-articular drug delivery device that is cemented to both sides of the joint without removing too much bone in the process. The RUC recommended a work RVU of 2.15, with 25 minutes of intraservice time and 28 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 36476 (*Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (work RVU = 2.65 and 30 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We are proposing the RUC-recommended work RVU of 2.15 with 25 minutes of intraservice time and 28 minutes of total time for 206X5.

(3) Bone Biopsy Trocar-Needle (CPT Codes 20220 and 20225)

In October 2017, CPT code 20225 (*Biopsy, bone, trocar, or needle; deep (e.g., vertebral body, femur)*) was identified as being performed by a different specialty than the one that originally surveyed this service. CPT code 20220 (*Biopsy, bone, trocar, or needle; superficial (e.g., ilium, sternum, spinous process, ribs)*) was added as part of the family, and both codes were surveyed and reviewed for the January 2019 RUC meeting.

We disagree with the RUC-recommended work RVU of 1.93 for CPT code 20220 and we are proposing a work RVU of 1.65 based on a crosswalk to CPT code 47000 (*Biopsy of liver, needle; percutaneous*). CPT code 47000 shares the same intraservice time of 20 minutes with CPT code 20220 and has slightly higher total time at 55 minutes as compared to 50 minutes. It

is also one of the top reference codes selected by the survey respondents. In our review of CPT code 20220, we noted that the recommended intraservice time is decreasing from 22 minutes to 20 minutes (9 percent reduction), and that the recommended total time is increasing from 49 minutes to 50 minutes (2 percent increase). However, the RUC-recommended work RVU is increasing from 1.27 to 1.93, which is an increase of 52 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, changes in surveyed work time should be appropriately reflected in the proposed work RVUs.

In the case of CPT code 20220, we believe that it would be more accurate to propose a work RVU of 1.65, based on a crosswalk to CPT code 47000, to account for the decrease in the surveyed intraservice work time. We believe that the work carried out by the practitioner in CPT code 47000 is potentially more intense than the work performed in CPT code 20220, as the reviewed code is a superficial bone biopsy as opposed to the non-superficial biopsy taking place on an internal organ (the liver) described by CPT code 47000. We also note that the survey respondents considered CPT code 47000 to have similar intensity to CPT code 20220: 50 percent or more of the survey respondents rated the two codes as ''identical'' under the categories of Mental Effort and Judgment, Physical Effort Required, and Psychological Stress, along with a plurality of survey respondents rating the two codes as identical in the category of Technical Skill Required. We believe that this provides further support for our belief that CPT code 20220 should be crosswalked to CPT code 47000 at the same work RVU of 1.65.

We disagree with the RUC-recommended work RVU of 3.00 for CPT code 20225 and we are proposing a work RVU of 2.45 based on a crosswalk to CPT code 30906 (*Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; subsequent*). CPT code 30906 shares the same intraservice time of 30 minutes and has 1 fewer minute of total time as compared to CPT code 20225. When reviewing this code, we observed a pattern similar to what we had seen with CPT code 20220. We note that the recommended intraservice time for CPT code 20225 is decreasing from 60 minutes to 30 minutes (50 percent reduction), and the recommended total time is decreasing from 135 minutes to 64 minutes (53 percent reduction); however, the RUC-recommended work RVU is increasing from 1.87 to 3.00, which is an increase of about 60 percent. As we noted earlier, we do not believe that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, and we are not proposing a linear decrease in the work valuation based on these time ratios. Indeed, we agree with the RUC recommendation that the work RVU of CPT code 20225 should increase over the current valuation. However, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in changes to the work RVUs, and we do not believe that it would be accurate to propose the recommended work RVU of 3.00 given the significant decreases in surveyed work time.

Instead, we believe that it would be more accurate to propose a work RVU of 2.45 for CPT code 20225 based on a crosswalk to CPT code 30906. We note that this proposed work RVU is a very close match to the intraservice time ratio between the two codes in the family; we are proposing a work RVU of 1.65 for CPT code 20220 with 20 minutes of intraservice work time, and a work RVU of 2.45 for CPT code 20225 with 30 minutes of intraservice work time. (The exact intraservice time ratio calculates to a work RVU of 2.47.) We believe that the proposed work RVUs maintain the relative intensity of the two codes in the family, and better preserve relativity with the rest of the codes on the PFS.

For the direct PE inputs, we are proposing to replace the bone biopsy device (SF055) supply with the bone biopsy needle (SC077) in CPT code 20225. We note that this code currently makes use of the bone biopsy needle, and there was no rationale provided in the recommended materials to explain why it would now be typical for the bone biopsy needle to be replaced by the bone biopsy device. We are proposing to maintain the use of the current supply item. We are also proposing to adopt a 90 percent utilization rate for the use of the CT room (EL007) equipment in CPT code 20225. We previously finalized a policy in the CY 2010 PFS final rule (74 FR 61754 through 61755) to increase the equipment utilization rate to 90 percent for expensive diagnostic equipment priced at more than $1 million, and specifically cited the use of CT and MRI equipment which would be subject to this utilization rate.

(4) Trigger Point Dry Needling (CPT Codes 205X1 and 205X2)

For CY 2020, the CPT Editorial Panel approved two new codes to report dry needling of musculature trigger points. These codes were surveyed and reviewed by the HCPAC for the January 2019 RUC meeting.

We disagree with the HCPAC-recommended work RVU of 0.45 for CPT code 205X1 (*Needle insertion(s) without injection(s), 1 or 2 muscle(s)*) and we are proposing a work RVU of 0.32 based on a crosswalk to CPT code 36600 (*Arterial puncture, withdrawal of blood for diagnosis*). CPT code 36600 shares the identical intraservice time, total time, and intensity with CPT code 205X1, which makes it an appropriate choice for a crosswalk. In our review of CPT code 205X1, we compared the procedure to the top reference code chosen by the survey participants, CPT code 97140 (*Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes*). This therapy procedure has 50 percent more intraservice time than CPT code 205X1, as well as higher total time; however, the recommended work RVU of 0.45 was higher than the work RVU of 0.43 for the top reference code from the survey. We did not agree that CPT code 205X1 should be valued at a higher rate, and therefore, we are proposing a work RVU of 0.32 based on the aforementioned crosswalk to CPT code 36600.

We disagree with the HCPAC-recommended work RVU of 0.60 for CPT code 205X2 (*Needle insertion(s) without injection(s), 3 or more muscle(s)*) and we are proposing a work RVU of 0.48 based on a crosswalk to CPT codes 97113 (*Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises*) and 97542 (*Wheelchair management (e.g., assessment, fitting, training), each 15 minutes*). Both of these codes share the same work RVU of 0.48 and the same intraservice time of 15 minutes as CPT code 205X2, with CPT code 97113 having two fewer minutes of total time and CPT code 97542 having two additional minutes of total time. We note that this proposed work RVU is an exact match of the intraservice time ratio between the two codes in the family; we are proposing a work RVU of 0.32 for CPT code 205X1 with 10 minutes of intraservice work time, and a work RVU of 0.48 for CPT code 205X2 with 15 minutes of intraservice work time. We also considered crosswalking the work RVU of CPT code 205X2 to the

top reference code from the survey, CPT code 97140, at a work RVU of 0.43. However, we chose to employ the crosswalk to CPT codes 97113 and 97542 at a work RVU of 0.48 instead, due to the fact that the survey respondents indicated that CPT code 205X2 was more intense than CPT code 97140.

We are also proposing to designate CPT codes 205X1 and 205X2 as ''always therapy'' procedures, and we are soliciting comments on this designation. We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(5) Closed Treatment Vertebral Fracture (CPT Code 22310)

This service was identified through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes.

For CPT code 22310 (*Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing*), we disagree with the recommended work RVU of 3.75 because we do not believe that this reduction in work RVU from the current value of 3.89 is commensurate with the RUC-recommended a 33-minute reduction in intraservice time and a 105-minute reduction in total time. While we understand that the RUC considers the current Harvard study time values for this service to be invalid estimations, we believe that a further reduction in work RVUs is warranted given the significance of the RUC-recommended reduction in physician time. We believe that it would be more accurate to propose a work RVU of 3.45 with a crosswalk to CPT code 21073 (*Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care)*), which has an identical intraservice time and similar total time as those proposed by the RUC for CPT code 22310, as we believe that this better accounts for the decrease in the surveyed work time.

For the direct PE inputs, we are proposing to refine the equipment time for the power table (EF031) to conform to our established standard for non-highly technical equipment.

(6) Tendon Sheath Procedures (CPT Codes 26020, 26055, and 26160)

The RUC identified these services through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. For CPT code 26020 (Drainage of tendon sheath, digit and/or palm, each), we do not agree with the RUC-recommended work RVU of 7.79 based on the survey median. While we agree that the survey data validate an increase in work RVU, we see no compelling reason that this service would be significantly more intense to furnish than services of similar time values. Therefore, we are proposing a work RVU of 6.84 which is the survey 25th percentile. As further support for this value, we note that it falls between the work RVUs of CPT code 28122 *(Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus*), with a work RVU of 6.76, and CPT code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*), with a work RVU of 6.90; both codes have intraservice time values that are identical to, and total time values that are similar to, the RUC-recommended time values for CPT code 26020.

For CPT code 26055 (*Tendon sheath incision (e.g., for trigger finger)*), we do not agree with the RUC recommendation to increase the work RVU to 3.75 despite a reduction in physician time. Instead, we are proposing to maintain the current work RVU of 3.11; we are supporting this based on a total time increment methodology between the CPT code 26020 and CPT code 26055. The total time ratio between the recommended time of 119 minutes and the recommended 262 minutes for code 26020 equals 45 percent, and 45 percent of our proposed RVU of 6.84 for CPT code 26020 equals a work RVU of 3.10, which we believe validates the current work RVU of 3.11. We are proposing the RUC-recommended work RVU of 3.57 for CPT code 26160 (*Excision of lesion of tendon sheath or joint capsule (e.g., cyst, mucous cyst, or ganglion), hand or finger*). We note that our proposed work RVUs validate the RUC's contention that CPT code 26160 is slightly more intense to perform than CPT code 26055.

For the direct PE inputs, we are proposing to refine the quantity of the impervious staff gown (SB027) supply from 2 to 1 for CPT codes 26055 and 26160. We believe that the second impervious staff gown supply is duplicative due to the inclusion of this same supply in the surgical cleaning pack (SA043). The recommended materials state that a gown is worn by the practitioner and one assistant, which are provided by one standalone gown and a second gown in the surgical cleaning pack.

(7) Closed Treatment Fracture—Hip (CPT Code 27220)

This service was identified through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. For CPT code 27220 (*Closed treatment of acetabulum (hip socket) fracture(s); without manipulation*), we disagree with the RUC-recommended work RVU of 6.00 based on the survey median value, because we do not believe that this reduction in work RVU from the current value of 6.83 is commensurate with the RUC-recommended a 19-minute reduction in intraservice time and an 80-minute reduction in total time. While we understand that the RUC considers the current Harvard study time values for this service to be invalid estimations, we believe that a further reduction in work RVUs is warranted given the significance of the RUC-recommended reduction in physician time. We believe that it would be more accurate to propose the survey 25th percentile work RVU of 5.50, and we are supporting this value with a crosswalk to CPT code 27267 (*Closed treatment of femoral fracture, proximal end, head; without manipulation*) to account for the decrease in the surveyed work time.

For the direct PE inputs, we are proposing to refine the equipment time for the power table (EF031) to conform to our established standard for non-highly technical equipment.

(8) Arthrodesis—Sacroliliac Joint (CPT Code 27279)

In the CY 2018 PFS final rule (82 FR 53017), CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) was nominated for review by stakeholders as a potentially misvalued service. We stated that CPT code 27279 is potentially misvalued, and that a comprehensive review of the code values was warranted. This code was subsequently reviewed by the RUC. According to the specialty societies, the previous 2014 survey of CPT code 27279, was based on flawed methodology that resulted in an underestimation of intraoperative intensity. When CPT code 27279 was surveyed in 2014, there was a low rate of response. Due to the dearth of survey data and the RUC's agreement with the specialty society at the time that the

survey respondents had somewhat overvalued the work involved in performing this service, the RUC used a crosswalk to CPT code 62287 (*Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar*) to recommend a work RVU of 9.03. The specialty societies indicated that with increased and broader utilization of this technique, the 2018 survey is a more robust assessment of physician work and intensity and provides more data with which to make a crosswalk recommendation. According to the RUC, there is no compelling evidence that the physician work, intensity or complexity has changed for this service.

We are proposing to maintain the current work RVU of 9.03 as recommended by the RUC. A stakeholder stated that maintaining this RVU would constitute the continued undervaluation of this service, and that this would incentivize use of a more intensive and invasive procedure, CPT code 27280 (*Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed*), as well as incentivize this service to be inappropriately furnished on an inpatient basis. This stakeholder has requested that, in the interest of protecting patient access, we implement payment parity between the two services by proposing to crosswalk the work RVU of CPT code 27279 to that of CPT code 27280, which has a work RVU of 20.00. While we are proposing the RUC-recommended work RVU, we are soliciting public comment on whether an alternative valuation of 20.00 would be more appropriate. This alternative valuation would recognize relative parity between these two services in terms of the work inherent in furnishing them.

We are proposing the RUC-recommended direct PE inputs for CPT code 27279.

(9) Pericardiocentesis and Pericardial Drainage (CPT Code 3X000, 3X001, 3X002, and 3X003)

CPT code 33015 (*Tube pericardiostomy*) was identified as potentially misvalued on a Relativity Assessment Workgroup (RAW) screen of codes with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS or other source codes. In September 2018, the CPT Editorial Panel deleted four existing codes and created four new codes to describe periodcardiocentesis drainage procedures to differentiate by age and to include imaging guidance.

We are proposing to refine the work RVU for all four codes in the family. We disagree with the RUC-recommended work RVU of 5.00 for CPT code 3X000 (*Pericardiocentesis, including imaging guidance, when performed*) and are proposing a work RVU of 4.40 based on a crosswalk to CPT code 43244 (*Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices*). CPT code 43244 shares the same intraservice time of 30 minutes with CPT code 3X000 and has a slightly longer total time of 81 minutes as compared to 75 minutes for the reviewed code. In our review of CPT code 3X000, we noted that the recommended intraservice time as compared to the current initial pericardiocentesis procedure (CPT code 33010) is increasing from 24 minutes to 30 minutes (25 percent), and the recommended total time is remaining the same at 75 minutes; however, the RUC-recommended work RVU is increasing from 1.99 to 5.00, which is an increase of 151 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, modest increases in time should be appropriately reflected with a commensurate increase the work RVUs. We also conducted a search in the RUC database among 0-day global codes with 30 minutes of intraservice time and comparable total time of 65–85 minutes. Our search identified 49 codes and all 49 of these codes had a work RVU lower than 5.00. We do not believe that it would serve the interests of relativity to establish a new maximum work RVU for this range of time values.

As a result, we believe that it is more accurate to propose a work RVU of 4.40 for CPT code 3X000 based on a crosswalk to CPT code 43244 to account for these modest increases in the surveyed work time as compared to the predecessor pericardiocentesis codes. We are aware that CPT code 3X000 is bundling imaging guidance into the new procedure, which was not included in the previous pericardiocentesis codes. However, we do not believe that the recoding of the services in this family has resulted in an increase in their intensity, only a change in the way in which they will be reported, and therefore, we do not believe that it would serve the interests of relativity to propose the RUC-recommended work values for all of the codes in this family. We also note that, through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular servicers. For example, a practitioner would not be carrying out the full preservice work twice for CPT codes 33010 and 76930, but preservice times were assigned to both codes under the old coding. We believe the new coding assigns more accurate work times, and thus, reflects efficiencies in resource costs that existed but were not reflected in the services as they were previously reported. If the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which were largely unchanged from the predecessor codes.

We disagree with the RUC-recommended work RVU of 5.50 for CPT code 3X001 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; 6 years and older without congenital cardiac anomaly*) and are proposing a work RVU of 4.62 based on a crosswalk to CPT code 52234 (*Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; SMALL bladder tumor(s) (0.5 up to 2.0 cm)*). CPT code 52234 shares the same intraservice time of 30 minutes with CPT code 3X001 and has 2 additional minutes of total time at 79 minutes as compared to 77 minutes for the reviewed code. In our review of CPT code 3X001, we noted many of the same issues that we had raised with CPT code 3X000, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. We searched the RUC database again for 0-day global codes with 30 minutes of intraservice time and comparable total time of 67–87 minutes. Our search identified 43 codes and again all 43 of these codes had a work RVU lower than 5.50. As we stated with regard to CPT code 3X000, we do not believe that it would serve the interests of relativity to establish a new maximum work RVU for this range of time values. We believe that it is more accurate to propose a work RVU of 4.62 for CPT code 3X001 based on a crosswalk to CPT code 52234 based on the same rationale that we

detailed with regards to CPT code 3X000.

We disagree with the RUC-recommended work RVU of 6.00 for CPT code 3X002 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; birth through 5 years of age, or any age with congenital cardiac anomaly*) and are proposing a work RVU of 5.00 based on the survey 25th percentile value. In our review of CPT code 3X002, we noted many of the same issues that we had raised with CPT codes 3X000 and 3X001, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. The recommended work RVU of 6.00 was based on a crosswalk to CPT code 31603 (*Tracheostomy, emergency procedure; transtracheal*), which shares the same intraservice time of 30 minutes with CPT code 3X002 and very similar total time. While we agree that CPT code 31603 is a close match to the surveyed work times for CPT code 3X002, we do not believe that it is the most accurate choice for a crosswalk due to the fact that CPT code 31603 is a clear outlier in work valuation. We searched for 0-day global codes in the RUC database with 30 minutes of intraservice time and a comparable 90–120 minutes of total time. There were 21 codes that met this criteria, and the recommended crosswalk to CPT code 31603 had the highest work RVU of any of these codes at the recommended 6.00. Furthermore, there was only one other code with a work RVU above 5.00, another tracheostomy procedure described by CPT code 31600 (Tracheostomy, planned (separate procedure)) at a work RVU of 5.56. None of the other codes had a work RVU higher than 4.69, and the median work RVU of the group comes out to only 4.00. The two tracheostomy procedures have work RVUs more than a full standard deviation above any of the other codes in this group of 0-day global procedures.

We do not mean to suggest that the work RVU for a given service must always fall in the middle of a range of codes with similar time values. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. However, we also do not believe that it would serve the interests of relativity by crosswalking the work RVU of CPT code 3X002 to tracheostomy procedures that are higher than anything else in this group of codes, procedures that we believe to be outliers due to the serious risk of patient mortality associated with their performance. We believe that it is this patient risk which is responsible for the otherwise anomalously high intensity in CPT codes 31600 and 31603. Therefore, we are proposing a work RVU of 5.00 for CPT code 3X002 based on the survey 25th percentile, which we believe more accurately captures both the time and intensity associated with the procedure.

We disagree with the RUC-recommended work RVU of 5.00 for CPT code 3X003 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including CT guidance*) and are proposing a work RVU of 4.29 based on the survey 25th percentile value. In our review of CPT code 3X003, we noted many of the same issues that we had raised with CPT codes 3X000–3X002, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. We searched for 0-day global codes in the RUC database with 30 minutes of intraservice time (slightly higher than the 28 minutes of intraservice time in CPT code 3X003) and a comparable 70–100 minutes of total time. Our search identified 45 codes and again all 45 of these codes had a work RVU lower than 5.00, which led us to believe that the recommended work RVU for CPT code 3X003 was overvalued. We also compared CPT code 3X003 to the most similar code in the family, CPT code 3X001, and noted that the survey respondents indicated that CPT code 3X003 should have a lower work RVU at both the survey 25th percentile and survey median values. Therefore, we are proposing a work RVU of 4.29 for CPT code 3X003 based on the survey 25th percentile value. We are supporting this proposal with a reference to CPT code 31254 (*Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)*), a recently-reviewed code with an intraservice work time of 30 minutes, a total time of 84 minutes, and a work RVU of 4.27.

The RUC did not recommend and we are not proposing any direct PE inputs for the codes in this family.

(10) Pericardiotomy (CPT Codes 33020 and 33025)

CPT code 33020 (*Pericardiotomy for removal of clot or foreign body (primary procedure)*) was identified as potentially misvalued on a Relativity Assessment Workgroup (RAW) screen of codes with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS or other source codes. The RAW determined that CPT code 33020 should be surveyed for April 2018; CPT code 33025 (*Creation of pericardial window or partial resection for drainage*) was included for review as part of this code family.

We disagree with the RUC-recommended work RVU of 14.31 (25th percentile survey value) for CPT code 33020 and are proposing a work RVU of 12.95. Our proposed work RVU is based on a crosswalk to CPT code 58700 (*Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)*), which has an identical work RVU of 12.95, identical 60 minutes intraservice time, and near identical total time values as CPT code 33020.

In our review of CPT code 33020, we note that the RUC-recommended intraservice time is decreasing from 85 minutes to 60 minutes (29 percent reduction), and that the RUC-recommended total time is decreasing from 565 minutes to 321 minutes (43 percent reduction). However, the RUC-recommended work RVU is only decreasing from 14.95 to 14.31, which is a reduction of less than 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 33020, we believe that it would be more accurate to propose a work RVU of 12.95, based on a crosswalk to CPT code 58700 to account for these decreases in surveyed work times.

For CPT code 33025, the RUC recommended a work RVU of 13.20 (survey 25th percentile value). Although we disagree with the RUC-recommended work RVU of 13.20, based on RUC survey results and the time resources involved in furnishing these two procedures we agree that the relative difference in work RVUs between CPT codes 33020 and 33025 is equivalent to the RUC-recommended incremental difference of 1.11 less work RVUs. Therefore, we are proposing a work RVU of 11.84 based on a reference to CPT code 34712 (*Transcatheter delivery of enhanced fixation devices(s) to the endograft (e.g., anchor, screw,*

tack) and all associated radiological supervision and interpretation), which has a work RVU of 12.00, identical intraservice time of 60 minutes, and similar total time as CPT code 33025.

In reviewing CPT code 33025, we note that the RUC-recommended intraservice time is decreasing from 66 minutes to 60 minutes (9 percent reduction), and that the RUC-recommended total time is decreasing from 410 minutes to 301 minutes (27 percent reduction). However, the RUC-recommended work RVU is only decreasing from 13.70 to 13.20, which is a reduction of less than 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 33025, we believe that it would be more accurate to propose a work RVU of 11.84, based on less the incremental difference of 1.11 work RVUs between CPT codes 33020 and 33025 and a crosswalk to CPT code 34712 to account for these decreases in surveyed work times.

We are proposing the RUC-recommended direct PE inputs for all the codes in this family.

(11) Transcatheter Aortic Valve Replacement (TAVR) (CPT Codes 33361, 33362, 33363, 33364, 33365, and 33366)

In October 2016, the RUC's RAW reviewed codes that had been flagged in the period from October 2011 to April 2012, using 3 years of available Medicare claims data (2013, 2014 and preliminary 2015 data). The RUC workgroup determined that the technology for these transcatheter aortic valve replacement (TAVR) services was evolving, as the typical site of service had shifted from being provided in academic centers to private centers, and the RUC recommended that CPT codes 33361–33366 be resurveyed for physician work and practice expense. These six codes were surveyed and reviewed at the April 2018 RUC meeting using a survey methodology that reflected the unique nature of these codes. CPT codes 33361–33366 are currently the only codes on the PFS where the -62 co-surgeon modifier is required 100 percent of the time.

We are proposing the RUC-recommended work RVU for all six of the codes in this family. We are proposing a work RVU of 22.47 for CPT code 33361 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach*), a work RVU of 24.54 for CPT code 33362 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach*), a work RVU of 25.47 for CPT code 33363 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach*), a work RVU of 25.97 for CPT code 33364 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach*), a work RVU of 26.59 for CPT code 33365 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)*), and a work RVU of 29.35 for CPT code 33366 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)*).

Although we have some concerns that the RUC-recommended work RVUs for these six codes do not match the decreases in surveyed work time, we recognize that the technology described by the TAVR procedures is in the process of being adopted by a much wider audience, and that there will be greater intensity on the part of the practitioner when this particular new technology is first being adopted. However, we intend to continue examining whether these services are appropriately valued, in light of the proposed national coverage determination proposing to use TAVR for the treatment of symptomatic aortic valve stenosis that we posted on March 26, 2019. We will also consider any further improvements to the valuation of these services, as their use becomes more commonplace, through future notice and comment rulemaking. The text of the proposed national coverage determination is available on the CMS website at *https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=293*.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(12) Aortic Graft Procedures (CPT Codes 338XX, 338X1, 33863, 33864, 338X2, and 33866)

In 2017, CPT created a new add-on code, CPT code 33866 (*Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)*). For CY 2019, we finalized the RUC's recommended work RVU for this code on an interim basis (83 FR 59528). CPT revised the code set to develop distinct codes for ascending aortic repair for dissection and ascending aortic repair for other ascending aortic disease such as aneurysms and congenital anomalies, creating two new codes, as well as revaluating the two other codes in the family.

For CPT code 338XX (*Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic dissection*), we disagree with the RUC-recommended work RVU of 65.00, because the RUC is recommending an increase in work RVU that is not commensurate with a reduction in physician time, and because we do not believe that the RUC's recommendation that this service be increased to a value that would place it among the highest valued of all services of similar physician time is appropriate; we think a comparison to other services of similar time indicates that the RUC's recommended increase overstates the work. Instead, we are proposing to increase the work RVU to 63.40 based on a crosswalk to CPT code 61697 (*Surgery of complex intracranial aneurysm, intracranial approach; carotid circulation*). For CPT code 338X1 (*Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic disease other than dissection (e.g., aneurysm)*), we disagree with the RUC-recommended work RVU of 50.00, because we do not believe it adequately reflects the recommended decrease in physician time, and because we do not believe this service should be assigned a value that is among the highest of all 90-day global services with similar physician time values. Instead, we are proposing a work RVU of 45.13 based on a crosswalk to CPT code 33468 (*Tricuspid valve repositioning and plication for Ebstein anomaly*), which is a code with an identical intraservice time and similar total time value.

For CPT code 33863 (*Ascending aorta graft, with cardiopulmonary bypass, with aortic root replacement using valved conduit and coronary reconstruction (e.g., Bentall)*), according to the RUC, the survey respondents underestimated the intraservice time of the procedure and the RUC recommended a work RVU of 59.00 based on the 75th percentile of survey responses for intraservice time. We believe the use of the survey 75th percentile value to be problematic, as the intraservice time values should generally reflect the survey median. We are requesting that this code be

resurveyed to determine more accurate physician time values, and we are proposing to maintain the current RVU of 58.79 for CY 2020. For CPT code 33864 (*Ascending aorta graft, with cardiopulmonary bypass with valve suspension, with coronary reconstruction and valve-sparing aortic root remodeling (e.g., David Procedure, Yacoub procedure)*), we do not agree with the RUC-recommended work RVU of 63.00, because we believe this increase is not justified given that the intraservice time is not changing from its current value, and the physician total time value is decreasing. Therefore, we are proposing to maintain the current work RVU of 60.08 for this service.

For CPT code 338X2 (*Transverse aortic arch graft, with cardiopulmonary bypass, with profound hypothermia, total circulatory arrest and isolated cerebral perfusion with reimplantation of arch vessel(s) (e.g., island pedicle or individual arch vessel reimplantation)*), we disagree with the RUC's recommended work RVU of 65.75. While we agree that an increase in work RVU is justified, as discussed above, we believe that the use of the 75th percentile of physician intraservice work time is problematic, and believe such a significant increase in work RVU is not validated. Therefore, we are proposing a less significant increase to 60.88 using the RUC-recommended difference in work value between CPT code 338X1 and the code in question, CPT code 338X2 (a difference of 15.75). As further support for this value, we note that it falls between CPT codes 33782 (*Aortic root translocation with ventricular septal defect and pulmonary stenosis repair (i.e., Nikaidoh procedure); without coronary ostium reimplantation*), which has a work RVU of 60.08, and CPT code 43112 (*Total or near total esophagectomy, with thoracotomy; with pharyngogastrostomy or cervical esophagogastrostomy, with or without pyloroplasty (i.e., McKeown esophagectomy or tri-incisional esophagectomy)*), which has a work RVU of 62.00. Both of these bracketing reference codes have similar intraservice and total time values. For CPT code 33X01 (*Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)*), we are proposing the RUC-recommended work RVU of 17.75.

For the direct PE inputs, we are proposing to refine the clinical labor to align with the number of post-operative visits. Thus, we are proposing to add 12 minutes of clinical labor time for ''Discharge day management'' for CPT codes 338X1, 33863, 33864, and 338X2, as each of these codes include a 99238 discharge visit within their global periods that should be reflected in the clinical labor inputs.

(13) Iliac Branched Endograft Placement (CPT Codes 34X00 and 34X01)

For CY 2018, the CPT Editorial Panel created a family of 20 new and revised codes that redefined coding for endovascular repair of the aorta and iliac arteries. The iliac branched endograft technology has become more mainstream over time, and two new CPT codes were created to capture the work of iliac artery endovascular repair with an iliac branched endograft. These two new codes were surveyed and reviewed for the January 2019 RUC meeting.

We are proposing the RUC-recommended work RVU of 9.00 for CPT code 34X00 (*Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for rupture or other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer, traumatic disruption), unilateral*) and the RUC-recommended work RVU of 24.00 for CPT code 34X01 (*Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral*).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(14) Exploration of Artery (CPT Codes 35701, 35X01, and 35X01)

CPT code 35701 (*Exploration not followed by surgical repair, artery; neck (e.g., carotid, subclavian)*) was identified via a screen for services with a ne.g.ative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. In September 2018, the CPT Editorial Panel revised one code, added two new codes, and deleted three existing codes in the family to report major artery exploration procedures and to condense the code set due to low frequency.

We are proposing the RUC-recommended work RVU for all three codes in the family. We are proposing a work RVU of 7.50 for CPT code 35701, a work RVU of 7.12 for CPT code 35X00 (*Exploration not followed by surgical repair, artery; upper extremity (e.g., axillary, brachial, radial, ulnar)*), and a work RVU of 7.50 for CPT code 35X01 (*Exploration not followed by surgical repair, artery; lower extremity (e.g., common femoral, deep femoral, superficial femoral, popliteal, tibial, peroneal)*).

For the direct PE inputs, we are proposing to refine the clinical labor, supplies, and equipment to match the number of office visits contained in the global periods of the codes under review. We are proposing to refine the clinical labor time for the ''Post-operative visits (total time)'' (CA039) activity from 36 minutes to 27 minutes for CPT codes 35701 and 35X00, and from 63 minutes to 27 minutes for CPT code 35X01. Each of these CPT codes contains a single postoperative level 2 office visit (CPT code 99212) in its global period, and 27 minutes of clinical labor is the time associated with this office visit. We are proposing to refine the equipment time for the exam table (EF023) to the same time of 27 minutes for each code to match the clinical labor time. Finally, we are also proposing to refine the quantity of the minimum multi-specialty visit pack (SA048) from 2 to 1 for CPT code 35X01 to match the single postoperative visit in the code's global period. We believe that the additional direct PE inputs in the recommended materials were an accidental oversight due to revisions that took place at the RUC meeting following the approval of the PE inputs for these codes.

(15) Intravascular Ultrasound (CPT Codes 37252 and 37253)

In CY 2014, the CPT Editorial Panel deleted CPT codes 37250 (*Ultrasound evaluation of blood vessel during*

diagnosis or treatment)and 37251 (*Ultrasound evaluation of blood vessel during diagnosis or treatment*) and created new bundled codes 37252 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel*) and 37253 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel*) to describe intravascular ultrasound (IVUS). CPT codes 37252 and 37253 were reviewed at the January 2015 RUC meeting. The RUC's recommendation for these codes were to result in an overall work savings that should have been redistributed back to the Medicare conversion factor. The codes have had a 44 percent increase in work RVUs over the old codes, CPT codes 37250 and 37251, from 2015 to 2016 and the utilization has doubled from that of the previous coding structure, not considering the radiological activities. In April 2018, the RUC reviewed this code family and determined the utilization of the bundling of these services was underestimated. Consequently, the RUC recommended that these services be surveyed for October 2018. The RUC indicated that the specialty societies should research why there was such an increase in the utilization. Accordingly, the specialty society surveyed these ZZZ-day global codes, and the survey results indicated the intraservice and total work times, along with the work RVU should remain the same despite the underestimation in utilization.

We disagreed with the RUC-recommended work RVU of 1.80 for CPT code 37252 and are proposing a work RVU of 1.55 based on a crosswalk to CPT code 19084. CPT code 19084 is a recently reviewed code with 20 minutes of intraservice time and 25 minutes of total time. In reviewing CPT code 37252, we note, as mentioned above, that in CY 2015 the specialty society stated that bundling this service would achieve savings. However, since 2015 observed utilization for CPT code 37252 has greatly exceeded proposed estimates, thus we are proposing to restore work neutrality to the intravascular ultrasound code family to achieve the initial estimated savings.

For CPT code 37253, we disagreed with the RUC-recommended work RVU of 1.44 and we are proposing a work RVU of 1.19. Although we disagreed with the RUC-recommended work RVU, we note the relative difference in work between CPT codes 37252 and 37253 is an interval of 0.36 RVUs. Therefore, we are proposing a work RVU of 1.19 for CPT code 37253, based on the recommended interval of 0.36 fewer RVUs than our proposed work RVU of 1.55 for CPT code 37252.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(16) Stab Phlebectomy of Varicose Veins (CPT Codes 37765 and 37766)

These services were identified in February 2008 via the High Volume Growth screen, for services with a total Medicare utilization of 1,000 or more that have increased by at least 100 percent from 2004 through 2006. The RUC subsequently recommended monitoring and reviewing changes in utilization over multiple years. In October 2017, the RUC recommended that this service be surveyed for April 2018. We are proposing the RUC-recommended work RVUs of 4.80 for CPT code 37765 (*Stab phlebectomy of varicose veins, 1 extremity; 10–20 stab incisions*) and 6.00 for CPT code 37766 (*Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions*). We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(17) Biopsy of Mouth Lesion (CPT Code 40808)

CPT code 40808 (*Biopsy, vestibule of mouth*) was identified via a screen for services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes.

We disagree with the RUC's recommended work RVU of 1.05 with a crosswalk to CPT code 11440 (*Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less*), as we believe this increase in work RVU is not commensurate with the RUC-recommended 5-minute reduction in intraservice time and a 10-minute reduction in total time. While we understand that the RUC considers the current time values for this service to be invalid estimations, we do not see compelling evidence that would indicate that an increase in work RVU that would be concurrent with a reduction in physician time is appropriate. Therefore, we are proposing to maintain the current work RVU of 1.01, and note that implementing the current work RVU with the RUC-recommended revised physician time values would correct the negative IWPUT anomaly.

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes. As we detailed when discussing this issue in the CY 2019 PFS final rule (83 FR 59463 through 59464), CPT code 40808 does not include the old clinical labor task ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' on a prior version of the PE worksheet, nor does the code contain any clinical labor for the CA007 activity (''Review patient clinical extant information and questionnaire''). CPT code 40808 does not appear to be an instance where an old clinical labor task was split into two new clinical labor activities, and we continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished.

We are also proposing to refine the equipment time for the electrocautery-hyfrecator (EQ110) to conform to our established standard for non-highly technical equipment.

(18) Transanal Hemorrhoidal Dearterialization (CPT Codes 46945, 46946, and 46X48)

We are proposing the RUC-recommended work RVU for all three codes in the family. We are proposing a work RVU of 3.69 for CPT code 46945 (*Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group, without imaging guidance*), a work RVU of 4.50 for CPT code 46946 (*2 or more hemorrhoid columns/groups, without imaging guidance*), and a work RVU of 5.57 for CPT code 46X48 (*Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy when performed*).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(19) Preperitoneal Pelvic Packing (CPT Codes 490X1 and 490X2)

In May 2018, the CPT Editorial Panel approved the addition of two codes for preperitoneal pelvic packing, removal

and/or repacking for hemorrhage associated with pelvic trauma. These new codes were surveyed and reviewed for the October 2018 RUC meeting.

We disagree with the RUC-recommended work RVU of 8.35 for CPT code 490X1 (*Preperitoneal pelvic packing for hemorrhage associated with pelvic trauma, including local exploration*) and are proposing a work RVU of 7.55 based on a crosswalk to CPT code 52345 (*Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (e.g., balloon dilation, laser, electrocautery, and incision)*). We are also proposing to reduce the immediate postservice work time from 60 minutes to 45 minutes, which results in a total work time of 140 minutes for this procedure. We believe that the survey respondents overstated the immediate postservice work time that would typically be required to perform CPT code 490X1, which we investigated by comparing this new service against the existing 0-day global codes on the PFS. We found that among the roughly 1,100 codes with 0-day global periods, only 21 codes had an immediate postservice work time of 60 minutes or longer. The 21 codes that fell into this category had significantly higher intraservice work times than CPT code 490X1, with an average intraservice work time of 111 minutes as compared to the 45 minutes of intraservice work time in CPT code 490X1. Generally speaking, it is extremely rare for a service to have more immediate postservice work time than intraservice work time, and in fact only 28 out of the roughly 1,100 codes with 0-day global periods had more immediate postservice work time than intraservice work time. While we agree that each service on the PFS is its own unique entity, these comparisons to other 0-day global codes suggest that the survey respondents overestimated the amount of immediate postservice work time that would typically be associated with CPT code 490X1.

As a result, we believe that it would be more accurate to reduce the immediate postservice work time to 45 minutes and to propose a work RVU of 7.55 based on a crosswalk to CPT code 52345. This crosswalk code shares an intraservice work time of 45 minutes and a similar total time of 135 minutes after taking into account the reduced immediate postservice work time that we are proposing for CPT code 490X1. We searched the RUC database for 0-day global procedures with 45 minutes of intraservice work time, and at the recommended work RVU of 8.35, CPT code 490X1 would establish a new maximum value, higher than all of the 79 other codes that fall into this category. We recognize that CPT code 490X1 describes a preperitoneal pelvic packing service associated with pelvic trauma, and that this is a difficult and intensive procedure that rightly has a higher work RVU than many of these other 0-day global codes. However, we believe that it better maintains relativity to propose a crosswalk to CPT code 52345 at a work RVU of 7.55, which would still assign this code the second-highest work RVU among all 0 day global codes with 45 minutes of intraservice work time, as opposed to proposing the survey median work RVU of 8.35 at a rate higher than anything in the current RUC database.

We disagree with the RUC-recommended work RVU of 6.73 for CPT code 490X2 (Re-exploration of pelvic wound with removal of preperitoneal pelvic packing including repacking, when performed) and are proposing a work RVU of 5.70 based on the 25th percentile survey value. We believe that the survey 25th percentile work RVU more accurately describes the work of re-exploring this type of pelvic wound, and by proposing the survey 25th percentile we are maintaining the general increment in RVUs between the two codes in the family (a difference of 1.62 RVUs as recommended by the RUC as compared to 1.85 RVUs as proposed here). We are supporting this valuation with a reference to CPT code 39401 (*Mediastinoscopy; includes biopsy(ies) of mediastinal mass (e.g., lymphoma), when performed*), a recently reviewed code from CY 2015 which shares the same intraservice time of 45 minutes, a slightly higher total time of 142 minutes and a lower work RVU of 5.44.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(20) Cystourethroscopy Insertion Transprostatic Implant (CPT Codes 52441 and 52442)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the AMA/Specialty Society RVS Update Committee. This service was reviewed at the October 2018 RAW meeting, and the RAW indicated that the utilization is increasing and questioned the time required to perform these services. These two codes were surveyed and reviewed for the January 2019 RUC meeting.

We disagree with the RUC-recommended work RVU of 4.50 (current value) for CPT code 52441 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant*) and are proposing a work RVU of 4.00. This proposed work RVU is based on a crosswalk from recently reviewed CPT code 58562 (*Hysterscopy, surgical; with removal of impacted foreign body*), which has a work RVU of 4.00, and an identical 25 minutes of intraservice time as CPT code 52441.

We disagree with the RUC-recommended work RVU of 1.20 (current value) for CPT code 52442 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)*) and are proposing a work RVU of 1.01. This proposed work RVU is based on a crosswalk from CPT code 36218 (*Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)*), which has a work RVU of 1.01, and an identical 15 minutes of intraservice time as CPT code 52442. The RUC survey showed a reduction in time, and the work should reflect these changes.

We are proposing the RUC-recommended direct PE inputs for all codes in the family without refinement.

(21) Orchiopexy (CPT Code 54640)

The CPT Editorial Panel revised existing CPT code 54640 to describe an additional approach for orchiopexy (scrotal) and to clearly indicate that hernia repair is separately reportable. This code was surveyed and reviewed for the January 2019 RUC meeting.

We are proposing to maintain the current work RVU of 7.73 as recommended by the RUC. We are proposing the RUC-recommended direct PE inputs for CPT code 54640 without refinement.

(22) Radiofrequency Neurootomy Sacroiliac Joint (CPT Codes 6XX00, 6XX01)

In September 2018, the CPT Editorial Panel created two new codes to describe injection and radiofrequency ablation of the sacroiliac joint with image guidance for somatic nerve procedures. We are proposing the RUC-recommended work RVU of 1.52 for CPT code 6XX00 (*Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)*) and the RUC-recommended work RVU of 3.39 for CPT code 6XX01 (*Radiofrequency ablation, nerves innervating the sacroiliac joint, with*

image guidance (i.e., fluoroscopy or computed tomography)).

For the direct PE inputs, we are proposing to refine the quantity of the ''needle, 18–26g 1.5–3.5in, spinal'' (SC028) supply from 3 to 1 for CPT code 6XX00. There are no spinal needles in use in the reference code associated with CPT code 6XX00, and there was no explanation in the recommended materials explaining why three such needles would be typical for this procedure. We agree that the service being performed in CPT code 6XX00 would require a spinal needle, but we do not believe that the use of three such needles would be typical.

We are proposing to refine the quantity of the ''cannula (radiofrequency denervation) (SMK–C10)'' (SD011) supply from 4 to 2 for CPT code 6XX01. We do not believe that the use of 4 of these cannula would be typical for the procedure, as the reference code currently used for destruction by neurolytic agent contains only a single cannula. We believe that the nerves would typically be ablated one at a time using this cannula, as opposed to ablating four of them simultaneously as suggested in the recommended direct PE inputs. We also searched in the RUC database for other CPT codes that made use of the SD011 supply, and out of the seven codes that currently use this item, none of them include more than 2 cannula. As a result, we are proposing to refine the supply quantity to 2 cannula to match the highest amount contained in an existing code on the PFS. We are also refining the equipment time for the ''radiofrequency kit for destruction by neurolytic agent'' (EQ354) equipment from 164 minutes to 82 minutes. The RUC's equipment time recommendation was predicated on the use of 4 of the SD011 supplies for 41 minutes apiece, and we are refining the equipment time to reflect our supply refinement to 2 cannula. It was unclear in the recommended materials as to whether the radiofrequency kit equipment was in use simultaneously or sequentially along with the cannula supplies, and therefore, we are soliciting comments on the typical use of this equipment.

Finally, we are proposing to refine the equipment time for the technologist PACS workstation (ED050) equipment to match our standard equipment time formulas, which results in an increase of 5 minutes of equipment time for both codes.

(23) Lumbar Puncture (CPT Codes 62270, 622X0, 62272, and 622X1)

In October 2017, these services were identified as being performed by a different specialty than the specialty that originally surveyed this service. In January 2018, the RUC recommended that these services be referred to CPT to bundle image guidance. At the September 2018 CPT Editorial Panel meeting, the Panel created two new codes to bundle diagnostic and therapeutic lumbar puncture with fluoroscopic or CT image guidance and revised the existing diagnostic and therapeutic lumbar puncture codes so they would only be reported without fluoroscopic or CT guidance.

For CPT code 62270 (*Spinal puncture, lumbar, diagnostic*), we disagree with the RUC-recommended work RVU of 1.44 and we are proposing a work RVU of 1.22 based on a crosswalk to CPT code 40490 (*Biopsy of lip*). CPT code 40490 has the same intraservice time of 15 minutes and 2 additional minutes of total time. In reviewing CPT code 62270, we noted that the recommended intraservice time is decreasing from 20 minutes to 15 minutes (25 percent reduction), and the recommended total time is decreasing from 40 minutes to 32 minutes (20 percent reduction); however, the RUC-recommended work RVU is increasing from 1.37 to 1.44, which is an increase of just over 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 62270, we believed that it was more accurate to propose a work RVU of 1.22 based on a crosswalk to CPT code 40490 to account for these decreases in the surveyed work time.

For CPT code 622X0 (*Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance*), we disagree with the RUC-recommended work RVU of 1.95 and we are proposing a work RVU of 1.73. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 622X0 is equivalent to an interval of 0.51 RVUs. Therefore, we are proposing a work RVU of 1.73 for CPT code 622X0, based on the recommended interval of 0.51 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

For CPT code 62272 (*Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter*), we disagree with the RUC-recommended work RVU of 1.80 and we are proposing a work RVU of 1.58. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 622X0 is equivalent to the RUC-recommended interval of 0.36 RVUs. Therefore, we are proposing a work RVU of 1.58 for CPT code 62272, based on the recommended interval of 0.36 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

For CPT code 622X1 (*Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance*), we disagree with the RUC-recommended work RVU of 2.25 and we are proposing a work RVU of 2.03. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 622X1 is equivalent to the recommended interval of 0.81 RVUs. Therefore, we are proposing a work RVU of 2.03 for CPT code 622X1, based on the recommended interval of 0.81 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

(24) Electronic Analysis of Implanted Pump (CPT Codes 62367, 62368, 62369, and 62370)

CPT code 62368 (*Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming*) was identified by the RUC on a list of services which were originally surveyed by one specialty but are now typically performed by a different specialty. It was reviewed along with three other codes in the family for PE only at the April 2018 RUC meeting. The RUC did not recommend work RVUs for these codes and we are not proposing to change the current work RVUs.

For the direct PE inputs, we are proposing to remove the minimum multi-specialty visit pack (SA048) from CPT code 62370 as a duplicative supply due to the fact that this code is typically billed with an E/M or other evaluation service.

(25) Somatic Nerve Injection (CPT Codes 64400, 64408, 64415, 64416, 64417, 64420, 64421, 64425, 64430, 64435, 64445, 64446, 64447, 64448, 64449, and 64450)

In May 2018, the CPT Editorial Panel approved the revision of descriptors and guidelines for the codes in this family and the deletion of three CPT codes to clarify reporting (*i.e., separate reporting of imaging guidance, number of units and a change from a 0-day global to ZZZ for one of the CPT codes in this*

family). This family of services describe the injection of an anesthetic agent(s) and/or steroid into a nerve plexus, nerve, or branch; reported once per nerve plexus, nerve, or branch as described in the descriptor regardless of the number of injections performed along the nerve plexus, nerve, or branch described by the code.

CPT codes 64400 (*Injection(s), anesthetic agent(s); trigeminal nerve, each branch (ie ophthalmic, maxillary, mandibular)), 64408 (Injection(s), anesthetic agent(s), and/or steroid; vagus nerve*), 64415 (*Injection(s), anesthetic agent(s) and/or steroid; brachial plexus), 64416 (Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)*), 64417 (*Injection(s), anesthetic agent(s) and/or steroid; axillary nerve), 64420 (Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level*), 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerves, each additional level (List separately in addition to code for primary procedure*)), 64425 (*Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves*), 64430 (*Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve), 64435 (Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve*), 64445 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve*), 64446 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)*), 64447 (*Injection(s), anesthetic agent(s); femoral nerve*), 64448 (*Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement)*), 64449 (*Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)*), and 64450 (*Injection(s), anesthetic agent(s); other peripheral nerve or branch*) were reviewed for work and PE at the October 2018 RUC meeting. The PE for CPT code 64450 was re-reviewed during the RUC January 2019 meeting.

During the October 2018 RUC presentation for this family of services, the specialty societies stated that CPT codes 64415, 64416, 64417, 64446, 66447, and 64448 were reported with CPT code 76942 (*Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation)* more than 50 percent of the time. Specifically, 76 percent with CPT code 64415, 85 percent with CPT code 64416, 68 percent with CPT code 64417, 77 percent with CPT code 64446, 77 percent with CPT code 66447, and 79 percent with CPT code 64448. It was also noted in the RUC recommendations that this overlap was accounted for in the RUC recommendations submitted for these services. Furthermore, the RUC recommendations sated that the RUC referred CPT codes 64415, 64416, 64417, 64446, 64447 and 64448 to be bundled with ultrasound guidance, CPT code 76942 to the CPT Editorial Panel for CPT 2021.

In reviewing this family of services, our proposed work and PE values for CPT codes 64415, 64416, 64417, 64446, 64447 and 64448 do not consider the overlap of imaging as noted in the RUC recommendations. We note that the RUC recommendations did not include values to support the valuation for the bundling of imaging in their work or PE recommendations and that the CPT code descriptors do not state that imaging is included.

For CY 2020, we are proposing the RUC-recommended work RVUs for CPT codes 64417 (work RVU of 1.27), 64435 (work RVU of 0.75), 64447 (work RVU of 1.10), and 64450 (work RVU of 0.75), the RUC reaffirmed work RVU of 0.94 for CPT code 64405 (*Injection, anesthetic agent; greater occipital nerve*), which is the current work RVU finalized in the CY 2019 final rule (83 FR 59542), and the RUC reaffirmed work RVU of 1.10 for CPT code 64418 (*Injection, anesthetic agent; suprascapular nerve*), which is the current work RVU value finalized in the CY 2018 final rule (82 FR 53054). Although we are proposing the RUC reaffirmed work RVUs for these two codes, as submitted in the RUC recommendations, we note that comparable codes in this family of services have lower work RVUs. Thus, these two codes may have become misvalued since their last valuation, as they were not resurveyed under this code family during the October 2018 RUC meeting.

In continuing our review of this code family, we disagree with the RUC-recommended work RVU of 1.00 for CPT code 64400 and are proposing a work RVU of 0.75, to maintain rank order in this code family. Our proposed work RVU is based on a crosswalk to another code in this family, CPT code 64450, which has an identical work RVU of 0.75 and near identical intraservice and total time values to CPT code 64400.

We note that the RUC-recommended intraservice time decreased from 37 to 6 minutes (84 percent reduction) and the RUC-recommended total time decreased from 69 to 20 minutes (71 percent reduction) for CPT code 64400. However, the RUC-recommended work RVU only decreased by 0.11, a 10 percent reduction. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64400, we believe that it would be more accurate to propose a work RVU of .075 based on a crosswalk to CPT code 64450, which has an identical work RVU of 0.75 and near identical intraservice and total times to CPT code 64400. We further note that our proposed work RVU maintains rank order in this code family among comparable codes.

For CPT code 64408, we disagree with the RUC-recommended work RVU of 0.90 and are proposing a work RVU of 0.75, to maintain rank order in this code family. Our proposed work RVU is based on a crosswalk to another code in this family, CPT code 64450, which has an identical work RVU of 0.75, and near identical intraservice and total time values to CPT code 64408.

We note that the RUC-recommended intraservice time decreased from 16 to 5 minutes (69 percent reduction) and RUC-recommended total time decreased from 36 to 20 minutes (44 percent reduction) for CPT code 64408. Although the RUC-recommended work RVU decreased by 0.51, a 36 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64408, we believe that it would be more accurate to propose a work RVU of .075, based on a crosswalk CPT code 64450,

to account for these decrease in the surveyed work times. We further note that our proposed work RVU maintains rank order in this code family among comparable codes.

For CPT code 64415, we disagree with the RUC-recommended work RVU of 1.42 and are proposing a work RVU of 1.35, based on our time ratio methodology and further supported by a reference to CPT code 49450 (*Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injections(s), image documentation and report*), which has a work RVU of 1.36 and similar intraservice and total time values to CPT code 64415.

We note that the RUC-recommended intraservice time decreased from 15 to 12 minutes (20 percent reduction) and RUC-recommended total time decreased from 44 to 40 minutes (9 percent reduction). However, the RUC-recommended work RVU only decreased by 0.06, which is a 4 percent reduction. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64415, we believe that it would be more accurate to propose a work RVU of 1.35, based on our time ratio methodology and a reference to CPT code 49450, to account for these decrease in the surveyed work times.

For CPT code 64416, we disagree with the RUC-recommended work RVU of 1.81 and are proposing a work RVU of 1.48, based on our time ratio methodology and further supported by a bracket of CPT code 62270 (*Spinal puncture, lumbar, diagnostic*), which has a work RVU of 1.37, identical intraservice, and similar total time to CPT code 64416 and CPT code 91035 (*Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation*), which has a work RVU of 1.59, identical intraservice, and near identical total time values to CPT code 64416.

We note that while the RUC-recommended intraservice time remained unchanged, the RUC-recommended total time decreased from 60 to 49 minutes (18 percent reduction). However, the RUC recommended maintaining the current work RVU of 1.81. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed total time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64416, we believe that it would be more accurate to propose a work RVU of 1.48, based on our time ratios methodology and a bracket of CPT code 62270 and CPT code 91035, to account for these decreases in the surveyed work times.

For CPT code 64420, we disagree with the RUC-recommended work RVU of 1.18 and are proposing a work RVU of 1.08, based on our time ratio methodology and further supported by a reference to CPT code 12011 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less*), which has a work RVU of 1.07 and similar intraservice and total time values to CPT code 64420.

We note that the RUC-recommended intraservice time decreased from 17 to 10 minutes (41 percent reduction) and the RUC-recommended total time decreased from 37 to 34 minutes (8 percent reduction). However, the RUC recommended to maintaining the current work RVU of 1.18. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64420, we believe that it would be more accurate to propose a work RVU of 1.08 based on our times ratio methodology and a crosswalk to CPT code 12011, to account for these decreases in the surveyed work times.

For CPT code 64421, we disagree with the RUC-recommended work RVU of 0.60 and are proposing a work RVU of 0.50, based on our time ratio methodology and to maintain rank order among comparable codes in the family. Our proposed work RVU is further supported by a crosswalk to CPT code 15276 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)*), which has a work RVU of 0.50 and identical intraservice and total times to CPT code 64421.

We note that our time ratio methodology suggests the code is better valued at 0.50. Furthermore, the RUC-recommended work RVU of 0.60 creates a rank order anomaly in the code family. In the case of CPT code 64421, we believe that it would be more accurate to propose a work RVU of 0.50, based on our time ratio methodology and a crosswalk to CPT code 15276, to maintain rank order among comparable codes in the family.

For CPT code 64425, we disagree with the RUC-recommended work RVU of 1.19 and are proposing a work RVU of 1.00, to maintain rank order among comparable codes in the family, based on a bracket of CPT code 12001 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 2.5 cm or less*) which has a work RVU of 0.84 and near identical intraservice and total time values to CPT code 64425 and CPT code 30901 (*Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method*), which has a work RVU of 1.10 and near identical intraservice and total times to CPT code 64425.

We note that the RUC-recommended work RVU of 1.19 creates a rank order anomaly in the code family. In the case of CPT code 64425, we believe that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 12001 and 30901 to maintain rank order among comparable codes in the family.

For CPT code 64430, we disagree with the RUC-recommended work RVU of 1.15 and are proposing a work RVU of 1.00, to maintain rank order among comparable codes in the family, based on a bracket of CPT code 45330 (*Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*), which has a work RVU of 0.84 and near identical

intraservice and total time values to CPT code 64430 and CPT code 31576 (*Laryngoscopy, flexible; with biopsy(ies)*), which has a work RVU of 1.89 and near identical intraservice and total time values to CPT code 64430.

We note that the RUC-recommended intraservice time decreased from 17 to 10 minutes (41 percent reduction) and the RUC-recommended total time increased from 39 to 43 minutes (10 percent increase). While the RUC-recommended work RVU is decreasing by 0.31, a 21 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64430, we believe that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 45300 and 31576 to account for these decreases in surveyed work times and to maintain rank order among comparable codes in this family.

For CPT code 64445, we disagree with the RUC-recommended work RVU of 1.18 and are proposing a work RVU of 1.00, based on our time ratio methodology and to maintain rank order among comparable codes in the family. Our proposed work RVU is based on a bracket of CPT code 12001 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 2.5 cm or less*), which has a work RVU of 0.84 and near identical intraservice and total times to CPT code 64445 and CPT code 30901 (*Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method*), which has a work RVU of 1.10 and near identical intraservice and total time values to CPT code 64445.

We note that the RUC-recommended intraservice time decreased from 15 to 10 minutes (33 percent reduction) and the RUC-recommended total time decreased from 48 to 24 minutes (50 percent reduction). While the RUC-recommended work RVU is decreasing by 0.30, a 21 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64445, we believe that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 12001 and 30901 to account for these decreases in surveyed work times and to maintain rank order among comparable codes in the family.

For CPT code 64446, we disagree with the RUC-recommended work RVU of 1.54 and are proposing a work RVU of 1.36 based on our time ratios methodology and further supported by a reference to CPT code 51710 (*Change of cystostomy tube; complicated*), which has a near identical work RVU of 1.35 and near identical intraservice and total time values to CPT code 64446.

We note that RUC-recommended intraservice time decreased from 20 to 15 minutes (25 percent reduction) and the RUC-recommended total time decreased from 64 to 40 minutes (38 percent reduction). While the RUC-recommended work RVU is decreasing by 0.27, a 15 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64446, we believe that it would be more accurate to propose a work RVU of 1.36, based on our time ratios methodology and a reference to CPT code 51710 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For CPT code 64448, we disagree with the RUC-recommended work RVU of 1.55 and are proposing a work RVU of 1.41, based our time ratio methodology and a reference to CPT code 27096 (*Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed*), which has a work RVU of 1.48 and near identical intraservice time and identical total time values to CPT code 64448.

We note that RUC-recommended intraservice time decreased from 15 to 13 minutes (13 percent reduction) and the RUC-recommended total time decreased from 55 to 38 minutes (62 percent reduction). While the RUC-recommended work RVU is only decreasing by 0.08, which is only a 5 percent reduction. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64448, we believe that it would be more accurate to propose a work RVU of 1.41, based on our time ratios methodology and a crosswalk to CPT code 27096 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For CPT code 64449, we disagree with the RUC-recommended work RVU of 1.55 and are proposing a work RVU of 1.27, based our time ratio methodology and a reference to CPT code 11755 (*Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)*), which has a work RVU of 1.25 and near identical intraservice and total times to CPT code 64449.

We note that RUC-recommended intraservice time decreased from 20 to 14 minutes (30 percent reduction) and the RUC-recommended total time decreased from 60 to 38 minutes (37 percent reduction). While the RUC-recommended work RVU is decreasing by 0.26, a 14 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to

work RVUs. In the case of CPT code 64449, we believe that it would be more accurate to propose a work RVU of 1.27, based on our time ratios methodology and a reference to CPT code 11755 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For the direct PE inputs, we are proposing to remove the clinical labor time for the ''Confirm availability of prior images/studies'' (CA006) activity for CPT code 64450. This code does not currently include this clinical labor time, and unlike the new code, CPT code 64XX1, in the Genicular Injection and RFA code family, in which the PE for CPT code 64450 was resurveyed at the January 2019 RUC for PE, CPT code 64450 does not include imaging guidance in its code descriptor. When CPT code 64450 is performed with imaging guidance, it would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images. As a result, it would be duplicative to include this clinical labor time in CPT code 64450. We are also proposing to refine the clinical labor time for the ''*Assist physician or other qualified healthcare professional—directly related to physician work time (100 percent)*'' (CA018) activity from 10 to 5 minutes for CPT code 64450, to match the intraservice work time and proposing to refine the equipment times in accordance with our standard equipment time formulas for CPT code 64450.

Additionally, we are proposing to refine the clinical labor time for the ''provide education/obtain consent'' (CA011) from 3 minutes to 2 minutes, for CPT codes 64400, 64408, 64415, 64417, 64420, 64425, 64430, 64435, 64445, 64447 and 64450, to conform to the standard for this clinical labor task. We are also proposing to refine the equipment time in accordance with our standard equipment time formula for these codes. We note that there were no RUC-recommended direct PE inputs provided for CPT codes 64416, 64446, and 64448.

(26) Genicular Injection and RFA (CPT Codes 64640, 64XX0, and 64XX1)

In May 2018, the CPT Editorial Panel approved the addition of two codes to report injection of anesthetic and destruction of genicular nerves by neurolytic agent. In October 2018, the RUC discussed the issues surrounding the survey of this family of services and supported the specialty societies' request for CPT codes 64640 (*Destruction by neurolytic agent; other peripheral nerve or branch*), 64XX0 (*Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches including imaging guidance, when performed*), and 64XX1 (*Destruction by neurolytic agent genicular nerve branches including imaging guidance, when performed*) to be resurveyed and presented at the January 2019 RUC meeting, based on their concern that many survey respondents appeared to be confused about the number of nerve branch injections involved with these three codes. The RUC resurveyed these services at the January 2019 RUC meeting.

For CY 2020, we are proposing the RUC-recommended work RVUs for two of the three codes in this family. We are proposing the RUC-recommended work RVU of 1.98 (25th percentile survey value) for CPT code 64640 and the RUC-recommended work RVU of 1.52 (25th percentile survey value) for CPT code of 64XX0.

For CPT code 64XX1, we disagree with the RUC-recommended work RVU of 2.62, which is higher than the 25th percentile survey value, a work RVU 2.50, and are proposing a work RVU of 2.50 (25th percentile survey value) based on a reference to CPT code 11622 (*Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 1.1 to 2.0 cm*), which has a work RVU of 2.41 and near identical intraservice and total times to CPT code 64XX1.

In our review of CPT code 64XX1, we examined the intraservice time ratio for the new code, CPT code 64XX1, in relation to an existing code in this family of services, CPT code 64640. CPT code 64XX1 has a RUC-recommended work RVU of 2.62, 25 minutes of intraservice time, and 74 minutes of total time. CPT code 64640 has a RUC-recommended work RVU of 1.98, 20 minutes of intraservice time, and 64 minutes of total time. To derive our proposed work RVU of 2.50, we calculated the intraservice time ratio between these two codes, which is a calculated value of 1.25, and applied this ratio times the RUC-recommended work RVU of 1.98 for CPT code 64650, which resulted in a calculated value of 2.48. This value is nearly identical to the January 2018 RUC 25th percentile survey value for CPT code 64XX1, a work RVU of 2.50. Our proposed work RVU of 2.50 is further supported by a reference to CPT code 11622.

For the direct PE inputs, we are proposing to remove the clinical labor time for the ''Confirm availability of prior images/studies'' (CA006) activity for CPT code 64640. This code does not currently include this clinical labor time, and unlike the new code in the family (CPT code 64XX1), CPT code 64640 does not include imaging guidance in its code descriptor. When CPT code 64640 is performed with imaging guidance, it would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images. As a result, it would be duplicative to include this clinical labor time in CPT code 64640. We are proposing to refine the clinical labor time for the ''Assist physician or other qualified healthcare professional—directly related to physician work time (100 percent)'' (CA018) activity from 25 to 20 minutes for CPT code 64640, to match the intraservice work time. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas for CPT code 64640.

We are proposing the RUC-recommended direct PE inputs for CPT code 64XX0 without refinement.

For CPT code 64XX1, we are proposing to refine the quantity of the ''cannula (radiofrequency denervation) (SMK–C10)'' (SD011) supply from 3 to 1. We do not believe that the use of 3 of this supply item would be typical for the procedure. We note that the RUC recommendations for another code in this family, CPT code 64640 only contains 1 of this supply item. We believe that the nerves would typically be ablated one at a time using this cannula, as opposed to ablating three of them simultaneously as suggested in the recommended direct PE inputs. We also searched in the RUC database for other CPT codes that made use of the SD011 supply, and out of the seven codes that currently use this item, none of them include more than 2 cannula. As a result, we are proposing to refine the supply quantity to 2 cannula to match the highest amount contained in an existing code on the PFS. We are also refining the equipment time for the ''radiofrequency kit for destruction by neurolytic agent'' (EQ354) equipment from 141 minutes to 47 minutes. The equipment time recommendation was predicated on the use of 3 of the SD011 supplies for 47 minutes apiece, and we are refining the equipment time to reflect our supply refinement to 1 cannula. It was unclear in the RUC recommendation materials as to whether the radiofrequency kit equipment was in use simultaneously or sequentially along with the cannula supplies, and therefore, we are soliciting comments on the typical use of this equipment.

(27) Cyclophotocoagulation (CPT Codes 66711, 66982, 66983, 66984, 66X01, and 66X02)

In October 2017, CPT codes 66711 (*Ciliary body destruction; cyclophotocoagulation, endoscopic*) and 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification*) were identified as codes reported together 75 percent of the time or more. The RUC reviewed action plans to determine whether a code bundle solution should be developed for these services. In January 2018, the RUC recommended to refer to CPT to bundle 66711 with 66984 for CPT 2020. In May 2018, the CPT Editorial Panel revised three codes and created two new codes, CPT codes 66X01 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation*) and 66X02 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation*) to differentiate cataract procedures performed with and without endoscopic cyclophotocoagulation.

The codes discussed above and CPT codes 66982 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage*) and 66983 *(Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)*) were reviewed at the January 2019 RUC meeting.

For CY 2020, we are proposing the RUC-recommended work RVU of 10.25 for CPT code 66982, the RUC recommendation to contractor-price CPT code 66983, and the RUC-recommended work RVU of 7.35 for CPT code 66984. We disagree with the RUC recommendations for CPT codes 66711, 66X01, and 66X02.

For CPT code 66711, we disagree with the RUC-recommended work RVU of 6.36 and are proposing a work RVU of 5.62, based on crosswalk to CPT code 28285 (*Correction, hammertoe (e.g., interphalangeal fusion, partial or total phalangectomy*), which has an identical work RVU of 5.62, and similar intraservice and total times.

In our review of CPT code 66711, we note that the recommended intraservice time is decreasing from 20 minutes to 10 minutes (33 percent reduction), and that the recommended total time is decreasing from 192 minutes to 191 minutes (0.5 percent reduction). While the RUC-recommended work RVU is decreasing from 7.93 to 6.36, which is a 20 percent reduction, we do not believe it appropriately accounts for the decreases in survey time. Time ratio methodology suggest that CPT code 66711 is better valued at a work RVU of 5.29, thus it is overvalued with consideration to the decreases in survey times. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 66711, we believe that it would be more accurate to propose a work RVU of 5.62, based on our time ratio methodology and a crosswalk to CPT code 28285 to account for these decreases in surveyed work times.

For CPT code 66X01, the RUC recommended a work RVU of 13.15, we disagree with the RUC-recommended work RVU and are proposing contractor-pricing for this code. In reviewing this code, we note that the RUC recommendation survey values do not support the RUC-recommended work RVU of 13.15 and furthermore, the RUC recommendations do not include a crosswalk to support the RUC-recommended work RVU. The RUC recommendations noted a lack of potential crosswalk codes due to the complete lack of similarly intense major surgical procedures comparable in the amount of skin-to-skin time, operating room time and amount of post-operative care. We note that the RUC-recommended work RVU of 13.15 is higher than similarly timed codes on the PFS. Given that lack of both survey data and a crosswalk to support the RUC-recommended work RVU for this new code, and that the RUC-recommended work RVU of 13.15 is higher than similarly timed codes on the PFS, we believe it is more appropriate to propose contractor-pricing for CPT code 66X01. We also note that the RUC recommended contractor-pricing for another code in this family, CPT code 66983, which we are proposing for CY 2020.

For CPT code 66X02, the RUC recommended a work RVU of 10.25, we disagree with the RUC-recommended work RVU and are proposing contractor-pricing for this code. In reviewing this code, we note that the RUC recommendation survey values do not support the RUC-recommended work RVU of 10.25. Furthermore, we are concerned with the RUC recommended crosswalk, CPT code 67110 (*Repair of retinal detachment; by injection of air or other gas (e.g., pneumatic retinopexy)*, which is the same crosswalk used to support the RUC-recommended work RVU of 10.25 for another code in this family, CPT code 66982. CPT code 67110 has 30 minutes of intraservice time and 196 minutes of total time. Although CPT code 67110 has the identical intraservice time to CPT codes 66982 and 66X02, we note that CPT code 67110 has 196 minutes of total time, which is 21 minutes less than the 175 minutes of total time of CPT code 66982, and 6 minutes less than the 202 minutes of total time of CPT Code 66X02. However, the RUC is recommending the same work RVU of 10.25 for CPT codes 66982 and 66X02, supported by the same crosswalk to CPT code 67110.

Given that lack of survey data and our concern for the RUC-recommended crosswalk to support the RUC-recommended work RVU of 10.25 for CPT code 66X02, we believe it is appropriate to propose contractor-pricing for CPT code 66X02. We also note that the RUC recommended contractor-pricing for another code in this family, CPT code 66983, which we are prosing for CY 2020.

We are proposing to remove all the direct PE inputs for CPT codes 66X01 and 66X02, given our proposal for contractor-pricing for these codes. We are proposing the RUC-recommended direct PE inputs for the other codes in this family.

(28) X-Ray Exam—Sinuses (CPT Codes 70210 and 70220)

CPT code 70210 (*Radiologic examination, sinuses, paranasal, less than 3 views*) and CPT code 70220 (*Radiologic examination, sinuses, paranasal, complete, minimum of 3 views*) were identified as potentially misvalued through a screen for

Medicare services with utilization of 30,000 or more annually. These two codes were first reviewed by the RUC in April 2018, but were subsequently surveyed by the specialty societies and reviewed again by the RUC in January 2019.

The RUC recommended a work RVU for CPT code 70210 of 0.20, which is a slight increase over the current work RVU for this code (0.17). The RUC's recommendation is consistent with 25th percentile of survey results and is based on a comparison of the survey code with the two key reference services. The first key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*), has a work RVU of 0.22, 4 minutes of intraservice time, and 6 minutes of total time. The RUC noted that the survey code has one minute less intraservice and total time compared with the first key reference service (CPT code 71046), which accounts for the slightly lower work RVU for the survey code. The RUC also compared CPT code 70210 to CPT code 70355 (*Orthopantogram (e.g., panoramic X-ray)*), with a work RVU of 0.20, 5 minutes of intraservice time, and 6 minutes of total time. Although the intraservice and total times are lower for CPT code 70210 than for CPT code 70355, the work is slightly more intense for the survey code, according to the RUC, justifying an identical work RVU of 0.20 for CPT code 70210. We disagree with the RUC's recommendation to increase the work RVU for CPT code 70210 from the current value (0.17) to 0.20 for two main reasons. First, the total time (5 minutes) for this code has not changed from the current total time and without a corresponding explanation for an increase in valuation despite maintaining the same total time, we do are not convinced that the work RVU for this code should increase. In addition, we note that based on a general comparison of CPT codes with identical intraservice time and total time (approximately 23 comparison codes, excluding those currently under review), a work RVU of 0.20 would establish a new upper threshold among this cohort. We are proposing to maintain the work RVU for CPT code 70210 of 0.17 work RVUs, bracketed by two services. On the upper side, we identified CPT code 73501 (*Radiologic examination, hip, unilateral, with pelvis when performed; 1 view*) with a work RVU of 0.18, and on the lower side, we identified CPT code 73560 (*Radiologic examination, knee; 1 or 2 views*) with a work RVU of 0.16. For CPT code 70220, we are proposing the RUC-recommended work RVU of 0.22.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(29) X-Ray Exam—Skull (CPT Codes 70250 and 70260)

CPT code 70250 (*Radiologic examination, skull, less than 4 views*) was identified as potentially misvalued through a screen of Medicare services with utilization of 30,000 or more annually. CPT code 70260 (*Radiologic examination, skull; complete, minimum of 4 views*) was included as part of the same family. These two codes were first reviewed by the RUC in April 2018, but were subsequently surveyed by the specialty societies and reviewed by the RUC again in January 2019.

The RUC-recommended work RVU for CPT code 70250 is 0.20, which is a slight decrease from the current work RVU for this code (0.24). The decrease, according to the RUC, reflects a slightly lower total time required to furnish the service (from 7 minutes to 5 minutes) and is consistent with the 25th percentile work RVU from the survey results. The RUC-recommended work RVU is bracketed by two CPT codes: Top key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*) with 4 minutes of intraservice time, 6 minutes total time, and a work RVU of 0.22; and key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*), with intraservice time of 4 minutes, total time of 6 minutes, and a work RVU of 0.18. The RUC noted that while the survey code has less time than CPT code 71046, the work is slightly more intense due to anatomical and contextual complexity. The survey code is also more intense compared with the second key reference service, CPT code 73562, according to the RUC, because of the higher level of technical skill involved in an X-ray of the skull (axial skeleton) compared with an X-ray of the knee (appendicular skeleton). The RUC further indicated that a comparison between the survey code and CPT codes with a work RVU of 0.18 would not be appropriate given the higher level of complexity associated with an X-ray of the skull than with other CPT codes that have similar times. We disagree with the recommended work RVU of 0.20 for CPT code 70250. The total time for furnishing the service has decreased by 2 minutes while the description of the work involved in furnishing the service has not changed. This suggests that a value closer to the total time ratio (TTR) calculation (0.17 work RVU) might be more appropriate. In addition, a search of CPT codes with 3 minutes of intraservice time and 5 minutes of total time indicates that the maximum work RVU for codes with these times is 0.18, meaning that a work RVU of 0.20 would establish a new relative high work RVU for codes with these times. We believe that a crosswalk to CPT code 73501 (*Radiologic examination, hip, unilateral, with pelvis when performed; 1 view*) with a work RVU of 0.18, 3 minutes of intraservice time, and 5 minutes of total time, accurately reflects both the time and intensity of furnishing the service described by CPT code 70250. Therefore, we are proposing a work RVU of 0.18 for CPT code 70250.

The RUC recommended a work RVU of 0.29 for CPT code 70260, which is lower than the current work RVU of 0.34. The survey times for furnishing the service are 4 minutes of intraservice time and 7 minutes total time, compared with the current intraservice time and total time of 7 minutes. However, in developing their recommendation, the RUC reduced the total time for this code from 7 minutes to 6 minutes. Although the RUC's recommended work RVU reflects the 25th percentile of survey results, the survey 25th percentile is based on an additional minute of total time compared with the RUC's total time for this CPT code. Moreover, since we are proposing a lower work RVU for the base code for this family (work RVU of 0.18 for CPT code 70250), we believe a lower work RVU for CPT code 70260 is warranted. To identify an alternative value, we calculated the increment between the current work RVU for CPT code 72050 (work RVU of 0.24) and the current work RVU for CPT code 72060 (work RVU of 0.34) and applied it to the CMS proposed work RVU for CPT code 70250 (0.18 + 0.10) to calculate a work RVU of 0.28. We believe that applying this increment is a better reflection of the work time and intensity involved in furnishing CPT code 70260. We are proposing a work RVU for CPT code 70260 of 0.28.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(30) X-Ray Exam—Neck (CPT Code 70360)

CPT code 70360 (*Radiologic examination; neck, soft tissue*) was identified as potentially misvalued through a screen of CPT codes with annual Medicare utilization of 30,000 or more. CPT code 70360 was first reviewed by the RUC in April 2018 but was subsequently surveyed by the specialty societies and reviewed by the RUC again in January 2019.

The RUC recommended a work RVU of 0.20 for CPT code 70360, which is an increase over the current work RVU

(0.17). To support their recommendation, the RUC cited the survey key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*), with a work RVU of 0.22, 4 minutes of intraservice time, and 6 minutes of total time. They noted that the key reference code has one minute higher intraservice and total time, accounting for the slightly higher work RVU compared with the survey code, CPT code 70360. The RUC also cited the second highest key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*) with a work RVU of 0.18, intraservice time of 4 minutes, and total time of 6 minutes. They noted that, while the survey code has lower intraservice time (3 minutes) and total time (5 minutes) compared with CPT code 73562, the survey code is more complex than the key reference service, thereby supporting a higher work RVU for the survey code (CPT code 70360) of 0.20. We do not agree with the RUC that the work RVU for CPT code 70360 should increase from 0.17 to 0.20. The total time for the CPT code, as recommended by the RUC (5 minutes), is unchanged from the existing total time. Without a corresponding discussion of why the current work RVU is insufficient, we do not agree that there should be an increase in the work RVU. Furthermore, although the RUC's recommendation is consistent with the 25th percentile of survey results for the work RVU, the total time from the survey results was 6 minutes, not the RUC-recommended time of 5 minutes. When we looked at CPT codes with identical times to the survey code for a crosswalk, we identified CPT code 73552 (*Radiologic examination, femur; minimum 2 views*), with a work RVU of 0.18. We believe this is a more appropriate valuation for CPT code 70360 and we are proposing a work RVU for this CPT code of 0.18.

We are proposing the RUC-recommended direct PE inputs for CPT code 70360.

(31) X-Ray Exam—Spine (CPT Codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120)

CPT codes 72020 (*Radiologic examination spine, single view, specify level*) *and 72072* (*Radiologic examination, spine; thoracic, 3 views*) were identified through a screen of CMS/Other Source codes with Medicare utilization greater than 100,000 services annually. The code family was expanded to include 10 additional CPT codes to be reviewed together as a group: CPT code 72040 (*Radiologic examination, spine, cervical; 2 or 3 views*), CPT code 72050 (*Radiologic examination, spine, cervical; 4 or 5 views*), CPT code 72052 (*Radiologic examination, spine cervical; 6 or more views*), CPT code 72070 (*Radiologic examination spine; thoracic, 2 views*), CPT code 72074 (*Radiologic examination, spine; thoracic, minimum of 4 views*), CPT code 72080 (*Radiologic examination, spine; thoracolumbar junction, minimum of 2 views*), CPT code 72100 (*Radiologic examination, spine, lumbosacral; 2 or 3 views*), CPT code 72110 (*Radiologic examination, spine, lumbosacral; minimum of 4 views*), CPT code 72114 (*Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views*), and CPT code 72120 (*Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views*). This family of CPT codes was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey these codes and the RUC reviewed them again in January 2019.

For the majority of CPT codes in this family, the RUC recommended a work RVU that is slightly different (higher or lower) than the current work RVU. Three CPT codes in this family are maintaining the current work RVU. We are proposing the RUC-recommended work RVU for all 12 CPT codes in this family as follows: CPT code 72020 (work RVU = 0.16); CPT code 72040 (work RVU = 0.22); CPT code 72050 (work RVU = 0.27); CPT code 72052 (work RVU = 0.30); CPT code 72070 (work RVU = 0.20); CPT code 72072 (work RVU = 0.23); CPT code 72074 (work RVU = 0.25); 72080 (work RVU = 0.21); CPT code 72100 (work RVU = 0.22); CPT code 72110 (work RVU =0.26); CPT code 72114 (work RVU = 0.30); and CPT code 72120 (work RVU = 0.22).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(32) CT-Orbit-Ear-Fossa (CPT Codes 70480, 70481, and 70482)

In October 2017, the RAW requested that AMA staff develop a list of CMS/Other codes with Medicare utilization of 30,000 or more. CPT code 70480 (*Computed tomography (CT), orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material*) was identified. In addition, the code family was expanded to include two related CT codes, CPT code 70481 (*Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material*) and CPT code 70482 (*Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material followed by contrast material(s) and further sections*). In 2018, the RUC recommended this code family be surveyed.

For CPT code 70840, we disagree with the RUC-recommended work RVU of 1.28 and propose instead a work RVU of 1.13. We are proposing a lower work RVU because 1.13 represents the commensurate 12 percent decrease in work time reflected in survey values. We reference the work RVUs of CPT codes 72128 (*Computed tomography, chest, spine; without dye*) and 71250 (*Computed tomography, thorax without dye*) both of which have the same intraservice time (that is, 15 minutes) as CPT code 70840 but longer total times (that is, 25 minutes versus 22 minutes). We believe that CPT code 72128 with a work RVU of 1.0 and CPT code 71250 with a work RVU of 1.16 more accurately reflect the relative work values of CPT code 70840.

We also disagree with the RUC-recommended work RVU of 1.13 for CPT code 70481. Instead, we are proposing a work RVU of 1.06 for CPT code 70481. As with CPT code 70840, we are proposing a lower work RVU for CPT code 70481 because a work RVU of 1.06 is commensurate with the 23 percent decrease in surveyed total time from 26 to 20 minutes. We believe CPT code 76641 (*Ultrasound, breast, unilateral*) with a work RVU of 0.73 and CPT code 70460 (*Computed Tomography, head or brain, without contrast*) with a work RVU of 1.13 serve as appropriate references for our proposed work RVU for CPT code 70841. Although CPT codes 76641 and 70460 have longer total times at 22 minutes and lower intraservice times at 12 minutes, we believe they better reflect the relative work value of CPT code 70481 with a proposed work RVU of 1.06, total time of 20 minutes, and intraservice time of 13 minutes.

For the third code in the family, CPT code 70482, we are proposing the RUC-recommended work RVU of 1.27.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(33) CT Spine (CPT Codes 72125, 72126, 72127, 72128, 72129, 72130, 72131, 72132, and 72133)

CPT code 72132 (*Computed tomography, lumbar spine; with contrast material*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare

utilization of 30,000 or more. Eight other spine CT codes were identified as part of the family, and they were surveyed and reviewed together at the April 2018 RUC meeting.

We are proposing the RUC-recommended work RVU for eight of the nine codes in the family. We are proposing a work RVU of 1.22 for CPT code 72126 (*Computed tomography, cervical spine; with contrast material*), a work RVU of 1.27 for CPT code 72127 (*Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections*), a work RVU of 1.00 for CPT code 72128 (*Computed tomography, thoracic spine; without contrast material*), a work RVU of 1.22 for CPT code 72129 (*Computed tomography, thoracic spine; with contrast material*), a work RVU of 1.27 for CPT code 72130 (*Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections*), a work RVU of 1.00 for CPT code 72131 (*Computed tomography, lumbar spine; without contrast material*), a work RVU of 1.22 for CPT code 72132 (*Computed tomography, lumbar spine; with contrast material*), and a work RVU of 1.27 for CPT code 72133 (*Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections*).

We disagree with the RUC-recommended work RVU of 1.07 for CPT code 72125 (*Computed tomography, cervical spine; without contrast material*) and we are proposing a work RVU of 1.00 to match the other without contrast codes in the family. The cervical spine CT procedure described by CPT code 72125 shares the identical surveyed work time as the thoracic spine CT procedure described by CPT code 72128 and the lumbar spine CT procedure described by CPT code 72131, and we believe that this indicates that these three CPT codes should share the same work RVU of 1.00. Our proposed work RVU would also match the pattern established by the rest of the codes in this family, in which the contrast procedures (CPT codes 72126, 72129, and 72132) share a proposed work RVU of 1.22 and the without/with contrast procedures (CPT codes 72127, 72130, and 72133) share a proposed work RVU of 1.27.

We recognize that the RUC has stated that they believe CPT code 72125 to be a more complex study than CPT codes 72128 and 72131 because the cervical spine is subject to an increased number of injuries and there are a larger number of articulations to evaluate. This was the basis for their recommendation that this code should be valued slightly higher than the other without contrast codes. However, if CPT code 72125 has a more difficult patient population and requires a larger number of articulations to evaluate as compared to CPT codes 72128 and 72131, we do not understand why this was not reflected in the surveyed work times, which were identical for the three procedures. We believe that if the intensity of the procedure were higher due to these additional difficulties, it would be reflected in a longer surveyed work time. In addition, the survey respondents selected a higher work RVU for CPT code 72131 than CPT code 72125 at both the survey 25th percentile (1.20 to 1.18) and survey median values (1.39 to 1.28), which does not suggest that CPT code 72125 should be valued at a higher rate.

We also note that the surveyed intraservice work time for CPT code 72125 is decreasing from 15 minutes to 12 minutes, and we believe that this provides additional support for a slight reduction in the work RVU to match the other without contrast codes in the family. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of prior work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(34) X-Ray Exam—Pelvis (CPT Codes 72170 and 72190)

CPT code 72190 (*Radiologic examination, pelvis; complete, minimum of 3 views*) was identified as potentially misvalued through a screen of CMS/Other codes with Medicare utilization of 30,000 or more annually. CPT code 72170 (*Radiologic examination, pelvis; 1 or 2 views*) was added as part of the family. The RUC originally reviewed these two codes after specialty societies employed a crosswalk methodology to value work and PE. However, after we expressed concern about the use of this approach, the specialty society agreed to survey the codes and the RUC reviewed them again at the meeting in January 2019.

The RUC recommended a work RVU of 0.17 for CPT code 72170, which maintains the current value. For CPT code 72190, the RUC recommended a work RVU of 0.25, which is slightly higher than the current value (0.21). We are proposing the RUC-recommended values for these two CPT codes.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(35) X-Ray Exam—Sacrum (CPT Codes 72200, 72202, and 72220)

CPT code 72220 (*Radiologic examination, sacrum and coccyx, minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 annually. CPT codes 72200 (*Radiologic examination, sacroiliac joints; less than 3 views*) and 72202 (*Radiologic examination, sacroiliac joints; 3 or more views*) were also included for review as part of the same family of codes. These three codes were originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey these codes and the RUC reviewed them again in January 2019.

For CPT code 72200, the RUC is recommending a work RVU of 0.20, which is higher than the current work RVU (0.17). To support their recommendation, the RUC compared the survey code to the key reference service, CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views*), with a work RVU of 0.29, 5 minutes of intraservice time and 7 minutes of total time. The intraservice and total times for the key reference service are one minute higher than the survey code (*4 minutes intraservice time, 6 minutes total time for CPT code 72200*) and the survey code is less intense, according to the RUC, thereby supporting a slightly lower work RVU of 0.20 for CPT code 72200. The second key reference service is CPT code 73562 (*Radiologic examination, knee; 3 views*), with 4 minutes of intraservice time, 6 minutes of total time, and a work RVU of 0.18. The RUC noted that this second key reference service is less intense to furnish than the survey code, which justifies a slightly lower work RVU despite identical intraservice time (4 minutes) and total time (6 minutes). The

RUC supported their recommendation of a work RVU for CPT code 72200 of 0.20 with two bracketing codes: CPT code 93042 (*Rhythm ECG, 1–3 leads; interpretation and report only*) with work RVU of 0.15, and CPT code 70355 (*Orthopantogram (e.g. panoramic x-ray)*) with a work RVU of 0.20 (which is identical to the RUC-recommended work RVU for CPT code 72200 but has one additional minute of intraservice time). A work RVU of 0.20 is consistent with the work RVU estimated by the TTR and reflects the 25th percentile of survey results. Nevertheless, we do not agree that there is sufficient justification for an increase in work RVU for CPT code 72200. We are concerned that the large variation in specialty societies' survey times is indicative of differences in patient population, practice workflow, or even possibly some ambiguity associated with the survey vignette. We also note that the 25th percentile of survey results are based on the overall survey total time, which is 8 minutes, rather than the RUC's recommended 6 minutes. The time parameters for furnishing the service affect all other points of comparison for purpose of valuing the code, including TTR, identification of potential crosswalks, and increment calculations. We found no corresponding explanation for the variability in survey times, leading us to question why there should be an increase in work RVU from the current value. Therefore, we are proposing to maintain the current work RVU for CPT code 72200 at 0.17.

For CPT code 72202, the RUC recommended a work RVU of 0.26, which is considerably higher than the current work RUV for this code of 0.19. The RUC supported their recommendation with two key reference services. The first is CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views*) with 5 minutes intraservice time, 7 minutes total time, and a work RVU of 0.29. They note that this code has an additional minute for intraservice and total time compared with the survey code, reflecting the additional views associated with evaluating bilateral hip joints. The second key reference service is CPT code 73562 (*Radiologic examination, knee; 3 views*) with 4 minutes intraservice time, 6 minutes total time, and a work RVU of 0.18. The RUC notes that the survey code has the same times but requires more intensity and includes an additional view compared with the reference service, which justifies a higher work RVU for the survey code. We disagree with the RUC's recommended work RVU for CPT code 72202. Given that there is no change in the total time required to furnish the service and there is no corresponding description of an increase in the intensity of the work relative to the existing value, we do not believe an increase of 0.07 work RVUs is warranted. The TTR calculation yields a work RVU of .019, suggesting that a value closer to the current work RVU would be more appropriate. In addition, since we consider the RUC-recommended work RVU for this code as an incremental change from the prior code in this family, we believe that an increase of 0.06 over the proposed work RVU of 0.18 for CPT code 72200, which yields a work RVU of 0.23, is a better reflection of the time and intensity required to furnish CPT code 72202. Our proposed value work RVU of 0.23 is bracketed by CPT code 73521 (*Radiologic examination, hips, bilateral, with pelvis when performed; 2 views*) on the lower end (work RVU = .22), and CPT code 74021 (*Radiologic examination, abdomen; 3 or more views*), on the higher end (work RVU = 0.27). CPT code 73521 has the same times as the survey code but describes a bilateral service with 2 views, which is slightly less intense. CPT code 74021 also has identical times but involves X-ray of the abdomen with 3 views, a slightly higher intensity than the survey code.

The RUC-recommended work RVU for CPT code 72220 is 0.20, which reflects an increase over the current work RVU for this code (0.17). The key reference service from the survey results is CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed, 2–4 views*), with a work RVU of 0.29, 5 minutes intraservice time, and 7 minutes total time. The RUC noted that the recommended work RVU for CPT code 72220 has a lower value than the top key reference code (CPT code 73522) because of the shorter time and lower intensity involved in furnishing the survey code. The second highest key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*) has a work RVU of 0.18 with 4 minutes of intraservice time and 6 minutes of total time. The RUC notes that this second key reference service has a lower work RVU than the survey code despite having a slightly higher intraservice time and total time because it involves an X-ray of just one knee. We disagree with the RUC's recommended increase in the work RVU for CPT code 72220 from 0.17 to 0.20. We note that there is no change in the total time required to furnish the service. We also note that a work RVU of 0.20 for CPT code 72220 would place it near the maximum work RVU for CPT codes with identical intraservice time (3 minutes) and total time (5 minutes). Instead, we are proposing to maintain the work RVU for this service at 0.17, which is consistent with our proposal to maintain the current work RVU for CPT code 72200 at 0.17 as well.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(36) X-Ray Exam—Clavicle-Shoulder (CPT Codes 73000, 73010, 73020, 73030, and 73050)

CPT code 73030 (*Radiologic examination, shoulder; complete, minimum of 2 views*) was identified as potentially misvalued through a screen of services with more than 100,000 utilization annually. CPT codes 73000 (*Radiologic examination; clavicle, complete), 73010 (Radiologic examination; scapula, complete*), 73020 (*Radiologic examination, shoulder; 1 view*), and 73050 (*Radiologic examination, acromioclavicular joints, bilateral, with or without weighted distraction*) were included for review as part of the same family. We are proposing the RUC-recommended work RVUs for all five codes in this family as follows: CPT code 73000 (work RVU = 0.16); CPT code 73010 (work RVU = 0.17); CPT code 73020 (work RVU = 0.15); CPT code 73030 (work RVU = 0.18); and CPT code 73050 (work RVU = 0.18).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(37) CT Lower Extremity (CPT Codes 73700, 73701, and 73702)

CPT code 73701 (*Computed tomography, lower extremity; with contrast material(s)*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. Two other lower extremity CT codes were identified as part of the family, and they were surveyed and reviewed together at the April 2018 RUC meeting.

We are proposing the RUC-recommended work RVU for all three codes in this family. We are proposing a work RVU of 1.00 for CPT code 73700 (*Computed tomography, lower extremity; without contrast material*), a work RVU of 1.16 for CPT code 73701 (*Computed tomography, lower extremity; with contrast material(s)*), and a work RVU of 1.22 for CPT code 73702 (*Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further sections*).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(38) X-Ray Elbow-Forearm (CPT Codes 73070, 73080, and 73090)

CPT codes 73070 (*Radiologic examination, elbow; 2 views*) and 73090 (*Radiologic examination; forearm, 2 views*) were identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73080 (*Radiologic examination, elbow; complete, minimum of 3 views*) was included for review as part of the same code family. All three CPT codes in this family were originally valued by the specialty societies using a crosswalk methodology approved by the RUC research committee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the codes and the RUC reviewed them again at the meeting in January 2019. We are proposing the RUC-recommended work RVU for all three codes in this family as follows: CPT code 73070 (work RVU = 0. 16); CPT code 73080 (work RVU = 0.17); and CPT code 73090 (work RVU = 0.16).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(39) X-Ray Heel (CPT Code 73650)

CPT code 73650 (*Radiologic examination; calcaneous, minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73650 was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the code and the RUC reviewed it again in January 2019. For CPT code 73650, we are proposing the RUC-recommended work RVU of 0.16. We are also proposing the RUC-recommended direct PE inputs for CPT code 73650.

(40) X-Ray Toe (CPT Code 73660)

CPT code 73660 (*Radiologic examination; toe(s), minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73660 was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the code and the RUC reviewed it again in January 2019. We are proposing the RUC-recommended work RVU for this code of 0.13 for CPT code 73660. We are also proposing the RUC-recommended direct PE inputs for CPT code 73660.

(41) Upper Gastrointestinal Tract Imaging (CPT Codes 74210, 74220, 74230, 74X00, 74240, 74246, and 74X01)

These services were identified through a list of list of CMS/Other codes with Medicare utilization of 30,000 or more. The CPT Editorial Panel subsequently revised this code set in order to conform to other families of radiologic examinations.

We are proposing the RUC-recommended work RVUs of 0.59 for CPT code 74210 (*Radiologic examination, pharynx and/or cervical esophagus, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*), 0.60 for CPT code 74220 (*Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*), 0.70 for CPT code 74X00 (*Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high-density barium and effervescent agent) study*), 0.53 for CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*), 0.80 for CPT code 74240 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*) 0.90 for CPT code 74246 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high-density barium and effervescent agent) study, including glucagon, when administered*), and 0.70 for CPT code 74X01 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; with small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure)*). We are also proposing the reaffirmed work RVU of 0.59 for CPT code 74210 (*Radiologic examination, pharynx and/or cervical esophagus, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*) and the reaffirmed work RVU of 0.53 for CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*).

For the direct PE clinical labor input CA021 ''Perform procedure/service—NOT directly related to physician work time,'' we note that no rationale was given for the RUC-recommended times for these codes, and we are requesting comment on the appropriateness of the RUC-recommended clinical labor times for this activity of 13 minutes, 13 minutes, 15 minutes, 15 minutes, 19 minutes, 22 minutes, and 15 minutes for CPT codes 74210, 74220, 74X00, 74230, 74240, and 74246, respectively. In addition, for CPT code 74230, we are proposing to refine the clinical labor times for the ''Prepare room, equipment and supplies'' (CA013) and ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity codes to the standard values of 2 minutes each, as well as to refine the equipment times to reflect these changes in clinical labor.

(42) Lower Gastrointestinal Tract Imaging (CPT Codes 74250, 74251, 74270, and 74280)

These services were identified through a list CMS/Other codes with Medicare utilization of 30,000 or more. We are proposing the RUC-recommended work RVUs of 0.81 for CPT code 74250 (*Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; single-contrast (e.g., barium) study*), 1.17 for CPT code 74251 (*Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; double-contrast (e.g., high-density barium and air via enteroclysis tube) study, including glucagon, when administered*), 1.04 for 74270 (*Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*), and 1.26 for CPT code 74280 (*Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high density barium and air) study, including glucagon, when administered*).

For the direct PE clinical labor input CA021 ''Perform procedure/service—NOT directly related to physician work time,'' we note that no rationale was given for the recommended times for these codes, and we are requesting comment on the appropriateness of the RUC-recommended clinical labor times for this activity of 19 minutes, 30 minutes, 25 minutes, and 36 minutes for CPT codes 74250, 74251, 74270, and 74280, respectively. In addition, we are proposing to refine the equipment time for the room, radiographic-fluoroscopic (EL014) for CPT code 74250 to conform to our established standard for highly technical equipment and to match the rest of the codes in the family.

(43) Urography (CPT Code 74425)

The physician time and work described by CPT code 74425 (Urography, antegrade (pyelostogram, nephrostogram, loopogram), radiological supervision and interpretation) was combined with services describing genitourinary catheter procedures in CY 2016, resulting in CPT codes 50431 (*Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (e.g., ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; existing access*) and 50432 (*Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation*). CPT code 74425 was not deleted at the time, but the RUC agreed with the specialty societies that 2 years of Medicare claims data should be available for analysis before the code was resurveyed for valuation to allow for any changes in the characteristics and process involved in furnishing the service separately from the genitourinary catheter procedures. The specialty society surveyed CPT code 74425 and reviewed the results with the RUC in October 2018.

The results of the specialty society surveys indicated a large increase in the amount of time required to furnish the service and, correspondingly, to the work RVU. The total time for CPT code 74425 based on the survey results was 34 minutes, an increase of 25 minutes over the current total time of 9 minutes. In reviewing the survey results, the RUC revised the total time for this CPT code to 24 minutes, with a recommended work RVU of 0.51. The reason for the large increase in time according to the RUC, is a change in the typical patient profile in which the typical patient is one with an ileal conduit through which nephrostomy tubes have been placed for post-operative obstruction. Based on the described change in patient population and increased time required to furnish the service, we are proposing the RUC-recommended work RVU of 0.51 for CPT code 74425.

We are proposing the RUC-recommended direct PE inputs for CPT code 74425.

(44) Abdominal Aortography (CPT Codes 75625 and 75630)

In October 2017, the RAW requested that AMA staff compile a list of CMS/Other codes with Medicare utilization of 30,000 or more. In January 2018, the RUC recommended to survey these services for the October 2018 RUC meeting. Subsequently, the specialty society surveyed these codes.

We disagree with the RUC-recommended work RVU of 1.75 for CPT code 75625 (*Aortography, abdominal, by serialography, radiological supervision and interpretation*). In reviewing CPT code 75625, we note that the key reference service, CPT Code 75710 (*Angiography, extremity, unilateral, radiological supervision and interpretation*), has 10 additional minutes of intraservice time, 10 additional minutes of total time and the same work RVU, which would indicate the RUC-recommended work RVU of 1.75 appears to be overvalued. When we compared the intraservice time ratio between the RUC-recommended time of 30 minutes and the reference code intraservice time of 40 minutes we found a ratio of 25 percent. 25 percent of the reference code work RVU of 1.75 equals a work RVU of 1.31. When we compared the total service time ratio between the RUC-recommended time of 60 minutes and the reference code total service time of 70 minutes we found a ratio of 14 percent. 14 percent of the reference code work RVU of 1.75 equals a work RVU of 1.51. Therefore, we believe an accurate value would lie between 1.31 and 1.52 RVUs. In looking for a comparative code, we have identified CPT code 38222. CPT Code 38222 is a recently reviewed CPT code with the identical intraservice and total times. As a result, we believe that it is more accurate to propose a work RVU of 1.44 based on a crosswalk to CPT code 38222.

In case of CPT code 75630 (*Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation*), we are proposing the RUC-recommended value of 2.00 RVUs.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(45) Angiography (CPT Codes 75726 and 75774)

We are proposing the RUC-recommend work RVU for both codes in this family. We are proposing a work RVU of 2.05 for CPT code 75726 (*Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation*), a work RVU of 1.01 for CPT code 75774 (*Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure*).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(46) X-Ray Exam Specimen (CPT Code 76098)

CPT code 70098 was reviewed by the RUC based on a request from the American College of Radiology (ACR) to determine whether CPT code 76098 was undervalued because of the assumption that the service is typically furnished concurrently with a placement of localization device service (CPT codes 19281 through 19288 each representing a different imaging modality). In a letter to the RUC, ACR expressed concern about the appropriateness of a codes valuation process in which physician time and intensity for a code are reduced to account for overlap with codes that are furnished to a patient on the same day. During the April 2018 RUC meeting, the specialty societies requested a work RVU of 0.40 for CPT code 76098, with intraservice time of 5 minutes and total time of 15 minutes. Currently, this service has a work RVU of 0.16, with 5 minutes of total time and no available intraservice time. In April 2018, the RUC and the specialty society agreed that additional analysis of the data was warranted in consideration of the relatively large change in survey time and work RVU for this service. The RUC agreed to review the CPT code (CPT code 76098) again in October 2018.

The RUC recommended a work RVU, based on the October 2018 meeting, of 0.31 for CPT code 76098, which represents an increase over the current value (0.16) but a decrease relative to the specialty society's original request of 0.40. The intraservice time for this CPT code is 5 minutes, and the total time is 11 minutes. Based on the parameters we

typically use to review and evaluate RUC recommendations, which rely heavily on survey data, we agree that a work RVU of 0.31 for a CPT code with 5 minutes intraservice and 11 minutes total time is consistent with other CPT codes with similar times and levels of intensity. We are proposing the RUC-recommended work RVU for CPT code 76098 of 0.31.

We share the ACR's interest in establishing or clarifying parameters that indicate when CPT codes that are furnished concurrently by the same provider should be valued to account for the overlap in physician work time and intensity, and even PE. We are broadly interested in stakeholder feedback and suggestions about what those parameters might be and whether or how they should affect code valuation.

We are proposing the RUC-recommended direct PE inputs for CPT code 76098.

(47) 3D Rendering (CPT Code 76376)

CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. It was surveyed and reviewed at the April 2018 RUC meeting.

We are proposing the RUC-recommended work RVU of 0.20 for CPT code 76376. We are also proposing the RUC-recommended direct PE inputs for CPT code 76376.

(48) Ultrasound Exam—Chest (CPT Code 76604)

CPT code 76604 (*Ultrasound, chest (includes mediastinum), real time with image documentation*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. It was surveyed and reviewed for the April 2018 RUC meeting.

We are proposing the RUC-recommended work RVU of 0.59 for CPT code 76604. We are also proposing the RUC-recommended direct PE inputs for CPT code 76604.

(49) X-Ray Exam—Bone (CPT Codes 77073, 77074, 77075, 77076, and 77077)

CPT codes 77073 (*Bone length studies (orthoroentgenogram, scanogram)*), 77075 (*Radiologic examination, osseous survey; complete (axial and appendicular skeleton)*), and 77077 (*Joint survey, single view, 2 or more joints*) were identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. CPT codes 77074 (*Radiologic examination, osseous survey; limited (e.g., for metastases)*) and 77076 (*Radiologic examination, osseous survey, infant*) were reviewed as part of the same family.

We are proposing the RUC-recommended work RVUs for all five CPT codes in this family as follows: CPT code 77073 (work RVU = 0.26); CPT code 77074 (work RVU = 0.44); CPT code 77075 (work RVU = 0.55); CPT code 77076 (work RVU = 0.70); and CPT code 77077 (work RVU = 0.33).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(50) SPECT–CT Procedures (CPT Codes 78800, 78801, 78802, 78803, 78804, 788X0, 788X1, 788X2, and 788X3)

The CPT Editorial Panel revised five codes, created four new codes and deleted nine codes to better differentiate between planar radiopharmaceutical localization procedures and SPECT, SPECT–CT and multiple area or multiple day radiopharmaceutical localization/distribution procedures.

For CPT code 78800 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar limited single area (e.g., head, neck, chest pelvis), single day of imaging*), we disagree with the RUC recommendation to assign a work RVU of 0.70 based on the survey 25th percentile to this code, because we believe that it is inconsistent with the RUC-recommended reduction in physician time. We are proposing a work RVU of 0.64 based on the following total time ratio: The RUC-recommended 27 minutes divided by the current 28 minutes multiplied by the current work RVU of 0.66, which results in a work RVU of 0.64. We note that this value is bracketed by the work RVUs of CPT code 93287 (*Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system*), with a work RVU of 0.45, and CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*), with a work RVU of 0.70. Both of these supporting crosswalks have intraservice time values of 10 minutes, and they have similar total time values.

For CPT code 78801 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, 2 or more areas (e.g., abdomen and pelvis, head and chest), 1 or more days of imaging or single area imaging over 2 or more days*), we disagree with the RUC recommendation to maintain the current work RVU of 0.79 despite a 22-minute reduction in intraservice time. We believe a reduction from the current value is warranted given the recommended reduction in physician time, and also to be consistent with other services of similar time values. We are proposing a work RVU of 0.73 based on the RUC-recommended incremental relationship between this code and CPT code 78800 (a difference of 0.09 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 0.73, we note that it falls between the work RVUs of CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*) with a work RVU of 0.70, and CPT code 93280 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead pacemaker system*) with a work RVU of 0.77.

For CPT code 78802 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, whole body, single day of imaging*), we disagree with the RUC recommendation to maintain the current work RVU of 0.86, as we believe that it is inconsistent with a reduction in time values, and because we do not agree that a work RVU that is among the highest of other services of similar intraservice time values is appropriate. We are proposing a work RVU of 0.80 based on the RUC-recommended incremental

relationship between this code and CPT code 78800 (a difference of 0.16 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 0.80, we note that it falls between the work RVUs of CPT code 92520 (*Laryngeal function studies (i.e., aerodynamic testing and acoustic testing)*) with a work RVU of 0.75, and CPT code 93282 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system*) with a work RVU of 0.85.

For CPT code 78804 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, whole body, requiring 2 or more days of imaging*), we disagree with the RUC recommendation to maintain the current work RVU of 1.07, as we believe that it is inconsistent with a reduction in time values, and because this work RVU appears to be valued highly relative to other services of similar time values. We are proposing a work RVU of 1.01 based on the RUC-recommended incremental relationship between this code and CPT code 78800 (a difference of 0.37 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.01, we reference CPT code 91111 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report*), which has a work RVU of 1.00 and similar physician time values.

For CPT code 78803 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), single area (e.g., head, neck, chest pelvis), single day of imaging*), we disagree with the RUC recommendation to increase the work RVU to 1.20 based on the survey 25th percentile to this code, because we believe that it is inconsistent with the RUC-recommended reduction in physician time. We are proposing to maintain the current work RVU of 1.09. We support this value with a reference to CPT code 78266 (*Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel and colon transit, multiple days*), which has a work RVU of 1.08, and similar time values.

For CPT code 788X0 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (e.g., head, neck, chest or pelvis), single day of imaging*), we disagree with the RUC recommendation to assign a work RVU of 1.60 based on the survey 25th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we are proposing a work RVU of 1.49 for CPT code 788X0 based on the RUC-recommended incremental relationship between CPT code 788X0 and CPT code 78803 (a difference of 1.09 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.49, we note that it is bracketed by the work RVUs of CPT codes 72195 (*Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s)*) with a work RVU of 1.46, and 95861 (*Needle electromyography; 2 extremities with or without related paraspinal areas*) with a work RVU of 1.54. The physician time values of these services bracket those recommended for CPT code 778X0.

For CPT code 788X1 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), minimum 2 areas (e.g., pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days*), we disagree with the RUC recommendation to assign a work RVU of 1.93 based on the survey 50th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we are proposing a work RVU of 1.82 based on the RUC-recommended incremental relationship between this code and CPT code 78803 (a difference of 0.73 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.82, we note that it is bracketed by the work RVUs of the CPT codes which are members of the same code families referenced for the previous CPT code, 788X0: CPT codes 72191 (*Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing*) with a work RVU of 1.81, and 95863 (*Needle electromyography; 3 extremities with or without related paraspinal areas*) with a work RVU of 1.87. The physician time values of these services bracket those recommended for CPT code 778X1.

For CPT code 788X2 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (e.g., pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days imaging*), we disagree with the RUC recommendation to assign a work RVU of 2.23 based on the survey 50th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we are proposing a work RVU of 2.12 based on the RUC-recommended incremental relationship between this code and CPT code 78803 (a difference of 1.03 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 2.12, we reference CPT code 70554 (*Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration*), which has a work RVU of 2.11 and physician intraservice and total time values that are identical to those recommended for this service.

For CPT code 788X3 (*Radiopharmaceutical quantification measurement(s) single area*), we disagree with the RUC recommendation to assign a work RVU of 0.51 based on the survey 25th percentile to this code, because we wish to maintain relativity and proportionality among codes of this family. We based our values for the other codes in this family on their relative relationship to either CPT code 78800 or 788X2, depending on the type of service described by the code. For CPT code 788X0, which describes a single day of imaging and is thus analagous to CPT code 788X3 in terms of units of service, our analysis indicates a reduction from the RUC value of approximately 7 percent is appropriate. Therefore, we apply a

similar reduction of 7 percent to the RUC-recommended work RVU of 0.51 to arrive at an RVU of 0.47. We support this value by noting that it is bracketed by add-on CPT codes 77001 (*Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedure)*) with a work RVU of 0.38, and 77002 (*Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)*), with a work RVU of 0.54. Both of these reference CPT codes have intraservice time values that are similar to, and total time values that are identical to, those recommended for CPT code 788X3.

For the direct PE inputs, we are refining the number of minutes of clinical labor allocated to the activity ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' to the 2-minute standard for CPT codes 78800, 78801, 78802, 78804, 78803, 788X0, 788X1, and 788X2, as no rationale was provided for these codes to have times above the standard for this activity. We are also refining the equipment time formulas to reflect this clinical labor refinement for these codes. For CPT codes 78800, 78801, 78802, 78804, 78803, 788X0, 788X1, and 788X2, we are proposing to refine the equipment times to match our standard equipment time formula for the professional PACS workstation. For the supply item SM022 ''sanitizing cloth-wipe (surface, instruments, equipment),'' we are refining these supplies to quantities of 5 each for CPT codes 78801, 78804, and 788X2 to conform with other codes in the family.

(51) Myocardial PET (CPT Codes 78459, 78X29, 78491, 78X31, 78492, 78X32, 78X33, 78X34, and 78X35)

CPT code 78492 was identified via the High Volume Growth screen with total Medicare utilization over 10,000 that increased by at least 100 percent from 2009 through 2014. The CPT Editorial Panel revised this code set to reflect newer technology aspects such as wall motion, ejection fraction, flow reserve, and technology updates for hardware and software. The CPT Editorial Panel deleted a Category III code, added six Category I codes, and revised the three existing codes to separately identify component services included for myocardial imaging using positron emission tomography.

For CPT code 78491 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic)*), we disagree with the RUC-recommended work RVU of 1.56, which is the survey 25th percentile value, as we believe that the 30-minute reduction in intraservice time and 15-minute reduction in physician total time does not validate an increase in work RVU, and we believe that the significance of the reductions in recommended physician time values warrants a reduction in work RVU. We are proposing a work RVU of 1.00 based on the following total time ratio: The recommended 30 minutes divided by the current 45 minutes multiplied by the current work RVU of 1.50, which results in a work RVU of 1.00. As further support for this value, we note that it falls between CPT code 78278 (*Acute gastrointestinal blood loss imaging*), with a work RVU of 0.99, and CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), with a work RVU of 1.03.

For CPT code 78X31 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan*), we disagree with the RUC recommendation of 1.67 based on the survey 25th percentile, as we do not agree this service would be appropriately valued with an RVU that is among the highest of all services of similar times with this global period. We are proposing a work RVU of 1.11 by applying the RUC-recommended increment between CPT code 78491 and this code, an increment of 0.11, to our proposed value of 1.00 for CPT code 78491, thus maintaining the RUC's recommended incremental relationship between these codes. As further support for this value, we note that it falls between CPT codes 95977 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters*) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional)), with a work RVU of 0.97, and CPT code 93284 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system*), with a work RVU of 1.25; both of these codes have similar physician time values.

For CPT code 78459 (*Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study*), we disagree with the RUC recommendation to increase the work RVU to 1.61 based on the survey 25th percentile. We believe that the magnitude of the recommended reductions in physician time (a 50-minute reduction in intraservice time and a 32-minute reduction in total time) suggests that this value is overestimated; furthermore, we note that the RUC's recommendation is among the highest for all XXX-global period codes with similar time values. We are proposing a work RVU of 1.05 by applying the RUC-recommended increment between this code and CPT code 78491, a difference of 0.05, which we apply to our proposed value for the latter code. We support our RVU of 1.05 by referencing two CPT codes: 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), and 36440 (*Push transfusion, blood, 2 years or younger*), both of which have work RVUs of 1.03, as well as identical intraservice and similar total time values.

We disagree with the RUC's recommended valuation of 1.76 for CPT code 78X29 (*Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study; with concurrently acquired computed tomography transmission scan*), which is based on the survey 25th percentile, because we believe a work RVU that is greater than those of all other services of similar intraservice time values is not appropriate. We are proposing a work RVU of 1.20 for CPT code 78X29. We are proposing to value CPT code 78X29 with an incremental methodology, which preserves the RUC-recommended relationship among the codes in this family; the RUC

recommends an increment of 0.20 between CPT code 78X29 and CPT code 78491. We are proposing to apply this increment to our proposed value of 1.00 for CPT code 78491 to arrive at our value of 1.20.

We disagree with the RUC's recommendation of 1.80 for CPT code 78492 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); multiple studies at rest and stress (exercise or pharmacologic)*) given the magnitude of the recommended reduction in physician time values (a 35-minute reduction in intraservice time and a 17-minute reduction in total time), and also given the fact that the RUC's recommended value would be the highest of all codes of this intraservice time and global period. We are proposing a work RVU of 1.24 based on the RUC-recommended incremental difference between 78491 and 78492 of 0.24, which we add to our proposed value for 78491 for a work RVU of 1.24. As further support for this value, we reference CPT code 95908 (*Nerve conduction studies; 3–4 studies*), with a work RVU of 1.25, similar physician time values.

We disagree with the RUC's recommendation of 1.90 for CPT code 78X32 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan*) which is based on a crosswalk to CPT code 64617 (*Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed*), because the fact that this work RVU that is greater than those of all other services of similar intraservice time values suggests that it is an overestimate. Instead we are proposing a work RVU of 1.34 for CPT code 78X32, based on an incremental methodology. We apply the RUC-recommended increment between 78491 and CPT code 78X32, a difference of 0.34, to our proposed value of 1.00 for CPT code 78491, for a value of 1.34. We support this value by referencing CPT code 77261 (*Therapeutic radiology treatment planning; simple*), with a work RVU of 1.30, and CPT code 94003 (*Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day*), with a work RVU of 1.37. These codes have similar physician time values.

We disagree with the RUC's recommendation of 2.07 for CPT code 78X33 (*Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (e.g., myocardial viability)*), because we believe the fact that this work RVU is greater than those of all other services of similar intraservice time values suggests that it is an overestimate. We are proposing a work RVU of 1.51 for CPT code 78X33, based on an incremental methodology. We apply the RUC-recommended increment between 78491 and CPT code 78X33, a difference of 0.51, to our proposed value of 1.00 for CPT code 78491, for a value of 1.51. We support this value by referencing CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*), with a work RVU of 1.46, and similar physician time values.

Similarly for CPT code 78X34 (*Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan*), we disagree with the RUC's recommendation of 2.26 based on a crosswalk to CPT code 71552 (*Magnetic resonance (e.g., proton) imaging, chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s), followed by contrast material(s) and further sequences*), because we believe the fact that this work RVU is among the highest among services of similar intraservice time values suggests that it is an overestimate. We are proposing a work RVU of 1.70 by applying the RUC-recommended increment between CPT code 78X34 and CPT code 78491, which is a difference of 0.70, to our proposed value for CPT code 78491 for a value of 1.70. We support this value by referencing CPT codes 95924 (*Testing of autonomic nervous system function; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt*) and 74182 (*Magnetic resonance (e.g., proton) imaging, abdomen; with contrast material(s)*), both of which have work RVUs of 1.73.

For CPT code 78X35 (*Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography, rest and pharmacologic stress (List separately in addition to code for primary procedure)*), we disagree with the RUC recommendation to assign a work RVU of 0.63 to this code based on the survey 25th percentile, because we believe a comparison to other codes with a global period of ZZZ suggests that this is somewhat overvalued, and because we wish to maintain relativity and proportionality to other codes in this series. We based our values for the other codes in this family on their relative relationships to CPT code 78491; for that code our analysis indicates that a reduction from the RUC value of roughly ⅓ is appropriate, based on a ratio of the decrease in total time to the current work RVU. Therefore, we apply a similar reduction of ⅓ to the RUC-recommended work RVU of 0.63 to arrive at an RVU of approximately 0.42. Applying a reduction that is similar to the reduction we think is warranted from the RUC value for CPT code 78491 to CPT code 78X35 will maintain consistency in value among these services. We believe this work RVU is validated by noting that it is bracketed by CPT codes 15272 (*Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)*), with a work RVU of 0.33, and 11105 (*Punch biopsy of skin (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)*), with a work RVU of 0.45. A work RVU of 0.42 is thus consistent with ZZZ global period codes of similar physician times.

For the direct PE inputs, for several of the equipment items, we are proposing to refine the equipment times to conform to our established policies for non-highly, as well as for highly technical equipment. In addition, we are proposing to refine the equipment times to conform to our established policies for PACS Workstation. For the new equipment items ER110: ''PET Refurbished Imaging Cardiac Configuration'' and ER111: ''PET/CT Imaging Camera Cardiac Configuration,'' we are proposing to assume that a 90 percent equipment utilization rate is typical, as this would be consistent with our equipment utilization assumptions for expensive diagnostic imaging equipment. For the supply item SM022 ''sanitizing cloth-wipe (surface, instruments, equipment),'' we are refining these supplies to quantities of 5 each for CPT codes 78X33 and 78X34 to conform with other codes in the family. We are proposing that we will

not price the ''Software and hardware package for Absolute Quantitation'' as a new equipment item, due to the fact that the submitted invoices included a service contract and a combined software/hardware bundle with no breakdown on individual pricing. Based on our lack of specific pricing data, we believe that this software is more accurately characterized as an indirect PE input that is not individually allocable to a particular patient for a particular service.

(52) Cytopathology, Cervical-Vaginal (CPT Code 88141, HCPCS Codes G0124, G0141, and P3001)

CPT code 88141 (*Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician*), HCPCS code G0124 (*Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician*), HCPCS code G0141 (*Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician*), and HCPCS code P3001 (*Screening Papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician*) were identified as potentially misvalued on a list of CMS or other source codes with Medicare utilization of 30,000 or more.

In the CY 2000 PFS final rule (64 FR 59408), we finalized a policy that it was more appropriate to evaluate the work, PE, and MP RVUs for HCPCS codes P3001, G0124, and G0141 identical or comparable to the values of CPT code 88141.

For CY 2020, the RUC recommended a work RVU of 0.42 for CPT code 88141 and HCPCS codes G0124, G0141, and P3001, based on the current value. We disagree with the RUC-recommended work RVU and are proposing a work RVU of 0.26 for all four codes in this family, based on our time ratio methodology and a crosswalk to CPT code 93313 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only*), which has an identical work RVU of 0.26, identical intraservice and total work times values to CPT code 88141 and HCPCS codes G0124, and G0141, and similar intraservice and total time values to HCPCS code P3001.

In reviewing this family of codes, we note that the intraservice and total work times for CPT code 88141 and HCPCS codes G0124, and G0141 are decreasing from 16 minutes to 10 minutes (38 percent reduction) and the intraservice and total work times for HCPCS code P3001 are decreasing from 16 minutes to 12 minutes (25 percent reduction). However, the RUC recommended a work RVU of 0.42 for all four codes in this family, based on the maintaining the current work RVU. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 88141 and HCPCS codes G0124, G0141, and P3001, we believe that it would be more accurate to propose a work RVU of 0.26, based on our time ratio methodology and a crosswalk to CPT code 93313 to account for these decreases in the surveyed work times.

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Perform regulatory mandated quality assurance activity'' (CA033) activity from 7 minutes to 5 minutes for all four codes in the family. We believe that these quality assurance activities would not typically take 7 minutes to perform, given that similar federally mandated MQSA activities were recommended and finalized at a time of 4 minutes for CPT codes 77065–77067 in CY 2017 (81 FR 80314–80316), and other related regulatory compliance activities were recommended and finalized at a time of 5 minutes for CPT codes 78012–78014 in CY 2013 (77 FR 69037). To preserve relativity between services, we are proposing a clinical labor time of 5 minutes for the codes in this family based on this prior allocation of clinical labor time.

We are also proposing to remove the 1-minute of clinical labor time for the ''File specimen, supplies, and other materials'' (PA008) activity from all four codes under the rationale that this task is a form of indirect PE. As we stated in the CY 2017 PFS final rule (81 FR 80324), we agree that filing specimens is an important task, and we agree that these would take more than zero minutes to perform. However, we continue to believe that these activities are correctly categorized under indirect PE as administrative functions, and therefore, we do not recognize the filing of specimens as a direct PE input, and we do not consider this task as typically performed by clinical labor on a per-service basis.

We are proposing to refine the equipment time for the compound microscope (EP024) equipment to 10 minutes for all four codes in the family to match the work time of the procedures. The recommended materials for this code family state that the compound microscope is utilized by the pathologist, and therefore, we believe that the 10-minute work time of the procedures would be the most accurate equipment time to propose.

(53) Biofeedback Training (CPT Codes 908XX and 909XX)

CPT code 90911 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry*) was identified as potentially misvalued on a RAW screen of codes with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS or other source codes. In September 2018, the CPT Editorial Panel replaced this code with two new codes to describe biofeedback training initial 15 minutes of one-on-one patient contact and each additional 15 minutes of biofeedback training.

We are proposing the RUC-recommended work RVU of 0.90 for CPT code 908XX (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry when performed; initial 15 minutes of one-on-one patient contact*), as well as the RUC-recommended work RVU of 0.50 for CPT code 909XX (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry when performed; each additional 15 minutes of one-on-one patient contact*). For the direct PE inputs, we are proposing to refine the equipment time for the power table (EF031) equipment in CPT code 908XX to conform to our established standard for non-highly technical equipment.

We are also proposing to designate CPT codes 908XX and 909XX as ''sometimes therapy'' procedures which means that an appropriate therapy modifier is always required when this service is furnished by therapists. For more information we direct readers to the Therapy Code List section of the CMS website at *https://www.cms.gov/Medicare/Billing/TherapyServices/AnnualTherapyUpdate.html*.

(54) Corneal Hysteresis Determination (CPT Code 92145)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the AMA/Specialty Society RVS Update Committee. The AMA RUC reviewed this service at the October 2018 RAW meeting, and indicated that the

utilization is continuing to increase for this service. This code was surveyed and reviewed for the January 2019 RUC meeting.

We are proposing the work RVU of 0.10 as recommended by the RUC. We are also proposing the RUC-recommended direct PE inputs for CPT code 92145 without refinement.

(55) Computerized Dynamic Posturography (CPT Codes 92548 and 92XX0)

CPT code 92548 (*Computerized dynamic posturography*) was identified via the negative IWPUT screen. CPT revised one code and added another code to more accurately describe the current clinical work and equipment necessary to provide this service.

We do not agree with the RUC's recommended work RVUs of 0.76 for CPT code 92548 (*Computerized dynamic posturography sensory organization test (CDP–SOT), 6 conditions (i.e., eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report*), or 0.96 for CPT code 92XX0 (*Computerized dynamic posturography sensory organization test (CDP–SOT), 6 conditions (i.e., eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)*). For CPT code 92548, we agree that an increase in work RVU is warranted; however, we believe the surveyed time values suggest an increase of a less significant magnitude than that recommended. We are proposing a work RVU of 0.67 based on the intraservice time ratio: we divide the RUC-recommended intraservice time value of 20 by the current value of 15 and multiply the product by the current work RVU of 0.50 for a ratio of 0.67. As a supporting crosswalk, we note that our value is greater than the work RVU of 0.60 for CPT code 93316 (*Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only*), which has identical intraservice and total times.

We are proposing to maintain relativity between these two codes by valuing CPT code 92XX0 by applying the RUC-recommended incremental difference between the two codes, a difference of 0.20, to our proposed value of 0.66 for CPT code 93316; therefore, we are proposing a work RVU of 0.87 for CPT code 92XX0. As further support for this value, we note that it falls between the work RVUs of CPT codes 95972 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*), with a work RVU of 0.80, and CPT code 38207 (*Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage*), with a work RVU of 0.89.

We are proposing the RUC-recommended direct PE inputs for these codes without refinement.

(56) Auditory Function Evaluation (CPT Codes 92626 and 92627)

CPT code 92626 (*Evaluation of auditory function for surgically implanted device(s), candidacy or post-operative status of a surgically implanted device(s); first hour*) appeared on the RAW 2016 high volume growth screen. In 2017, it was identified through a CMS request. CPT code 92627 (*Evaluation of auditory function for surgically implanted device(s), candidacy or post-operative status of a surgically implanted device(s); each additional 15 minutes*) the add-on code for CPT code for 92626, also was included in the CMS request to review audiology services.

For CY 2020, we are proposing the HCPAC-recommended work RVU of 1.40 for CPT code 92626, which is identical to its current RVU. We are also proposing the HCPAC-recommended work RVU of 0.33 for the add-on code, CPT code 92627. We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(57) Septostomy (CPT Codes 92992 and 92993)

CPT codes 92992 (*Atrial septectomy or septostomy; transvenous method, balloon (e.g., Rashkind type) (includes cardiac catheterization)*) and 92993 (*Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)*) were nominated as potentially misvalued services. These services are typically performed on children, a non-Medicare population, and are currently contractor-priced. These codes were surveyed and reviewed for the January 2019 RUC meeting.

We are proposing to maintain contractor pricing for CPT codes 92992 and 92993, as recommended by the RUC. These codes will be referred to the CPT Editorial Panel for revision and potential deletion. We are also proposing a change from 90-day to 0-day global period status for these two procedures, also as recommended by the RUC.

(58) Opthalmoscopy (CPT Codes 92X18 and 92X19)

CPT code 92225 was identified as potentially misvalued on a screen of codes with a negative IWPUT, with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. In February 2018, the CPT Editorial Panel deleted CPT codes 92225 and 92226 and created two new codes to specify what portion of the eye is examined for a service beyond the normal comprehensive eye exam.

We are proposing the RUC-recommended work RVUs of 0.40 for CPT code 92X18 (*Ophthalmoscopy, extended, with retinal drawing and scleral depression of peripheral retinal disease (e.g., for retinal tear, retinal detachment, retinal tumor) with interpretation and report, unilateral or bilateral*) and 0.26 for CPT code 92X19 (*Ophthalmoscopy, extended, with drawing of optic nerve or macula (e.g., for glaucoma, macular pathology, tumor) with interpretation and report, unilateral or bilateral*).

We are proposing the RUC-recommended direct PE inputs for this code family without refinement.

(59) Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299, and HCPCS Code GTTT1)

When the RUC previously reviewed the CPT code 93299 at the January 2017 RUC meeting, the specialty society submitted PE inputs for CPT code 93299 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisitions(s), receipt of transmissions and technician review, technical support and distribution of results*); the PE Subcommittee and RUC accepted the society recommendations. In the CY 2018 PFS final rule (82 FR 53064), we did not finalize our proposal to establish national pricing for CPT code 93299 and the code remained contractor-priced.

At the October 2018 RUC meeting, the RUC re-examined CPT code 93299. CPT codes 93297 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic*

monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional) and 93298 (*Interrogation device evaluation(s), remote up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis or recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional*) were added to this family of services. These three codes were reviewed for practice expense only.

CPT codes 93297 and 93298 are work-only codes and CPT code 93299 is meant to serve as the catch-all for both 30-day remote monitoring services. The RUC is unclear why the code family was designed this way, noting it may have been a way to allow for the possibility that the technical work would be provided by vendors, but they noted that this is not how the service is currently provided. Stating that in the decade since these codes were created, it has become clear that implantable cardiovascular monitor (ICM) and implantable loop recorder (ILR) services are very different and the PE cannot be appropriately captured for both services in a single technical code. They noted that CPT codes 93297–93299 will be placed on the new technology/new services list and be re-reviewed by the RUC in 3 years to ensure correct calculation and utilization assumptions. It was noted in the RUC recommendations that the specialty society intended to submit a coding proposal to the CPT Editorial Panel to delete CPT code 93299, as it will no longer be necessary to have a separate code for PE if CPT codes 93297 and 93298 are allocated direct PE in CY 2020.

In our review of these services, we note that the RUC recommendations did not provide a detailed description of the clinical labor tasks being performed or detailed information on the typical use of the supply and equipment used when furnishing these services. These details are important in order for us to review if the RUC-recommended PE inputs are appropriate to furnish these services. The RUC submitted PE inputs (which were not previously included) for the work-only CPT codes 93297 and 93298, but did not include details to substantiate these recommended PE inputs for any of the three codes in this family.

Additionally, we are concerned with the appropriateness of the RUC's reference code, CPT code 93296 (*Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*). CPT code 93296 is for remote monitoring over a 90-day period, but was used as a reference to derive the RUC-recommended direct PE inputs for CPT codes 93297–93299, which are for remote monitoring over a 30-day period.

For the CY 2020 direct PE inputs, we are proposing to remove the clinical labor time for ''Perform procedure/service—not directly related to physician work time'' (CA021); to remove the requested quantity for the supply ''Paper, laser printing (each sheet)'' (SK057); and to refine the equipment times in accordance with our standard equipment time formulas for CPT codes 93297 and 93298.

Although we are not proposing to allocate direct PE inputs for CPT codes 93297 and 93298, we are seeking additional comment on the appropriateness of CPT code 93296 as the reference code, details on the clinical labor tasks, and more information on the typical use of the supply and equipment used to furnish these services. For example, it was unclear in the RUC recommendations how many patients are monitored concurrently. As an additional example, it was unclear in the RUC recommendations as to what tasks are involved when clinical staff engage with the patient throughout the month to perform education about the device and re-education protocols after the initial enrollment.

The CPT Editorial Panel is deleting CPT code 93299 for CY 2020. We note this differs from the RUC recommendations for this code from the October 2018 meeting, which stated that the specialty society intended to submit a coding proposal to the CPT Editorial Panel to delete CPT code 93299, as it would no longer be necessary to have a separate code for PE, if CPT codes 93297 and 93298 are allocated direct PE for CY 2020. Given that we are proposing to not allocate direct PE inputs for CPT code 93297 and 93298 for CY 2020 and CPT code 93299 is being deleted for CY 2020, we are proposing to create a G-code to describe the services previously furnished under CPT code 93299. We are proposing to create HCPCS code GTTT1 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*), to describe the services previously furnished under CPT code 93299, effective for CY 2020.

(60) Duplex Scan Arterial Inflow-Venous Outflow (CPT Codes 93X00 and 93X01)

In September 2018, the CPT Editorial Panel recommended replacing one HCPCS code (G0365) with two new codes to describe the duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access for complete bilateral and unilateral study. We are proposing the RUC-recommended work RVU of 0.80 for CPT code 93X00 (*Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study*), as well as the RUC-recommended work RVU of 0.50 for CPT code 93X01 (*Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study*).

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity from 4 minutes to 2 minutes for both codes in the family. Two minutes is the standard time for this clinical labor activity, and 2 minutes is also the time assigned for this activity in the reference code, CPT code 93990 (*Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)*). There was no rationale provided in the recommended materials indicating why this additional clinical labor time would be typical for the procedures, and therefore, we are proposing to refine to the standard time of 2 minutes. We are also proposing to adjust the equipment times to conform to this change in the clinical labor time.

(61) Myocardial Strain Imaging (CPT Code 933X0)

The CPT Editorial Panel deleted one Category III code and created one new Category I add-on code CPT code 933X0 to describe the work of myocardial strain imaging performed in supplement to transthoracic echocardiography services. We are proposing the RUC-recommended work RVU of 0.24.

We are proposing the RUC-recommended direct PE inputs for CPT code 933X0. However, we note that no rationale was given for the RUC-recommended 12 minutes of clinical labor time for the activity CA021

''Perform procedure/service,'' and we are requesting comment on the appropriateness of this allocated time value.

(62) Lung Function Test (CPT Code 94200)

The RUC recommended this service for survey because it appeared on a list of CMS/Other codes with Medicare utilization of 30,000 or more. According to the RUC, this service is typically reported with an E/M service and another pulmonary function test, and the RUC-recommended times would appropriately account for any overlap with other services. The RUC stated that the intraservice time involves reading and interpreting the test to determine if a significant interval change has occurred and then generating a report, which supports the 5 minutes of physician work indicated in the survey. The RUC did not agree with the specialty society that communication of the report required an additional 2 minutes of physician time over the postservice time included in the other services reported on the same day. The RUC reduced the postservice time from 2 minutes to 1 minute because the service requires minimal time to enter the results into the medical record and communicate the results to the patient and the referring physician. Based in part on these reductions in physician time, the RUC recommended a reduction in work RVU from the current value with a crosswalk to CPT code 95905 (Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report).

For CPT code 94200 (*Maximum breathing capacity, maximal voluntary ventilation*), we are proposing the RUC-recommended work RVU of 0.05. A stakeholder stated that the RUC's recommended work RVU understates the costs inherent in performing this service, and that the survey 25th percentile value of 0.10 is more accurate for this service. While we are proposing the RUC-recommended 0.05, we are soliciting public comment on this stakeholder-recommended potential alternative value.

We are proposing the RUC-recommended direct PE inputs for CPT code 94200 without refinement.

(63) Long-Term EEG Monitoring (CPT Codes 95X01, 95X02, 95X03, 95X04, 95X05, 95X06, 95X07, 95X08, 95X09, 95X10, 95X11, 95X12, 95X13, 95X14, 95X15, 95X16, 95X17, 95X18, 95X19, 95X20, 95X21, 95X22, and 95X23)

In January 2017, the RUC identified CPT code 95951 via the high volume growth screen, which considers if the service has total Medicare utilization of 10,000 or more and if utilization has increased by at least 100 percent from 2009 through 2014. The RUC recommended that this service be referred to the CPT Editorial Panel for needed changes, including code deletions, revision of code descriptors, and the addition of new codes to this family. In May 2018, the CPT Editorial Panel approved the revision of one code, deletion of five codes, and addition of 23 new codes for reporting long-term EEG professional and technical services.

We are proposing the RUC-recommended work RVU for six of the professional component codes in this family. We are proposing a work RVU of 3.86 for CPT code 95X18 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 36 hours, up to 60 hours of EEG recording, without video*), a work RVU of 4.70 for CPT code 95X19 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 36 hours, up to 60 hours of EEG recording, with video*), a work RVU of 4.75 for CPT code 95X20 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 60 hours, up to 84 hours of EEG recording, without video*), a work RVU of 6.00 for CPT code 95X21 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 60 hours, up to 84 hours of EEG recording, with video*), a work RVU of 5.40 for CPT code 95X22 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 84 hours of EEG recording, without video*) and a work RVU of 7.58 for CPT code 95X23 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 84 hours of EEG recording, with video*).

We are also proposing the RUC-recommended work RVU of 0.00 for the 13 technical component codes in the family: CPT code 95X01 (*Electroencephalogram (EEG) continuous recording, with video when performed, set-up, patient education, and take down when performed, administered in-person by EEG technologist, minimum of 8 channels*), CPT code 95X02 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; unmonitored*), CPT code 95X03 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; with intermittent monitoring and maintenance*), CPT code 95X04 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; with continuous, real-time monitoring and maintenance*), CPT code 95X05 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; unmonitored*), CPT code 95X06 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; with intermittent monitoring and maintenance*), CPT code 95X07 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; with continuous, real-time monitoring and maintenance*), CPT code 95X08 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; unmonitored*), CPT code 95X09 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; with intermittent monitoring and maintenance*), CPT code 95X10 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; with continuous, real-time monitoring and maintenance*), CPT code 95X11 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; unmonitored*), CPT code 95X12 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; with intermittent monitoring and*

maintenance), and CPT code 95X13 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; with continuous, real-time monitoring and maintenance*).

We disagree with the RUC-recommended work RVU of 2.00 for CPT code 95X14 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, 2–12 hours of EEG recording; without video*) and we are proposing a work RVU of 1.85 based on a crosswalk to CPT code 93314 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only*). CPT code 93314 is a recently-reviewed code with 2 additional minutes of intraservice time and 4 additional minutes of total time as compared to CPT code 95X14. When considering the work RVU for CPT code 95X14, we looked to the second reference code chosen by the survey participants, CPT code 95957 (*Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)*). This code has 2 additional minutes of intraservice time and 9 additional minutes of total time as compared to CPT code 95X14, yet has a work RVU of 1.98, lower than the recommended work RVU of 2.00. These time values suggested that CPT code 95X14 would be more accurately valued at a work RVU slightly below the 1.98 of CPT code 95957. We also looked at the intraservice time ratio between CPT code 95X14 and some of its predecessor codes. The intraservice time ratio with CPT code 95953 (*Monitoring for localization of cerebral seizure focus by computerized portable 16 or more channel EEG, electroencephalographic (EEG) recording and interpretation, each 24 hours, unattended*) suggests a similar potential work RVU of 1.91 (28 minutes divided by 45 minutes times a work RVU of 3.08). Based on this information, we are proposing a work RVU of 1.85 for CPT code 95X14 based on the aforementioned crosswalk to CPT code 93314.

We disagree with the RUC-recommended work RVU of 2.50 for CPT code 95X15 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and report, 2–12 hours of EEG recording; with video (VEEG)*) and we are proposing a work RVU of 2.35. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 95X14 and 95X15 is equivalent to the recommended interval of 0.50 RVUs. Therefore, we are proposing a work RVU of 2.35 for CPT code 95X15, based on the recommended interval of 0.50 additional RVUs above our proposed work RVU of 1.85 for CPT code 95X14. We are supporting this work RVU with a reference to CPT code 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of the 3 key components*), which shares the same intraservice time of 35 minutes and the identical work RVU of 2.35. CPT code 99310 is a lower intensity procedure but has increased total work time as compared to CPT code 95X15.

We disagree with the RUC-recommended work RVU of 3.00 for CPT code 95X16 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; without video*) and we are proposing a work RVU of 2.60 based on a crosswalk to CPT code 99219 (*Initial observation care, per day, for the evaluation and management of a patient, which requires 3 key components*). CPT code 99219 shares the same intraservice time of 40 minutes and has a slightly higher total time as compared to CPT code 95X16. We also note that the observation care described by CPT code 99219 shares some clinical similarities to the long term EEG monitoring described by CPT code 95X16, although we note as always that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another, and that codes do not need to share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

In addition, we believe that the proposed crosswalk to CPT code 99219 at a work RVU of 2.60 more accurately captures the intensity of CPT code 95X16. At the recommended work RVU of 3.00, the intensity of CPT code 95X16 is anomalously high in comparison to the rest of the family, higher than any of the other professional component codes. We have no reason to believe that the 24-hour EEG monitoring done without video as described in CPT code 95X16 would be notably more intense than the other codes in the same family. Furthermore, the recommendations for this code family specifically state that the codes that describe video EEG monitoring are more intense than the codes that describe non-video EEG monitoring. However, at the recommended work RVU for CPT code 95X16, this non-video form of EEG monitoring had the highest intensity in the family. At our proposed work RVU of 2.60, the intensity of CPT code 95X16 is no longer anomalously high in comparison to the rest of the family, and also remains lower than the intensity of the 24 hour EEG monitoring with video procedure described by CPT code 95X17.

We disagree with the RUC-recommended work RVU of 3.86 for CPT code 95X17 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; with video (VEEG)*) and we are proposing a work RVU of 3.50 based on the survey 25th percentile value. The RUC-recommended work RVU of 3.86 was based on a crosswalk to CPT code 99223 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires 3 key components*), a code that shares the same intraservice time of 55 minutes but has 15 additional minutes of total time as compared to CPT code 95X17, at 90 minutes as compared to 75 minutes. We disagree with the use of this crosswalk, as the 15 minutes of additional total time in CPT code 99223 result in a higher work valuation that overstates the work RVU of CPT code 95X17. These 15 additional minutes of preservice and postservice work time in the recommended crosswalk code have a calculated work RVU of 0.34 under the building block methodology; subtracting out this work RVU of 0.34 from the crosswalk code's work RVU of 3.86 results in an estimated work RVU of 3.52, which is nearly identical to the survey 25th percentile work RVU of 3.50. Similarly, if we were to calculate a total time ratio between CPT code 95X17 and the recommended crosswalk code 99223, it would produce a noticeably lower work RVU of 3.22 (75 minutes divided by 90 minutes times a work RVU of 3.86). Based on this rationale, we do not believe that it would serve the interests of relativity to propose a work RVU of 3.86 based on the recommended crosswalk.

Instead, we are proposing a work RVU of 3.50 for CPT code 95X17 based on the

survey 25th percentile value. We note that among the predecessor codes for this family, CPT code 95956 (*Monitoring for localization of cerebral seizure focus by cable or radio, 16 or more channel telemetry, electroencephalographic (EEG) recording and interpretation, each 24 hours, attended by a technologist or nurse*) has a higher intraservice time of 60 minutes and a higher total time of 105 minutes at a work RVU of 3.61. This prior valuation of CPT code 95956 does not support the RUC-recommended work RVU of 3.86 for CPT code 95X17, but does support the proposed work RVU of 3.50 at the slightly lower newly surveyed work times. We also note that at the recommended work RVU of 3.86, the intensity of CPT code 95X17 was anomalously high in comparison to the rest of the family, the second-highest intensity as compared to the other professional component codes. We have no reason to believe that the 24 hour EEG monitoring done with video as described in CPT code 95X17 would be notably more intense than the other codes in the same family. At our proposed work RVU of 3.50, the intensity of CPT code 95X17 is no longer anomalously high in comparison to the rest of the family, while still remaining slightly higher than the intensity of the 24 hour EEG monitoring performed without video procedure described by CPT code 95X16.

For the direct PE inputs, we are proposing to make a series of refinements to the clinical labor times of CPT code 95X01. Many of the clinical labor times for this CPT code were derived using a survey process and were recommended to CMS at the survey median values. This was in contrast to the typical process for recommended direct PE inputs, where the inputs are usually based on either standard times or carried over from reference codes. We believe that when surveys are used to recommended direct PE inputs, we must apply a similar process of scrutiny to that used in assessing the work RVUs that are recommended based on a survey methodology. We have long expressed our concerns over the validity of the survey results used to produce work RVU recommendations, such as in the CY 2011 PFS final rule (75 FR 73328), and we have noted that over the past decade the AMA RUC has increasingly chosen to recommend the survey 25th percentile work RVU over the survey median value, potentially responding to the same concerns that we have identified.

As a result, we believe that when assessing the survey of direct PE inputs used to produce many of the recommendations for CPT code 95X01, it would be more accurate to propose the survey 25th percentile direct PE inputs as opposed to the recommended survey median direct PE inputs. Therefore, we are proposing to refine the clinical labor time for the ''Provide education/obtain consent'' (CA011) activity from 13 minutes to 7 minutes and to refine the clinical labor time for the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) activity from 10 minutes to 7 minutes. In both of these cases, the recommended clinical labor times based on the survey median values are more than double the standard time for these activities. Although we agree that additional clinical labor time would be required to carry out these activities for CPT code 95X01, we do not believe that the survey median times would be typical. We are proposing the survey 25th percentile times of 7 minutes for each activity as we believe that this time would be more typical for obtaining consent and reviewing home care instructions.

We are also proposing to refine the clinical labor time for the ''Complete pre-procedure phone calls and prescription'' (CA005) activity from 10 minutes to 3 minutes for CPT code 95X01. This is another situation where we are proposing the survey 25th percentile clinical labor time of 3 minutes instead of the survey median clinical labor time of 10 minutes. However, we also note that many of the tasks that fell under the CA005 activity code as described in the PE recommendations appear to constitute forms of indirect PE, such as collecting supplies for setup and loading equipment and supplies into vehicles. Collecting supplies and loading equipment are administrative tasks that are not individually allocable to a particular patient for a particular service, and therefore, constitute indirect PE under our methodology. Due to the fact that many of the tasks described under the CA005 activity code are forms of indirect PE, we believe that the RUC-recommended survey median clinical labor time of 10 minutes overstates the amount of direct clinical labor taking place. We believe that it is more accurate to propose the survey 25th percentile clinical labor time of 3 minutes for this activity code to reflect the non-administrative tasks performed by the clinical staff.

We are also proposing to refine the quantity of the non-sterile gloves (SB022) supply from 3 to 2 for CPT code 95X01. We note that the current reference code, CPT code 95953, uses 2 of these pairs of gloves and the survey also stated that 2 pairs of gloves were typical for the procedure. Although the recommended materials state that a pair of gloves is needed to set up the equipment, to take down the equipment, and a third is required for electrode changes, we do not agree that the use of a third pair of gloves would be typical given their usage in the reference code and in the responses from the survey.

We note that we are not proposing to refine many of the other clinical labor times for CPT code 95X01, which remain at the survey median clinical labor times. Due to the nature of the continuous recording EEG service taking place, we agree that the survey median clinical labor times of 12 minutes for the ''Prepare room, equipment and supplies'' (CA013) activity, 45 minutes for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity, and 22 minutes for the ''Clean room/equipment by clinical staff'' (CA024) activity would be typical for this procedure. We reiterate that we assess the direct PE inputs for each procedure individually based on our methodology of what would be reasonable and medically necessary for the typical patient.

For CPT codes 95X02–95X13, we are proposing to refine the clinical labor time for the ''Coordinate post-procedure services'' (CA038) activity from either 11 minutes to 5 minutes or from 22 minutes to 10 minutes as appropriate for the CPT code in question. The recommended materials for these procedures state that the tasks taking place constitute ''Merge EEG and Video files (partially automated program), confirm transfer of data, delete from laptop/computer if necessary''. We believe that many of the tasks detailed here are administrative in nature, consisting of forms of data entry, and therefore, would be considered types of indirect PE. We note that when CPT code 95812 (Electroencephalogram (EEG) extended monitoring; 41–60 minutes) was recently reviewed for CY 2017, we finalized the recommended clinical labor time of 2 minutes for ''Transfer data to reading station & archive data'', a task which we believe to be highly similar. Due to the longer duration of the procedures in CPT codes 95X02–95X13, we are proposing clinical labor times of 5 minutes and 10 minutes for the CA038 activity for these CPT codes. We are also refining the equipment time for the Technologist PACS workstation (ED050) to match the clinical labor time proposed for the CA038 activity.

For the four continuous monitoring procedures, CPT codes 95X04, 95X07, 95X10, and 95X13, we are proposing to refine the equipment time for the

ambulatory EEG review station (EQ016) equipment. The recommended equipment time for the ambulatory EEG review station was equal to four times the ''Perform procedure/service'' (CA021) clinical labor time plus a small amount of extra prep time. We do not agree that it would be typical to assign this much equipment time, as it is our understanding that one ambulatory EEG review station can be hooked up to as many as four monitors at a time for continuous monitoring. Therefore, we do not believe that each monitor would require its own review station, and that the equipment time should not be equal to four times the clinical labor of the ''Perform procedure/service'' (CA021) activity. As a result, we are proposing to refine the ambulatory EEG review station equipment time from 510 minutes to 150 minutes for CPT code 95X04, from 1,480 minutes to 400 minutes for CPT code 95X07, from 514 minutes to 154 minutes for CPT code 95X10, and from 1,495 minutes to 415 minutes for CPT code 95X13.

For the 10 professional component procedures, CPT codes 95X14–95X23, we are again proposing to refine the equipment time for the ambulatory EEG review station (EQ016) equipment. We believe that the use of the ambulatory EEG review station is analogous in these procedures to the use of the professional PACS workstation (ED053) in other procedures, and we are proposing to refine the equipment times for these 10 procedures to match our standard equipment time formula for the professional PACS workstation. Therefore, we are proposing an equipment time for the ambulatory EEG review station equal to half the preservice work time (rounded up) plus the intraservice work time for CPT codes 95X14 through 95X23. We believe that this equipment time is more accurate than the recommended equipment time, which was equal to the total work time of the procedures, as the work descriptors for CPT codes 95X14–95X23 make no mention of the ambulatory EEG review station in the postservice work period.

Finally, we are proposing to price the new ''EEG, digital, prolonged testing system with remote video, for patient home use'' (EQ394) equipment at $26,410.95 based on an invoice submission. We did not use a second invoice submitted for the new equipment for pricing, as it contained a disaggregated list of equipment components and it was not clear if they represented the same equipment item as the first invoice.

(64) Health and Behavioral Assessment and Intervention (CPT Codes 961X0, 961X1, 961X2, 961X3, 961X4, 961X5, 961X6, 961X7, and 961X8)

The 2001 Health and Behavior Assessment and Intervention (HBAI) RUC valuations were based on the old CPT code 90801 (*Psychiatric diagnostic interview evaluation*), a 60-minute service. The RUC originally recommended the Health and Behavior Assessment and Intervention procedures to be 15-minute services, approximately equal to one-quarter of the value of CPT code 90801, which we finalized without refinements. While the RUC may have assumed that these services would typically be reported in four, 15-minute services per single patient encounter, in actual claims data, there is wide variation in the number of services provided and submitted. The RUC reconsidered their rationale for the original RUC-recommended valuation of this family of codes in September 2018. The CPT Editorial Panel deleted the six existing Health and Behavior Assessment and Intervention procedure CPT codes and replaced them with nine new CPT codes.

The six deleted CPT codes include CPT code 96150 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment*), CPT code 96151 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; re-assessment*), CPT code 96152 (*Health and behavior intervention, each 15 minutes, face-to-face; individual*), CPT code 96153 (*Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)*), CPT code 96154 (*Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)*), and CPT code 96155 (*Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)*).

The nine replacement HBAI CPT codes include CPT code 961X0 (*Health behavior assessment, including re-assessment (i.e., health-focused clinical interview, behavioral observations, clinical decision making)*), CPT code 961X1 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*), CPT code 961X2 (*Health behavior intervention, individual, face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 961X3 (*Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes*), CPT code 961X4 (*Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 961X5 (*Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes*), CPT code 961X6 (*Health behavior intervention, family (with the patient present), face-to-face each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 961X7 (*Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*), CPT code 961X8 (*Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*).

We are proposing the RUC-recommended work RVUs for each of the codes in this family as follows.

- For CPT code 961X0, we are proposing a work RVU of 2.10.
- For CPT code 961X1, we are proposing a work RVU of 1.45.
- For CPT code 961X2, we are proposing a work RVU of 0.50.
- For CPT code 961X3, we are proposing a work RVU of 0.21.
- For CPT code 961X4, we are proposing a work RVU of 0.10.
- For CPT code 961X5, we are proposing a work RVU of 1.55.
- For CPT code 961X6, we are proposing a work RVU of 0.55.
- For CPT code 961X7, we are proposing a work RVU of 1.50 (but this code will be non-covered by Medicare).
- For CPT code 961X8, we are proposing a work RVU of 0.54 (but this code will be non-covered by Medicare).

We are proposing the RUC-recommended direct PE inputs for all of the CPT codes in this family without refinement.

(66) Cognitive Function Intervention (CPT Codes 971XX and 9XXX0)

In 2017, we received HCPAC recommendations for new CPT code 97127 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, 1*) that described the services under CPT code 97532 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, each 15 minutes*). CPT code 97532 was scheduled to be deleted and replaced by the new untimed code CPT code 97127. In the CY 2018 PFS final rule (82 FR 53074 through 53076); however, we

suggested that CPT code 97127 as an untimed/per day code did not appropriately account for the variable amounts of time spent with a patient depending upon the discipline and/or setting and assigned the code a procedure status of ''I'' (Invalid). In place of CPT code 97127, we established a new HCPCS G-code, G0515 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, each 15 minutes*), with a work RVU of 0.44. HCPCS code G0515 maintained the descriptor and values from the former CPT code 97532.

In September 2018, the CPT Editorial Panel revised CPT code 971XX (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing and sequencing tasks), direct (one-to-one) patient contact; initial 15 minutes*) and created an add-on code, CPT code 9XXX0 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing and sequencing tasks), direct (one-to-one) patient contact; each additional 15 minutes (list separately in addition to code for primary procedure)*).

We are proposing the RUC-recommended work RVUs of 0.50 for CPT code 971XX and 0.48 for CPT code 9XXX0. We are proposing the RUC-recommended direct PE inputs for all codes in the family. We are also proposing to designate CPT codes 971XX and 9XXX0 as sometime therapy codes because the services might be appropriately furnished by therapists under the outpatient therapy services benefit (includes physical therapy, occupational therapy, or speech-language pathology) or outside the therapy benefit by physicians, NPPs, and psychologists.

(67) Open Wound Debridement (CPT Codes 97597 and 97598)

CPT code 97598 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof*) was identified by the RUC on a list of services that were originally surveyed by one specialty but are now typically performed by a different specialty. It was reviewed along CPT code 97597 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less*) at the October 2018 RUC meeting.

We disagree with the RUC-recommended work RVU of 0.88 for CPT code 97597 and we are proposing a work RVU of 0.77 based on a crosswalk to CPT code 27369 (*Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography*). CPT code 27369 is a recently-reviewed code with the same intraservice time of 15 minutes and a total time of 28 minutes, one minute fewer than CPT code 97597. In reviewing this code, we noted that the recommended intraservice time is increasing from 14 minutes to 15 minutes (7 percent), and the recommended total time is increasing from 24 minutes to 29 minutes (21 percent); however, the RUC-recommended work RVU is increasing from 0.51 to 0.88, which is an increase of 73 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, modest increases in time should be appropriately reflected with a commensurate increase the work RVUs. In the case of CPT code 97597, we believed that it is more accurate to propose a work RVU of 0.77 based on a crosswalk to CPT code 27369 to account for these modest increases in the surveyed work time. We also note that even at the proposed work RVU of 0.77 the intensity of this procedure as measured by IWPUT is increasing by more than 50 percent over the current value.

We are proposing the RUC-recommended work RVU of 0.50 for CPT code 97598. We are also proposing the RUC-recommended direct PE inputs for all codes in the family.

(68) Negative Pressure Wound Therapy (CPT Codes 97607 and 97608)

In the CY 2013 final rule with comment period, we created two HCPCS codes to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries using equipment that is not paid for as durable medical equipment: G0456 (*Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters*) and G0457 (*Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq. cm*). For CY 2015, the CPT Editorial Panel created CPT codes 97607 (Negative *pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate*) and 97608 (Negative pressure wound therapy, (*e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate*) to describe negative pressure wound therapy with the use of a disposable system. In addition, CPT codes 97605 (*Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters*) and 97606 (*Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters*) were revised to specify the use of durable medical equipment. Based upon the revised coding scheme for negative pressure wound therapy, we deleted the G-codes. Due to concerns that we had with these services, we contractor priced CPT codes 97607 and 97608 beginning in CY 2015 (79 FR 67670). In the CY 2016 Final Rule (80 FR 71005),

in response to comment expressing disappointment with CMS' decision to contractor price these codes, we noted that there were obstacles to developing accurate payment rates for these services within the PE RVU methodology, including the indirect PE allocation for the typical practitioners who furnish these services and the diversity of the products used in furnishing these services.

We have received repeated requests from stakeholders, including in comment received in response to the CY 2019 PFS final rule, to assign an active status to these codes, meaning we would assign rates to the codes rather than allowing them to be contractor priced. In that rule, (83 FR 59473), we noted that we received a request that CMS should assign direct cost inputs and PE RVUs to CPT codes 97607 and 97608, and we indicated that we would take this feedback from commenters under consideration for future rulemaking.

In response to stakeholder feedback, we evaluated the codes and determined there was adequate volume to assign an active status. We are proposing to assign an active status to CPT codes 97607 and 97608 and we are proposing the work RVUs as recommended by the RUC that we received for CY 2015 when the CPT Editorial Panel created these codes. Thus, we are proposing a work RVU of 0.41 for CPT code 97607 and a work RVU of 0.46 for CPT code 97608. Similarly, we are proposing the RUC-recommended direct PE inputs originally for CY 2015 with the following refinement: For the clinical labor activity ''check dressings & wound/home care instructions/coordinate office visits/prescriptions,'' we are refining the clinical labor time to the standard 2 minutes for this task. In addition, the direct inputs for these codes include the new supply item, ''kit, negative pressure wound therapy, disposable.'' A search of publicly available commercial pricing data indicates that a unit price of approximately $100 is appropriate, and therefore, we are proposing this price for this supply item. If more accurate invoices are available, we are soliciting such invoices to more accurately price it.

(69) Ultrasonic Wound Assessment (CPT Code 97610)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the Committee. CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*) was flagged for CPT 2015 and reviewed at the October 2018 RAW meeting. The Workgroup indicated that the utilization is continuing to increase for this service, and recommended that it be resurveyed for physician work and practice expense for the January 2019 RUC meeting.

We are proposing the RUC-recommend work 0.40 for CPT code 97610. We are also proposing the RUC-recommended direct PE inputs for CPT code 97610.

(70) Online Digital Evaluation Service (e-Visit) (CPT Codes 98X00, 98X01, and 98X02)

In September 2018, the CPT Editorial Panel deleted two codes and replaced them with six new non-face-to-face codes to describe patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office. The HCPAC reviewed and made recommendations for CPT code 98X00 (*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), CPT code 98X01 (*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and CPT code 98X02 (*Qualified nonphysician qualified healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*). CPT codes 9X0X1–9X0X3 are for practitioners who can independently bill E/M services while CPT codes 98X00–98X02 are for practitioners who cannot independently bill E/M services.

The statutory requirements that govern the Medicare benefit are specific regarding which practitioners may bill for E/M services. As such, when codes are established that describe E/M services that fall outside the Medicare benefit category of the practitioners who may bill for that service, we have typically created parallel HCPCS G-codes with descriptors that refer to the performance of an ''assessment'' rather than an ''evaluation''. We acknowledge that there are qualified non-physician health care professionals who will likely perform these services. Therefore, for CY 2020, we are proposing separate payment for online digital assessments via three HCPCS G-codes that mirror the RUC recommendations for CPT codes 98X00–98X02. The proposed HCPCS G codes and descriptors are as follows:

- HCPCS code GNPP1 (*Qualified nonphysician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*);
- HCPCS code GNPP2 (*Qualified nonphysician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*); and
- HCPCS code GNPP3 (*Qualified nonphysician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*).

For CY 2020, we are proposing a work RVU of 0.25 for CPT code GNPP1, which reflects the RUC-recommended work RVU for CPT code 98X00. For HCPCS codes GNPP2 and GNPP3, we believe that the 25th percentile work RVU associated with CPT codes 98X01 and 98X02 respectively, better reflects the intensity of performing these services, as well as the methodology used to value the other codes in the family, all of which use the 25th percentile work RVU. Therefore, we are proposing a work RVU of 0.44 for HCPCS code GNPP1 and a work RVU of 0.69 for HCPCS code GNPP2.

We are proposing the direct PE inputs associated with CPT codes 98X00, 98X01, and 98X02 for GNPP1, GNPP2, and GNPP3 respectively.

(71) Emergency Department Visits (CPT Codes 99281, 99282, 99283, 99284, and 99285)

In the CY 2018 PFS final rule, we finalized a proposal to nominate CPT codes 99281–99285 as potentially misvalued based on information suggesting that the work RVUs for emergency department visits may not appropriately reflect the full resources involved in furnishing these services (FR 82 53018.) These five codes were surveyed and reviewed for the April 2018 RUC meeting. For CY 2020 we are proposing the RUC-recommended work RVUs of 0.48 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.42 for 99283, a work RVU of 2.60 for 99284, and a work RVU of 3.80 for CPT code 99285.

The RUC did not recommend and we are not proposing any direct PE inputs for the codes in this family.

(72) Self-Measured Blood Pressure Monitoring (CPT Codes 99X01, 99X02, 93784, 93786, 93788, and 93790)

In September 2018, the CPT Editorial Panel created two new codes and revised four other codes to describe self-measured blood pressure monitoring services and to differentiate self-measured blood pressuring monitoring services from ambulatory blood pressure monitoring services. The first of the two new codes that describe self-measured blood pressure monitoring is CPT code 99X01 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*) and is a PE only code. The second code is 99X02 (*Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings, one minute apart, twice daily over a 30-day period* (*minimum of 12 readings*), *collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*).

The remaining four codes, which monitor ambulatory blood pressure, include CPT code 93784 (*Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report*), CPT code 93786 (*Ambulatory blood pressure monitoring, recording only*), CPT code 93788 (*Ambulatory blood pressure monitoring, scanning analysis with report*), and CPT code 93790 (*Ambulatory blood pressure monitoring, review with interpretation and report*). CPT code 93784 is a composite code that is the sum of CPT codes 93786, 93788, and 93790. CPT codes 93786 and 93788 are PE only codes.

We are proposing the RUC-recommended work RVU of 0.18 for CPT code 99X02, the RUC-recommended work RVU of 0.38 for CPT code 93784, and the RUC-recommended work RVU of 0.38 for CPT code 93790. We are proposing the RUC-recommended work RVU of 0.00 for CPT codes 93786, 93788, and 99X01. We are also proposing the RUC-recommended direct PE inputs for all codes in the family.

(73) Online Digital Evaluation Service (e-Visit) (CPT Codes 9X0X1, 9X0X2, and 9X0X3)

In September 2018, the CPT Editorial Panel deleted two codes and replaced them with six new non-face-to face codes to describe patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office. The RUC reviewed and made recommendations for CPT code 9X0X1 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes*), CPT code 9X0X2 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*), and CPT code 9X0X3 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes*).

For CY 2020, we are proposing the RUC-recommended work RVUs of 0.25 for CPT code 9X0X1, 0.50 for CPT code 9X0X2, and 0.80 for CPT code 9X0X3. We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(74) Radiation Therapy Codes (HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017)

For CY 2015, CPT revised the radiation therapy code set for following identification of some of the codes as potentially misvalued and the affected specialty society's contention that the provision of radiation therapy could not be accurately reported under the existing code set. In the CY 2015 PFS final rule, we finalized that we were delaying implementation of this revised code set, citing concerns with our potentially having finalized a substantial coding revision on an interim final basis. In addition, we stated that substantial work needed to be done to assure the new valuations for these codes accurately reflect the coding changes. We finalized that we would maintain inputs at CY 2014 levels by creating G-codes as necessary to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. Following the publication of the CY 2015 PFS final rule, the Patient Access and Medicare Protection Act (Pub. L. 114–115, December 28, 2015) was enacted, which included the provision that the code definitions, the work relative value units and the direct inputs for the PE RVUs for radiation treatment delivery and related imaging services (identified in 2016 by HCPCS G-codes G6001 through G6015) for the fee schedule established under this subsection for services furnished in 2017 and 2018 shall be the same as such definitions, units, and inputs for such services for the fee schedule established for services furnished in 2016. In CY 2018, Congress extended this ''freeze'' in coding descriptions and inputs through CY 2019 as a provision of the Bipartisan Budget Act of 2018. For CY 2020, in the interest of payment stability, we are proposing to continue using these G-codes, as well as their current work RVUs and direct PE inputs. We are also proposing that, for CY 2020, our PE methodology will continue to include a utilization rate assumption of 60 percent for the equipment item: ER089, ''IMRT Accelerator.''

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TABLE 20: Proposed CY 2020 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
11981	Insertion, non-biodegradable drug delivery implant	1.48	1.30	1.14	No
11982	Removal, non-biodegradable drug delivery implant	1.78	1.70	1.34	No
11983	Removal with reinsertion, non-biodegradable drug delivery implant	3.30	2.10	1.91	No
15X00	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)	NEW	6.68	6.68	No
15X01	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate	NEW	6.73	6.73	No
15X02	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)	NEW	2.50	2.50	No
15X03	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate	NEW	6.83	6.83	No
15X04	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)	NEW	2.41	2.41	No
20220	Biopsy, bone, trocar, or needle; superficial (eg, ilium, sternum, spinous process, ribs)	1.27	1.93	1.65	No
20225	Biopsy, bone, trocar, or needle; deep (eg, vertebral body, femur)	1.87	3.00	2.45	No
205X1	Needle insertion(s) without injection(s); 1 or 2 muscle(s)	NEW	0.45	0.32	No
205X2	Needle insertion(s) without injection(s); 3 or more muscles	NEW	0.60	0.48	No
206X0	Manual preparation and insertion of drug-delivery device(s), deep (eg, subfascial) (List separately in addition to code for primary procedure)	NEW	1.50	1.32	No
206X1	Manual preparation and insertion of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)	NEW	2.50	1.70	No
206X2	Manual preparation and insertion of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure)	NEW	2.60	1.80	No
206X3	Removal of drug-delivery device(s), deep (eg, subfascial) (List separately in addition to code for primary procedure)	NEW	1.13	1.13	No
206X4	Removal of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)	NEW	1.80	1.80	No
206X5	Removal of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure)	NEW	2.15	2.15	No
22310	Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing	3.89	3.75	3.45	No
26020	Drainage of tendon sheath, digit and/or palm, each	5.08	7.79	6.84	No
26055	Tendon sheath incision (eg, for trigger finger)	3.11	3.75	3.11	No
26160	Excision of lesion of tendon sheath or joint capsule (eg, cyst, mucous cyst, or ganglion), hand or finger	3.57	3.57	3.57	No
27220	Closed treatment of acetabulum (hip socket) fracture(s); without manipulation	6.83	6.00	5.50	No
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	9.03	9.03	9.03	No
2XXX0	Excision of chest wall tumor including rib(s)	NEW		17.78	No
2XXX1	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	NEW		22.19	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
2XXX2	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	NEW		25.17	No
33020	Pericardiotomy for removal of clot or foreign body (primary procedure)	14.95	14.31	12.95	No
33025	Creation of pericardial window or partial resection for drainage	13.70	13.20	11.84	No
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	25.13	22.47	22.47	No
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	27.52	24.54	24.54	No
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	28.50	25.47	25.47	No
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	30.00	25.97	25.97	No
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)	33.12	26.59	26.59	No
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)	35.88	29.35	29.35	No
33863	Ascending aorta graft, with cardiopulmonary bypass, with aortic root replacement using valved conduit and coronary reconstruction (eg, Bentall)	58.79	59.00	58.79	No
33864	Ascending aorta graft, with cardiopulmonary bypass with valve suspension, with coronary reconstruction and valve-sparing aortic root remodeling (eg, David Procedure, Yacoub Procedure)	60.08	63.00	60.08	No
33866	Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)	19.74	17.75	17.75	No
338X1	Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic disease other than dissection (eg, aneurysm)	NEW	50.00	45.13	No
338X2	Transverse aortic arch graft, with cardiopulmonary bypass, with profound hypothermia, total circulatory arrest and isolated cerebral perfusion with reimplantation of arch vessel(s) (eg, island pedicle or individual arch vessel reimplantation)	NEW	65.75	60.88	No
338XX	Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic dissection	NEW	65.00	63.40	No
34X00	Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for rupture or other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer, traumatic disruption), unilateral (List separately in addition to code for primary procedure)	NEW	9.00	9.00	No
34X01	Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s)	NEW	24.00	24.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral				
35701	Exploration not followed by surgical repair, artery; neck (eg, carotid, subclavian)	9.19	7.50	7.50	No
35X00	Exploration not followed by surgical repair, artery; upper extremity (eg, axillary, brachial, radial, ulnar)	NEW	7.12	7.12	No
35X01	Exploration not followed by surgical repair, artery; lower extremity (eg, common femoral, deep femoral, superficial femoral, popliteal, tibial, peroneal)	NEW	7.50	7.50	No
37252	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel (List separately in addition to code for primary procedure)	1.80	1.80	1.55	No
37253	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure)	1.44	1.44	1.19	No
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions	7.71	4.80	4.80	No
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions	9.66	6.00	6.00	No
3X000	Pericardiocentesis, including imaging guidance, when performed	NEW	5.00	4.40	No
3X001	Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; 6 years and older without congenital cardiac anomaly	NEW	5.50	4.62	No
3X002	Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; birth through 5 years of age or any age with congenital cardiac anomaly	NEW	6.00	5.00	No
3X003	Pericardial drainage with insertion of indwelling catheter, percutaneous, including CT guidance	NEW	5.00	4.29	No
40808	Biopsy, vestibule of mouth	1.01	1.05	1.01	No
46945	Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group, without imaging guidance	2.21	3.69	3.69	No
46946	Hemorrhoidectomy, internal, by ligation other than rubber band; 2 or more hemorrhoid columns/groups, without imaging guidance	2.63	4.50	4.50	No
46X48	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed	NEW	5.57	5.57	No
490X1	Preperitoneal pelvic packing for hemorrhage associated with pelvic trauma, including local exploration	NEW	8.35	7.55	Yes
490X2	Re-exploration of pelvic wound with removal of preperitoneal pelvic packing, including repacking, when performed	NEW	6.73	5.70	No
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	4.50	4.50	4.00	No
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)	1.20	1.20	1.01	No
54640	Orchiopexy, inguinal or scrotal approach	7.73	7.73	7.73	No
62270	Spinal puncture, lumbar, diagnostic;	1.37	1.44	1.22	No
62272	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle	1.35	1.80	1.58	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	or catheter);				
622X0	Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance	NEW	1.95	1.73	No
622X1	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance	NEW	2.25	2.03	No
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill	0.48	0.48	0.48	No
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming	0.67	0.67	0.67	No
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill	0.67	0.67	0.67	No
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)	0.90	0.90	0.90	No
64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)	1.11	1.00	0.75	No
64408	Injection(s), anesthetic agent(s) and/or steroid; vagus nerve	1.41	0.90	0.75	No
64415	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus	1.48	1.42	1.35	No
64416	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)	1.81	1.81	1.48	No
64417	Injection(s), anesthetic agent(s) and/or steroid; axillary nerve	1.44	1.27	1.27	No
64420	Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level	1.18	1.18	1.08	No
64421	Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, each additional level (List separately in addition to code for primary procedure)	1.68	0.60	0.50	No
64425	Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves	1.75	1.19	1.00	No
64430	Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve	1.46	1.15	1.00	No
64435	Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve	1.45	0.75	0.75	No
64445	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve	1.48	1.18	1.00	No
64446	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)	1.81	1.54	1.36	No
64447	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve	1.50	1.10	1.10	No
64448	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement)	1.63	1.55	1.41	No
64449	Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)	1.81	1.55	1.27	No
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch	0.75	0.75	0.75	No
64640	#N/A	1.23	1.98	1.98	No
64XX0	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	NEW	1.52	1.52	No
64XX1	Destruction by neurolytic agent, genicular nerve branches, including imaging guidance, when performed	NEW	2.62	2.50	No
66711	Ciliary body destruction; cyclophotocoagulation, endoscopic, without concomitant removal of crystalline lens	7.93	6.36	5.62	No
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and	11.08	10.25	10.25	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation				
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)	10.43	C	C	No
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation	8.52	7.35	7.35	No
66X01	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	NEW	13.15	C	Yes
66X02	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	NEW	10.25	C	Yes
6XX00	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	NEW	1.52	1.52	No
6XX01	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	NEW	3.39	3.39	No
70210	Radiologic examination, sinuses, paranasal, less than 3 views	0.17	0.20	0.17	No
70220	Radiologic examination, sinuses, paranasal, complete, minimum of 3 views	0.25	0.22	0.22	No
70250	Radiologic examination, skull; less than 4 views	0.24	0.20	0.18	No
70260	Radiologic examination, skull; complete, minimum of 4 views	0.34	0.29	0.28	No
70360	Radiologic examination; neck, soft tissue	0.17	0.20	0.18	No
70480	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material	1.28	1.28	1.13	No
70481	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material(s)	1.38	1.13	1.06	No
70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material, followed by contrast material(s) and further sections	1.45	1.27	1.27	No
72020	Radiologic examination, spine, single view, specify level	0.15	0.16	0.16	No
72040	Radiologic examination, spine, cervical; 2 or 3 views	0.22	0.22	0.22	No
72050	Radiologic examination, spine, cervical; 4 or 5 views	0.31	0.27	0.27	No
72052	Radiologic examination, spine, cervical; 6 or more views	0.36	0.30	0.30	No
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.20	0.20	No
72072	Radiologic examination, spine; thoracic, 3 views	0.22	0.23	0.23	No
72074	Radiologic examination, spine; thoracic, minimum of 4 views	0.22	0.25	0.25	No
72080	Radiologic examination, spine; thoracolumbar junction, minimum of 2 views	0.22	0.21	0.21	No
72100	Radiologic examination, spine, lumbosacral; 2 or 3 views	0.22	0.22	0.22	No
72110	Radiologic examination, spine, lumbosacral; minimum of 4 views	0.31	0.26	0.26	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
72114	Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views	0.32	0.30	0.30	No
72120	Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views	0.22	0.22	0.22	No
72125	Computed tomography, cervical spine; without contrast material	1.07	1.07	1.00	No
72126	Computed tomography, cervical spine; with contrast material	1.22	1.22	1.22	No
72127	Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72128	Computed tomography, thoracic spine; without contrast material	1.00	1.00	1.00	No
72129	Computed tomography, thoracic spine; with contrast material	1.22	1.22	1.22	No
72130	Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72131	Computed tomography, lumbar spine; without contrast material	1.00	1.00	1.00	No
72132	Computed tomography, lumbar spine; with contrast material	1.22	1.22	1.22	No
72133	Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72170	Radiologic examination, pelvis; 1 or 2 views	0.17	0.17	0.17	No
72190	Radiologic examination, pelvis; complete, minimum of 3 views	0.21	0.25	0.25	No
72200	Radiologic examination, sacroiliac joints; less than 3 views	0.17	0.20	0.17	No
72202	Radiologic examination, sacroiliac joints; 3 or more views	0.19	0.26	0.23	No
72220	Radiologic examination, sacrum and coccyx, minimum of 2 views	0.17	0.20	0.17	No
73000	Radiologic examination; clavicle, complete	0.16	0.16	0.16	No
73010	Radiologic examination; scapula, complete	0.17	0.17	0.17	No
73020	Radiologic examination, shoulder; 1 view	0.15	0.15	0.15	No
73030	Radiologic examination, shoulder; complete, minimum of 2 views	0.18	0.18	0.18	No
73050	Radiologic examination; acromioclavicular joints, bilateral, with or without weighted distraction	0.20	0.18	0.18	No
73070	Radiologic examination, elbow; 2 views	0.15	0.16	0.16	No
73080	Radiologic examination, elbow; complete, minimum of 3 views	0.17	0.17	0.17	No
73090	Radiologic examination; forearm, 2 views	0.16	0.16	0.16	No
73650	Radiologic examination; calcaneus, minimum of 2 views	0.16	0.16	0.16	No
73660	Radiologic examination; toe(s), minimum of 2 views	0.13	0.13	0.13	No
73700	Computed tomography, lower extremity; without contrast material	1.00	1.00	1.00	No
73701	Computed tomography, lower extremity; with contrast material(s)	1.16	1.16	1.16	No
73702	Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further sections	1.22	1.22	1.22	No
74210	Radiologic examination, pharynx and/or cervical esophagus, including scout neck radiograph(s) and delayed image(s), when performed, contrast (eg, barium) study	0.59	0.59	0.59	No
74220	Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.67	0.60	0.60	No
74230	Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (eg, barium) study	0.53	0.53	0.53	No
74240	Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.69	0.80	0.80	No
74246	Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (eg, high-density barium and effervescent agent) study, including	0.69	0.90	0.90	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	glucagon, when administered				
74250	Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; single-contrast (eg, barium) study	0.47	0.81	0.81	No
74251	Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; double-contrast (eg, high-density barium and air via enteroclysis tube) study, including glucagon, when administered	0.69	1.17	1.17	No
74270	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.69	1.04	1.04	No
74280	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (eg, high density barium and air) study, including glucagon, when administered	0.99	1.26	1.26	No
74425	Urography, antegrade (pyelostogram, nephrostogram, loopogram), radiological supervision and interpretation	0.36	0.51	0.51	No
74X00	Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; double-contrast (eg, high-density barium and effervescent agent) study	NEW	0.70	0.70	No
74X01	Radiologic small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure for upper GI radiologic exam)	NEW	0.70	0.70	No
75625	Aortography, abdominal, by serialography, radiological supervision and interpretation	1.14	1.75	1.44	No
75630	Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation	1.79	2.00	2.00	No
75726	Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation	1.14	2.05	2.05	No
75774	Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure)	0.36	1.01	1.01	No
76098	Radiological examination, surgical specimen	0.16	0.31	0.31	No
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation	0.20	0.20	0.20	No
76604	Ultrasound, chest (includes mediastinum), real time with image documentation	0.55	0.59	0.59	No
77073	Bone length studies (orthoroentgenogram, scanogram)	0.27	0.26	0.26	No
77074	Radiologic examination, osseous survey; limited (eg, for metastases)	0.45	0.44	0.44	No
77075	Radiologic examination, osseous survey; complete (axial and appendicular skeleton)	0.54	0.55	0.55	No
77076	Radiologic examination, osseous survey, infant	0.70	0.70	0.70	No
77077	Joint survey, single view, 2 or more joints (specify)	0.31	0.33	0.33	No
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study;	1.50	1.61	1.25	No
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)	1.50	1.56	1.00	No
78492	Myocardial imaging, positron emission tomography (PET), perfusion	1.87	1.80	1.74	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)				
78800	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (eg, head, neck, chest, pelvis), single day of imaging	0.66	0.70	0.64	No
78801	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, 2 or more areas (eg, abdomen and pelvis, head and chest), 1 or more days of imaging or single area imaging over 2 or more days	0.79	0.79	0.73	No
78802	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, single day imaging	0.86	0.86	0.80	No
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis), single day of imaging	1.09	1.20	1.09	No
78804	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, requiring 2 or more days imaging	1.07	1.07	1.01	No
788X0	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis), single day of imaging	NEW	1.60	1.49	No
788X1	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days	NEW	1.93	1.82	No
788X2	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days imaging	NEW	2.23	2.12	No
788X3	Radiopharmaceutical quantification measurement(s) single area	NEW	0.51	0.47	No
78X29	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan	NEW	1.76	1.40	No
78X31	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography	NEW	1.67	1.11	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	transmission scan				
78X32	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	NEW	1.90	1.84	No
78X33	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	NEW	2.07	1.71	No
78X34	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	NEW	2.26	1.90	No
78X35	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)	NEW	0.63	0.42	No
88141	Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician	0.42	0.42	0.26	No
908XX	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	NEW	0.90	0.90	No
909XX	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)	NEW	0.50	0.50	No
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	0.17	0.10	0.10	No
92548	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report;	0.50	0.76	0.66	No
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or post-operative status of a surgically implanted device(s); first hour	1.40	1.40	1.40	No
92627	Evaluation of auditory function for surgically implanted device(s) candidacy or post-operative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)	0.33	0.33	0.33	No
92992	Atrial septectomy or septostomy; transvenous method, balloon (eg, Rashkind type) (includes cardiac catheterization)	C	C	C	No
92993	Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)	C	C	C	No
92X18	Ophthalmoscopy, extended; with retinal drawing and scleral depression, of peripheral retinal disease (eg, for retinal tear, retinal detachment, retinal tumor) with interpretation and report, unilateral or bilateral	NEW	0.40	0.40	No
92X19	Ophthalmoscopy, extended; with drawing of optic nerve or macula (eg, for glaucoma, macular pathology, tumor) with interpretation and report,	NEW	0.26	0.26	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	unilateral or bilateral				
92XX0	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)	NEW	0.96	0.86	No
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
933X0	Myocardial strain imaging using speckle–tracking derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)	NEW	0.24	0.24	No
93784	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report	0.38	0.38	0.38	No
93786	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; recording only	0.00	0.00	0.00	No
93788	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; scanning analysis with report	0.00	0.00	0.00	No
93790	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; review with interpretation and report	0.38	0.38	0.38	No
93X00	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	NEW	0.80	0.80	No
93X01	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	NEW	0.50	0.50	No
94200	Maximum breathing capacity, maximal voluntary ventilation	0.11	0.05	0.05	No
95X01	Electroencephalogram (EEG) continuous recording, with video when performed, setup, patient education, and takedown when performed, administered in person by EEG technologist, minimum of 8 channels	NEW	0.00	0.00	No
95X02	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; unmonitored	NEW	0.00	0.00	No
95X03	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95X04	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95X05	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored	NEW	0.00	0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
95X06	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95X07	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95X08	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; unmonitored	NEW	0.00	0.00	No
95X09	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95X10	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95X11	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored	NEW	0.00	0.00	No
95X12	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95X13	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95X14	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; without video	NEW	2.00	1.85	No
95X15	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; with video (VEEG)	NEW	2.50	2.35	No
95X16	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; without video	NEW	3.00	2.60	No
95X17	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; with video (VEEG)	NEW	3.86	3.50	No
95X18	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, without video	NEW	3.86	3.86	No
95X19	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, with video (VEEG)	NEW	4.70	4.70	No
95X20	Electroencephalogram, continuous recording, physician or other qualified	NEW	4.75	4.75	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, without video				
95X21	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, with video (VEEG)	NEW	6.00	6.00	No
95X22	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, without video	NEW	5.40	5.40	No
95X23	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, with video (VEEG)	NEW	7.58	7.58	No
961X0	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	NEW	2.10	2.10	No
961X1	Health behavior intervention, individual, face-to-face; initial 30 minutes	NEW	1.45	1.45	No
961X2	Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.50	0.50	No
961X3	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	NEW	0.21	0.21	No
961X4	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.10	0.10	No
961X5	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	NEW	1.55	1.55	No
961X6	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.55	0.55	No
961X7	Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes	NEW	1.50	1.50	No
961X8	Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.54	0.54	No
971XX	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes	NEW	0.50	0.50	No
97597	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less	0.51	0.88	0.77	No
97598	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm),	0.24	0.50	0.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)				
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters	C	0.41	0.41	No
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters	C	0.46	0.46	No
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	0.35	0.40	0.40	No
98X00	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	NEW	0.25	I	Yes
98X01	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	NEW	0.50	I	Yes
98X02	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	NEW	0.80	I	Yes
99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.	0.45	0.48	0.48	No
99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.	0.88	0.93	0.93	No
99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.	1.34	1.42	1.42	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.	2.56	2.60	2.60	No
99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.	3.80	3.80	3.80	No
99495	Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of at least moderate complexity during the service period Face-to-face visit, within 14 calendar days of discharge	2.11	2.36	2.36	No
99496	Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of high complexity during the service period Face-to-face visit, within 7 calendar days of discharge	3.05	3.10	3.10	No
994X0	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)	NEW	0.61	0.50	No
99X01	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration	NEW	0.00	0.00	No
99X02	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient	NEW	0.18	0.18	No
9X0X1	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	NEW	0.25	0.25	No
9X0X2	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	NEW	0.50	0.50	No
9X0X3	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	NEW	0.80	0.80	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
9XXX0	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	0.48	0.48	No
G0124	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician	0.42	0.42	0.26	No
G0141	Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician	0.42	0.42	0.26	No
GCCC1	Chronic care management services, first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; • chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; • comprehensive care plan established, implemented, revised, or monitored. (Chronic care management services of less than 20 minutes duration, in a calendar month, are not reported separately)	NEW		0.61	No
GCCC2	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Use GCCC2 in conjunction with GCCC1). (Do not report GCCC2 for care management services of less than 20 minutes additional to the first 20 minutes of chronic care management services during a calendar month).	NEW		0.54	No
GCCC3	Complex chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, • chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, • comprehensive care plan established, implemented, revised, or monitored, • moderate or high complexity medical decision making; • 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately).	NEW		1.00	No
GCCC4	Complex chronic care management services, each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3). (Do not report GCCC4 for care management services of less than 30 minutes additional to the first 60 minutes of complex chronic care management services during a calendar month).	NEW		0.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
GNPP1	Qualified nonphysician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	NEW		0.25	No
GNPP2	Qualified nonphysician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	NEW		0.44	No
GNPP3	Qualified nonphysician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	NEW		0.69	No
GPPP1	Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities	NEW		1.28	No
GPPP2	Comprehensive care management for a single high-risk disease services, e.g. Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: one complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities	NEW		0.61	No
GTTT1	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	NEW		0.00	No
GXXX1	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX2	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX3	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX4	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if	NEW		0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)				
GXXX5	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX6	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX7	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX8	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX9	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		C	No
GXX10	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX11	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX12	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX13	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode (only to be billed once every 6 months).	NEW		0.00	No
GXX14	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
GXX15	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX16	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX17	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX18	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		C	No
GXX19	Each additional 30 minutes of counseling in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW		0.00	No
GYYY1	Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.	NEW		7.06	No
GYYY2	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.	NEW		6.89	No
GYYY3	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes	NEW		0.82	No
P3001	Screening papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician	0.42	0.42	0.26	Yes

TABLE 21: Proposed CY 2020 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
20225	Bone biopsy trocar/nccdlc	SC077	needle, bone biopsy	NF		0	1	S8: Supply item replaces another item; see preamble SF055	68.50
20225	Bone biopsy trocar/needle	SF055	Bone biopsy device	NF		1	0	S7: Supply item replaced by another item; see preamble SC077	-158.43
22310	Closed tx vert fx w/o manj	EF031	table, power	NF		106	108	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
26055	Incise finger tendon sheath	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
26160	Remove tendon sheath lesion	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
27220	Treat hip socket fracture	EF031	table, power	NF		101	103	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
33863	Ascending aortic graft	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
33864	Ascending aortic graft	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
338X1	As-aort grf f/ds oth/thn dsj	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
338X2	Transvrs a-arch grf hypthrm	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
35701	Expl n/flwd surg neck art	EF023	table, exam	F		36	27	E15: Refined equipment time to conform to changes in clinical	-0.06

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								labor time	
35701	Expl n/flwd surg neck art	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	27	L9: Refined clinical labor to align with number of post-operative visits	-3.33
35X00	Expl n/flwd surg uxtr art	EF023	table, exam	F		36	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
35X00	Expl n/flwd surg uxtr art	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	27	L9: Refined clinical labor to align with number of post-operative visits	-3.33
35X01	Expl n/flwd surg lxtr art	EF023	table, exam	F		63	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.24
35X01	Expl n/flwd surg lxtr art	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	63	27	L9: Refined clinical labor to align with number of post-operative visits	-13.32
35X01	Expl n/flwd surg lxtr art	SA048	pack, minimum multi-specialty visit	F		2	1	S13: Refined supply quantity to align with number of post-operative visits	-3.08
40808	Biopsy of mouth lesion	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		17	29	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
40808	Biopsy of mouth lesion	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.37
40808	Biopsy of mouth lesion	L037D	RN/LPN/MTA	NF	Confirm order, protocol	1	0	G1: See preamble text	-0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					exam				
62370	Anl sp inf pmp w/mdreprg&fil	SA048	pack, minimum multi-specialty visit	NF		1	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-3.08
64400	Njx aa&/strd trigeminal nrv	EF015	mayo stand	NF		25	24	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64400	Njx aa&/strd trigeminal nrv	EF023	table, exam	NF		25	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64400	Njx aa&/strd trigeminal nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64408	Njx aa&/strd vagus nrv	EF008	chair with headrest, exam, reclining	NF		20	19	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64408	Njx aa&/strd vagus nrv	EF015	mayo stand	NF		20	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64408	Njx aa&/strd vagus nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64415	Njx aa&/strd brach plexus	EF015	mayo stand	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64415	Njx aa&/strd brach plexus	EF023	table, exam	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64415	Njx aa&/strd brach plexus	EQ011	ECG, 3-channel (with	NF		84	83	E15: Refined equipment time to conform to changes in clinical	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			SpO2, NIBP, temp, resp)					labor time	
64415	Njx aa&/strd brach plexus	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64417	Njx aa&/strd axillary nrv	EF015	mayo stand	NF		22	21	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64417	Njx aa&/strd axillary nrv	EF023	table, exam	NF		22	21	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64417	Njx aa&/strd axillary nrv	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		82	81	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64417	Njx aa&/strd axillary nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64420	Njx aa&/strd ntrcost nrv 1	EF015	mayo stand	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64420	Njx aa&/strd ntrcost nrv 1	EF023	table, exam	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64420	Njx aa&/strd ntrcost nrv 1	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	88	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64420	Njx aa&/strd ntrcost nrv 1	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64425	Njx aa&/strd ii ih nerves	EF015	mayo stand	NF		30	29	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64425	Njx aa&/strd ii ih nerves	EF023	table, exam	NF		30	29	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64425	Njx aa&/strd ii ih nerves	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		90	89	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64425	Njx aa&/strd ii ih nerves	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64430	Njx aa&/strd pudendal nerve	EF023	table, exam	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64430	Njx aa&/strd pudendal nerve	EF027	table, instrument, mobile	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64430	Njx aa&/strd pudendal nerve	EQ168	light, exam	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64430	Njx aa&/strd pudendal nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64435	Njx aa&/strd paracrv nrv	EF023	table, exam	NF		23	22	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64435	Njx aa&/strd paracrv nrv	EF027	table, instrument, mobile	NF		23	22	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64435	Njx aa&/strd	EQ168	light, exam	NF		23	22	E15: Refined equipment time to	0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	paracrv nrv							conform to changes in clinical labor time	
64435	Njx aa&/strd paracrv nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64445	Njx aa&/strd sciatic nerve	EF015	mayo stand	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64445	Njx aa&/strd sciatic nerve	EF023	table, exam	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64445	Njx aa&/strd sciatic nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	88	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64445	Njx aa&/strd sciatic nerve	EQ184	nerve stimulator (eg, for nerve block)	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64445	Njx aa&/strd sciatic nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64447	Njx aa&/strd femoral nerve	EF015	mayo stand	NF		18	17	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64447	Njx aa&/strd femoral nerve	EF023	table, exam	NF		18	17	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64447	Njx aa&/strd femoral nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		78	77	E15: Refined equipment time to conform to changes in clinical labor time	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64447	Njx aa&/strd femoral nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64450	Njx aa&/strd other pn/branch	EF015	mayo stand	NF		29	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64450	Njx aa&/strd other pn/branch	EF023	table, exam	NF		29	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
64450	Njx aa&/strd other pn/branch	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	84	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	F	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	NF	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly rclatcd to physician work time	10	5	L15: Refined clinical labor time to match intraservice work time	-1.85

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					(100% of physician intra-service time)				
64640	Injection treatment of nerve	EF015	mayo stand	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64640	Injection treatment of nerve	EF031	table, power	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
64640	Injection treatment of nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		64	59	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
64640	Injection treatment of nerve	EQ168	light, exam	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
64640	Injection treatment of nerve	EQ184	nerve stimulator (eg, for nerve block)	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64640	Injection treatment of nerve	EQ214	radiofrequency generator (NEURO)	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.68
64640	Injection treatment of nerve	EQ354	radiofrequency kit for destruction by neurolytic agent	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.20
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	F	Confirm availability of prior images/stu	2	0	G1: See preamble text	-0.74

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					dies				
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	NF	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (100% of physician intra-service time)	25	20	L15: Refined clinical labor time to match intraservice work time	-1.85
64XX1	Dstrj nulyt agt gnclr nrv	EQ354	radiofrequency kit for destruction by neurolytic agent	NF		141	47	G1: See preamble text	-3.80
64XX1	Dstrj nulyt agt gnclr nrv	SD011	cannula (radiofrequency denervation) (SMK-C10)	NF		3	1	G1: See preamble text	-49.23
66X01	Xcapsl ctrc rmvl cplx w/ecp	EL005	lane, exam (oph)	F		180	0	G1: See preamble text	-21.01
66X01	Xcapsl ctrc rmvl cplx w/ecp	EL006	lane, screening	F		27	0	G1: See preamble text	-3.06

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			(oph)						
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Coordinate pre-surgery services (including test results)	20	0	G1: See preamble text	-7.60
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Complete pre-service diagnostic and referral forms	5	0	G1: See preamble text	-1.90
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Schedule space and equipment in facility	8	0	G1: See preamble text	-3.04
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Provide pre-service education/obtain consent	20	0	G1: See preamble text	-7.60
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Post-operative visits (total time)	207	0	G1: See preamble text	-78.66
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Discharge day management	6	0	G1: See preamble text	-2.28
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Complete pre-procedure phone calls and prescriptio	7	0	G1: See preamble text	-2.66

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					n				
66X01	Xcapsl ctrc rmvl cplx w/ecp	SA050	pack, ophthalmology visit (no dilation)	F		1	0	G1: See preamble text	-1.95
66X01	Xcapsl ctrc rmvl cplx w/ecp	SA082	pack, ophthalmology visit (w-dilation)	F		5	0	G1: See preamble text	-14.77
66X02	Xcapsl ctrc rmvl w/ecp	EL005	lane, exam (oph)	F		144	0	G1: See preamble text	-16.81
66X02	Xcapsl ctrc rmvl w/ecp	EL006	lane, screening (oph)	F		27	0	G1: See preamble text	-3.06
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Complete pre-procedure phone calls and prescription	7	0	G1: See preamble text	-2.66
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Schedule space and equipment in facility	8	0	G1: See preamble text	-3.04
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Post-operative visits (total time)	171	0	G1: See preamble text	-64.98
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Discharge day management	6	0	G1: See preamble text	-2.28
66X02	Xcapsl ctrc rmvl	L038A	COMT/COT/	F	Complete	5	0	G1: See preamble text	-1.90

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	w/ecp		RN/CST		pre-service diagnostic and referral forms				
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/ RN/CST	F	Coordinate pre-surgery services (including test results)	20	0	G1: See preamble text	-7.60
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/ RN/CST	F	Provide pre-service education/obtain consent	20	0	G1: See preamble text	-7.60
66X02	Xcapsl ctrc rmvl w/ecp	SA050	pack, ophthalmology visit (no dilation)	F		1	0	G1: See preamble text	-1.95
66X02	Xcapsl ctrc rmvl w/ecp	SA082	pack, ophthalmology visit (w-dilation)	F		4	0	G1: See preamble text	-11.81
6XX00	Njx aa&/strd nrv nrvtg si jt	ED050	Technologist PACS workstation	NF		36	41	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
6XX00	Njx aa&/strd nrv nrvtg si jt	SC028	needle, 18-26g 1.5-3.5in, spinal	NF		3	1	G1: See preamble text	-13.27
6XX01	Rf abltj nrv nrvtg si jt	ED050	Technologist PACS workstation	NF		51	56	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
6XX01	Rf abltj nrv nrvtg si jt	EQ354	radiofrequency kit for destruction by	NF		164	82	G1: See preamble text	-3.31

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			neurolytic agent						
6XX01	Rf abltj nrv nrvtg si jt	SD011	cannula (radiofrequency denervation) (SMK-C10)	NF		4	2	G1: See preamble text	-49.23
70210	X-ray exam of sinuses	ED050	Technologist PACS workstation	NF		13	18	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
70220	X-ray exam of sinuses	ED050	Technologist PACS workstation	NF		16	21	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
74230	X-ray xm swlng funcj c+	ED050	Technologist PACS workstation	NF		30	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.07
74230	X-ray xm swlng funcj c+	EF008	chair with headrest, exam, reclining	NF		25	22	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
74230	X-ray xm swlng funcj c+	EL014	room, radiographic-fluoroscopic	NF		25	22	E15: Refined equipment time to conform to changes in clinical labor time	-5.94
74230	X-ray xm swlng funcj c+	L041B	Radiologic Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	3	2	L1: Refined time to standard for this clinical labor task	-0.41
74230	X-ray xm swlng funcj c+	L041B	Radiologic Technologist	NF	Prepare room, equipment and	4	2	L1: Refined time to standard for this clinical labor task	-0.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					supplies				
74250	X-ray exam of small bowel	EL014	room, radiographic-fluoroscopic	NF		29	26	E2: Refined equipment time to conform to established policies for highly technical equipment	-5.94
78459	Myocrd img pet single study	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.80
78459	Myocrd img pet single study	ED050	Technologist PACS workstation	NF		73	92	E18: Refined equipment time to conform to established policies for PACS Workstations	0.42
78459	Myocrd img pet single study	EF009	chair, medical recliner	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.06
78459	Myocrd img pet single study	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
78459	Myocrd img pet single study	ER027	dose calibrator (Atomlab)	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.43
78459	Myocrd img pet single study	ER033	gamma counter, automatic	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	1.17
78459	Myocrd img pet single study	ER054	radiation survey meter	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.05
78491	Myocrd img pet 1std rst/strs	ED020	computer workstation, nuclear	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.42

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			pharmacy management (hardware and software)						
78491	Myocrd img pet 1std rst/strs	ED050	Technologist PACS workstation	NF		73	85	E18: Refined equipment time to conform to established policies for PACS Workstations	0.26
78491	Myocrd img pet 1std rst/strs	ED053	Professional PACS Workstation	NF		17	19	E18: Refined equipment time to conform to established policies for PACS Workstations	0.12
78491	Myocrd img pet 1std rst/strs	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.04
78491	Myocrd img pet 1std rst/strs	ER027	dose calibrator (Atomlab)	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.23
78491	Myocrd img pet 1std rst/strs	ER033	gamma counter, automatic	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.62
78491	Myocrd img pet 1std rst/strs	ER054	radiation survey meter	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
78492	Myocrd img pet mlt rst&strs	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.42
78492	Myocrd img pet mlt rst&strs	ED050	Technologist PACS workstation	NF		103	117	E18: Refined equipment time to conform to established policies for PACS Workstations	0.31

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78492	Myocrd img pet mlt rst&strs	ED053	Professional PACS Workstation	NF		21	24	E18: Refined equipment time to conform to established policies for PACS Workstations	0.18
78492	Myocrd img pet mlt rst&strs	ER026	dosc calibration source vial set (Cs137, Co57, and Ba137)	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.04
78492	Myocrd img pet mlt rst&strs	ER027	dose calibrator (Atomlab)	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.23
78492	Myocrd img pet mlt rst&strs	ER033	gamma counter, automatic	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.62
78492	Myocrd img pet mlt rst&strs	ER054	radiation survey meter	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
78800	Rp loclzj tum 1 area 1 d img	ED019	computer workstation, nuclear medicine analysis-viewing	NF		51	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.21
78800	Rp loclzj tum 1 area 1 d img	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78800	Rp loclzj tum 1 area 1 d img	ED050	Technologist PACS workstation	NF		64	61	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.07
78800	Rp loclzj tum 1	EF009	chair, medical	NF		57	56	E15: Refined equipment time to	0.00

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	area 1 d img		recliner					conform to changes in clinical labor time	
78800	Rp loclzj tum 1 area 1 d img	ER016	collimator, medium energy (set of 2)	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78800	Rp loclzj tum 1 area 1 d img	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78800	Rp loclzj tum 1 area 1 d img	ER027	dose calibrator (Atomlab)	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
78800	Rp loclzj tum 1 area 1 d img	ER032	gamma camera system, single-dual head	NF		51	50	E15: Refined equipment time to conform to changes in clinical labor time	-2.14
78800	Rp loclzj tum 1 area 1 d img	ER033	gamma counter, automatic	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
78800	Rp loclzj tum 1 area 1 d img	ER053	radiation L-block tabletop shield	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78800	Rp loclzj tum 1 area 1 d img	ER054	radiation survey meter	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78800	Rp loclzj tum 1 arca 1 d img	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and	3	2	L1: Refined time to standard for this clinical labor task	-0.62

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					monitoring of patient				
78801	Rp loclzj tum 2+area 1+d img	ED019	computer workstation, nuclear medicine analysis-viewing	NF		58	57	E15: Refined equipment time to conform to changes in clinical labor time	-0.21
78801	Rp loclzj tum 2+area 1+d img	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78801	Rp loclzj tum 2+area 1+d img	ED050	Technologist PACS workstation	NF		75	72	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.07
78801	Rp loclzj tum 2+area 1+d img	EF009	chair, medical recliner	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78801	Rp loclzj tum 2+area 1+d img	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78801	Rp loclzj tum 2+area 1+d img	ER027	dose calibrator (Atomlab)	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
78801	Rp loclzj tum 2+area 1+d img	ER032	gamma camera system, single-dual head	NF		58	57	E15: Refined equipment time to conform to changes in clinical labor time	-2.14

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78801	Rp loclzj tum 2+area 1+d img	ER033	gamma counter, automatic	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
78801	Rp loclzj tum 2+area 1+d img	ER053	radiation L-block tabletop shield	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78801	Rp loclzj tum 2+area 1+d img	ER054	radiation survey meter	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78801	Rp loclzj tum 2+area 1+d img	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	3	2	L1: Refined time to standard for this clinical labor task	-0.62
78801	Rp loclzj tum 2+area 1+d img	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
78802	Rp loclzj tum whbdy 1 d img	ED019	computer workstation, nuclear medicine analysis-viewing	NF		68	67	E15: Refined equipment time to conform to changes in clinical labor time	-0.21
78802	Rp loclzj tum whbdy 1 d img	ED020	computer workstation, nuclear pharmacy management (hardware and	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	-0.05

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			software)						
78802	Rp loclzj tum whbdy 1 d img	ED050	Technologist PACS workstation	NF		85	82	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.07
78802	Rp loclzj tum whbdy 1 d img	EF009	chair, medical recliner	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78802	Rp loclzj tum whbdy 1 d img	ER016	collimator, medium energy (set of 2)	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78802	Rp loclzj tum whbdy 1 d img	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78802	Rp loclzj tum whbdy 1 d img	ER027	dose calibrator (Atomlab)	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
78802	Rp loclzj tum whbdy 1 d img	ER032	gamma camera system, single-dual head	NF		68	67	E15: Refined equipment time to conform to changes in clinical labor time	-2.14
78802	Rp loclzj tum whbdy 1 d img	ER033	gamma counter, automatic	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
78802	Rp loclzj tum whbdy 1 d img	ER053	radiation L-block tabletop shield	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78802	Rp loclzj tum whbdy 1 d img	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial	3	2	L1: Refined time to standard for this clinical labor task	-0.62

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					positioning and monitoring of patient				
78803	Rp loclzj tum spect 1 area	ED019	computer workstation, nuclear medicine analysis-viewing	NF		89	86	E15: Refined equipment time to conform to changes in clinical labor time	-0.63
78803	Rp loclzj tum spect 1 area	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.16
78803	Rp loclzj tum spect 1 area	ED050	Technologist PACS workstation	NF		103	98	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.11
78803	Rp loclzj tum spect 1 area	ED053	Professional PACS Workstation	NF		30	27	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
78803	Rp loclzj tum spect 1 area	EF009	chair, medical recliner	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
78803	Rp loclzj tum spect 1 area	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
78803	Rp loclzj tum spect 1 area	ER027	dosc calibrator (Atomlab)	NF		95	92	E15: Rcfincd cquipmcnt timc to conform to changes in clinical labor time	-0.09

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
78803	Rp loclzj tum spect 1 area	ER032	gamma camera system, single-dual head	NF		89	86	E15: Refined equipment time to conform to changes in clinical labor time	-6.42
78803	Rp loclzj tum spect 1 area	ER033	gamma counter, automatic	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.23
78803	Rp loclzj tum spect 1 area	ER053	radiation L-block tabletop shield	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
78803	Rp loclzj tum spect 1 area	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	5	2	L1: Refined time to standard for this clinical labor task	-1.85
78804	Rp loclzj tum whbdy 2+d img	ED019	computer workstation, nuclear medicine analysis-viewing	NF		163	162	E15: Refined equipment time to conform to changes in clinical labor time	-0.21
78804	Rp loclzj tum whbdy 2+d img	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78804	Rp loclzj tum whbdy 2+d img	ED050	Technologist PACS	NF		185	182	E18: Refined equipment time to conform to established policies for	-0.07

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			workstation					PACS Workstations	
78804	Rp loclzj tum whbdy 2+d img	ED053	Professional PACS Workstation	NF		23	20	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
78804	Rp loclzj tum whbdy 2+d img	EF009	chair, medical recliner	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78804	Rp loclzj tum whbdy 2+d img	ER016	collimator, medium energy (set of 2)	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78804	Rp loclzj tum whbdy 2+d img	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78804	Rp loclzj tum whbdy 2+d img	ER027	dose calibrator (Atomlab)	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
78804	Rp loclzj tum whbdy 2+d img	ER032	gamma camera system, single-dual head	NF		163	162	E15: Refined equipment time to conform to changes in clinical labor time	-2.14
78804	Rp loclzj tum whbdy 2+d img	ER033	gamma counter, automatic	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
78804	Rp loclzj tum whbdy 2+d img	ER053	radiation L-block tabletop shield	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78804	Rp loclzj tum whbdy 2+d img	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial	3	2	L1: Refined time to standard for this clinical labor task	-0.62

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					positioning and monitoring of patient				
78804	Rp loclzj tum whbdy 2+d img	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
788X0	Rp loclzj tum spect w/ct 1	ED019	computer workstation, nuclear medicine analysis-viewing	NF		99	96	E15: Refined equipment time to conform to changes in clinical labor time	-0.63
788X0	Rp loclzj tum spect w/ct 1	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.16
788X0	Rp loclzj tum spect w/ct 1	ED050	Technologist PACS workstation	NF		114	109	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.11
788X0	Rp loclzj tum spect w/ct 1	ED053	Professional PACS Workstation	NF		33	30	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
788X0	Rp loclzj tum spect w/ct 1	EF009	chair, medical recliner	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
788X0	Rp loclzj tum spect w/ct 1	ER026	dosc calibration source vial set	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			(Cs137, Co57, and Ba137)						
788X0	Rp loclzj tum spect w/ct 1	ER027	dose calibrator (Atomlab)	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
788X0	Rp loclzj tum spect w/ct 1	ER033	gamma counter, automatic	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.23
788X0	Rp loclzj tum spect w/ct 1	ER053	radiation L-block tabletop shield	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
788X0	Rp loclzj tum spect w/ct 1	ER097	gamma camera system, single-dual head SPECT CT	NF		99	96	E15: Refined equipment time to conform to changes in clinical labor time	-5.28
788X0	Rp loclzj tum spect w/ct 1	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	5	2	L1: Refined time to standard for this clinical labor task	-1.85
788X1	Rp loclzj tum spect 2 areas	ED019	computer workstation, nuclear medicine analysis-viewing	NF		175	170	E15: Refined equipment time to conform to changes in clinical labor time	-1.04
788X1	Rp loclzj tum spect 2 areas	ED020	computer workstation, nuclear	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.27

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			pharmacy management (hardware and software)						
788X1	Rp loclzj tum spect 2 areas	ED050	Technologist PACS workstation	NF		194	187	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.15
788X1	Rp loclzj tum spect 2 areas	ED053	Professional PACS Workstation	NF		38	35	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
788X1	Rp loclzj tum spect 2 areas	EF009	chair, medical recliner	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
788X1	Rp loclzj tum spect 2 areas	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
788X1	Rp loclzj tum spect 2 areas	ER027	dose calibrator (Atomlab)	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.14
788X1	Rp loclzj tum spect 2 areas	ER032	gamma camera system, single-dual head	NF		175	170	E15: Refined equipment time to conform to changes in clinical labor time	-10.70
788X1	Rp loclzj tum spect 2 areas	ER033	gamma counter, automatic	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.39
788X1	Rp loclzj tum spect 2 areas	ER053	radiation L-block tabletop shield	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
788X1	Rp loclzj tum spect 2 areas	L049A	Nuclear Medicine	NF	Prepare, set-up and	7	2	L1: Refined time to standard for this clinical labor task	-3.08

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			Technologist		start IV, initial positioning and monitoring of patient				
788X2	Rp loclzj tum spect w/ct 2	ED019	computer workstation, nuclear medicine analysis-viewing	NF		200	195	E15: Refined equipment time to conform to changes in clinical labor time	-1.04
788X2	Rp loclzj tum spect w/ct 2	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.27
788X2	Rp loclzj tum spect w/ct 2	ED050	Technologist PACS workstation	NF		227	220	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.15
788X2	Rp loclzj tum spect w/ct 2	ED053	Professional PACS Workstation	NF		43	40	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
788X2	Rp loclzj tum spect w/ct 2	EF009	chair, medical recliner	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
788X2	Rp loclzj tum spect w/ct 2	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
788X2	Rp loclzj tum	ER027	dose	NF		212	207	E15: Refined equipment time to	-0.14

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	spect w/ct 2		calibrator (Atomlab)					conform to changes in clinical labor time	
788X2	Rp loclzj tum spect w/ct 2	ER033	gamma counter, automatic	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.39
788X2	Rp loclzj tum spect w/ct 2	ER053	radiation L-block tabletop shield	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
788X2	Rp loclzj tum spect w/ct 2	ER097	gamma camera system, single-dual head SPECT CT	NF		200	195	E15: Refined equipment time to conform to changes in clinical labor time	-8.80
788X2	Rp loclzj tum spect w/ct 2	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	7	2	L1: Refined time to standard for this clinical labor task	-3.08
788X2	Rp loclzj tum spect w/ct 2	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
78X29	Myocrd img pet 1 std w/ct	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.80

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
78X29	Myocrd img pet 1 std w/ct	ED050	Technologist PACS workstation	NF		83	103	E18: Refined equipment time to conform to established policies for PACS Workstations	0.44
78X29	Myocrd img pet 1 std w/ct	ED053	Professional PACS Workstation	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.12
78X29	Myocrd img pet 1 std w/ct	EF009	chair, medical recliner	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.06
78X29	Myocrd img pet 1 std w/ct	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
78X29	Myocrd img pet 1 std w/ct	ER027	dose calibrator (Atomlab)	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.43
78X29	Myocrd img pet 1 std w/ct	ER033	gamma counter, automatic	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	1.17
78X29	Myocrd img pet 1 std w/ct	ER054	radiation survey meter	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.05
78X31	Myocrd img pet rst/strs w/ct	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.42
78X31	Myocrd img pet rst/strs w/ct	ED050	Technologist PACS workstation	NF		83	96	E18: Refined equipment time to conform to established policies for PACS Workstations	0.29
78X31	Myocrd img pet	ED053	Professional	NF		19	21	E18: Refined equipment time to	0.12

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	rst/strs w/ct		PACS Workstation					conform to established policies for PACS Workstations	
78X31	Myocrd img pet rst/strs w/ct	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.04
78X31	Myocrd img pet rst/strs w/ct	ER027	dose calibrator (Atomlab)	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.23
78X31	Myocrd img pet rst/strs w/ct	ER033	gamma counter, automatic	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.62
78X31	Myocrd img pet rst/strs w/ct	ER054	radiation survey meter	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
78X32	Myocrd img pet rst&strs ct	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.42
78X32	Myocrd img pet rst&strs ct	ED050	Technologist PACS workstation	NF		123	137	E18: Refined equipment time to conform to established policies for PACS Workstations	0.31
78X32	Myocrd img pet rst&strs ct	ED053	Professional PACS Workstation	NF		24	25	E18: Refined equipment time to conform to established policies for PACS Workstations	0.06
78X32	Myocrd img pet rst&strs ct	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.04

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
78X32	Myocrd img pet rst&strs ct	ER027	dose calibrator (Atomlab)	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.23
78X32	Myocrd img pet rst&strs ct	ER033	gamma counter, automatic	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.62
78X32	Myocrd img pet rst&strs ct	ER054	radiation survey meter	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
78X33	Myocrd img pet 2rtracer	ED019	computer workstation, nuclear medicine analysis-viewing	NF		175	150	E2: Refined equipment time to conform to established policies for highly technical equipment	-5.22
78X33	Myocrd img pet 2rtracer	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		146	164	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.96
78X33	Myocrd img pet 2rtracer	ED053	Professional PACS Workstation	NF		25	27	E18: Refined equipment time to conform to established policies for PACS Workstations	0.12
78X33	Myocrd img pet 2rtracer	EF009	chair, medical recliner	NF		146	164	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
78X33	Myocrd img pet 2rtracer	EQ007	ECG R-wave trigger (gating) device	NF		175	150	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.46
78X33	Myocrd img pet 2rtracer	ER026	dose calibration	NF		146	164	E1: Refined equipment time to conform to established policies for	0.08

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			source vial set (Cs137, Co57, and Ba137)					non-highly technical equipment	
78X33	Myocrd img pet 2rtracer	ER027	dosc calibrator (Atomlab)	NF		146	164	E1: Rcfincd cquipmcnt timc to conform to established policies for non-highly technical equipment	0.52
78X33	Myocrd img pet 2rtracer	ER033	gamma counter, automatic	NF		146	164	E1: Refined equipment time to conform to established policies for non-highly technical equipment	1.40
78X33	Myocrd img pet 2rtracer	ER054	radiation survey meter	NF		146	164	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.06
78X33	Myocrd img pet 2rtracer	ER109	PET Generator Infusion Cart	NF		175	150	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.02
78X33	Myocrd img pet 2rtracer	ER110	PET Refurbished Imaging Cardiac Configuration	NF		175	150	E2: Refined equipment time to conform to established policies for highly technical equipment	-22.37
78X33	Myocrd img pet 2rtracer	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
78X34	Myocrd img pet 2rtracer ct	ED019	computer workstation, nuclear medicine analysis-viewing	NF		195	170	E2: Refined equipment time to conform to established policies for highly technical equipment	-5.22
78X34	Myocrd img pet 2rtracer ct	ED020	computer workstation, nuclear	NF		166	184	E1: Rcfincd cquipmcnt timc to conform to established policies for non-highly technical equipment	0.96

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			pharmacy management (hardware and software)						
78X34	Myocrd img pet 2rtracer ct	ED053	Professional PACS Workstation	NF		25	29	E18: Refined equipment time to conform to established policies for PACS Workstations	0.24
78X34	Myocrd img pet 2rtracer ct	EF009	chair, medical recliner	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
78X34	Myocrd img pet 2rtracer ct	EQ007	ECG R-wave trigger (gating) device	NF		195	170	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.46
78X34	Myocrd img pet 2rtracer ct	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.08
78X34	Myocrd img pet 2rtracer ct	ER027	dose calibrator (Atomlab)	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.52
78X34	Myocrd img pet 2rtracer ct	ER033	gamma counter, automatic	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	1.40
78X34	Myocrd img pet 2rtracer ct	ER054	radiation survey meter	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.06
78X34	Myocrd img pet 2rtracer ct	ER109	PET Generator Infusion Cart	NF		195	170	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.02
78X34	Myocrd img pet 2rtracer ct	ER111	PET/CT Imaging Camera	NF		195	170	E2: Refined equipment time to conform to established policies for highly technical equipment	-64.85

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			Cardiac Configuration						
78X34	Myocrd img pet 2rtracer ct	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
78X35	Aqmbf pet rest & rx stress	ED019	computer workstation, nuclear medicine analysis-viewing	NF		23	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.63
78X35	Aqmbf pet rest & rx stress	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		20	21	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.05
78X35	Aqmbf pet rest & rx stress	EQ007	ECG R-wave trigger (gating) device	NF		23	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.05
78X35	Aqmbf pet rest & rx stress	ER109	PET Generator Infusion Cart	NF		23	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.36
78X35	Aqmbf pet rest & rx stress	ER111	PET/CT Imaging Camera Cardiac Configuration	NF		23	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-7.78
88141	Cytopath c/v interpret	EP024	microscope, compound	NF		14	10	G1: See preamble text	-0.13

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88141	Cytopath c/v interpret	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
88141	Cytopath c/v interpret	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90
908XX	Bfb training 1st 15 min	EF031	table, power	NF		31	29	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
93297	Icm device interrogat remotc	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		40	0	G1: See preamble text	-18.51
93297	Icm device interrogat remote	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	40	0	G1: See preamble text	-14.80
93297	Icm device interrogat remote	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93298	Ilr device	EQ198	pacemaker	NF		76	0	G1: See preamble text	-35.17

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	interrogat remote		follow-up system (incl software and hardware) (Paceart)						
93298	Ilr device interrogat remote	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	76	0	G1: See preamble text	-28.12
93298	Ilr device interrogat remote	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93299	Icm/ilr remote tech serv	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		76	0	G1: See preamble text	-35.17
93299	Icm/ilr remote tech serv	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	76	0	G1: See preamble text	-28.12
93299	Icm/ilr remote tech serv	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93X00	Dup-scan hemo	ED050	Technologist	NF		101	99	E15: Refined equipment time to	-0.04

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	compl bi std		PACS workstation					conform to changes in clinical labor time	
93X00	Dup-scan hemo compl bi std	EL016	room, ultrasound, vascular	NF		86	84	E15: Refined equipment time to conform to changes in clinical labor time	-3.57
93X00	Dup-scan hemo compl bi std	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	4	2	L1: Refined time to standard for this clinical labor task	-1.08
93X01	Dup-scan hemo compl uni std	ED050	Technologist PACS workstation	NF		60	58	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
93X01	Dup-scan hemo compl uni std	EL016	room, ultrasound, vascular	NF		47	45	E15: Refined equipment time to conform to changes in clinical labor time	-3.57
93X01	Dup-scan hemo compl uni std	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	4	2	L1: Refined time to standard for this clinical labor task	-1.08
95X01	Eeg cont rec w/vid eeg tech	L047B	REEGT	NF	Complete pre-procedure phone calls and prescription	10	3	G1: See preamble text	-3.29
95X01	Eeg cont rec w/vid eeg tech	L047B	REEGT	NF	Provide education/obtain consent	13	7	G1: See preamble text	-2.82
95X01	Eeg cont rec w/vid eeg tech	L047B	REEGT	NF	Review home care	10	7	G1: See preamble text	-1.41

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					instructions, coordinate visits/prescriptions				
95X01	Eeg cont rec w/vid eeg tech	SB022	gloves, non-sterile	NF		3	2	S6: Refined supply quantity to what is typical for the procedure	-0.19
95X02	Eeg w/o vid 2-12 hr unmntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X02	Eeg w/o vid 2-12 hr unmntr	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X03	Eeg wo vid 2-12hr intmt mntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X03	Eeg wo vid 2-12hr intmt mntr	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X04	Eeg w/o vid 2-12hr cont mntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X04	Eeg w/o vid 2-12hr cont mntr	EQ016	EEG review station, ambulatory	NF		510	150	G1: See preamble text	-11.34
95X04	Eeg w/o vid 2-12hr cont mntr	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X05	Eeg wo vid ea 12-26hr unmntr	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
95X05	Eeg wo vid ea 12-26hr unmntr	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X06	Eeg w/o vid ea 12-26hr intmt	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X06	Eeg w/o vid ea 12-26hr intmt	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X07	Eeg w/o vid ea 12-26hr cont	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X07	Eeg w/o vid ea 12-26hr cont	EQ016	EEG review station, ambulatory	NF		1480	400	G1: See preamble text	-34.02
95X07	Eeg w/o vid ea 12-26hr cont	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X08	Veeg 2-12 hr unmonitored	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X08	Veeg 2-12 hr unmonitored	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X09	Veeg 2-12 hr intmt mntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X09	Veeg 2-12 hr intmt mntr	L047B	REEGT	NF	Coordinate post-procedure	11	5	G1: See preamble text	-2.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					services				
95X10	Veeg 2-12 hr cont mntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X10	Veeg 2-12 hr cont mntr	EQ016	EEG review station, ambulatory	NF		514	154	G1: See preamble text	-11.34
95X10	Veeg 2-12 hr cont mntr	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X11	Veeg ea 12-26 hr unmntr	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X11	Veeg ea 12-26 hr unmntr	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X12	Veeg ea 12-26hr intmt mntr	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X12	Veeg ea 12-26hr intmt mntr	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X13	Veeg ea 12-26hr cont mntr	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X13	Veeg ea 12-26hr cont mntr	EQ016	EEG review station, ambulatory	NF		1495	415	G1: See preamble text	-34.02
95X13	Veeg ea 12-26hr cont mntr	L047B	REEGT	NF	Coordinate post-procedure	22	10	G1: See preamble text	-5.64

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					services				
95X14	Eeg phys/qhp 2-12 hr w/o vid	EQ016	EEG review station, ambulatory	NF		48	32	G1: See preamble text	-0.50
95X15	Eeg phys/qhp 2-12 hr w/veeg	EQ016	EEG review station, ambulatory	NF		55	40	G1: See preamble text	-0.47
95X16	Eeg phys/qhp ea incr w/o vid	EQ016	EEG review station, ambulatory	NF		60	45	G1: See preamble text	-0.47
95X17	Eeg phy/qhp ea incr w/veeg	EQ016	EEG review station, ambulatory	NF		75	60	G1: See preamble text	-0.47
95X18	Eeg phy/qhp>36<60 hr w/o vid	EQ016	EEG review station, ambulatory	NF		85	70	G1: See preamble text	-0.47
95X19	Eeg phy/qhp>36<60 hr w/veeg	EQ016	EEG review station, ambulatory	NF		100	85	G1: See preamble text	-0.47
95X20	Eeg phy/qhp>60<84 hr w/o vid	EQ016	EEG review station, ambulatory	NF		110	95	G1: See preamble text	-0.47
95X21	Eeg phy/qhp>60<84 hr w/veeg	EQ016	EEG review station, ambulatory	NF		130	115	G1: See preamble text	-0.47
95X22	Eeg phy/qhp>84 hr w/o vid	EQ016	EEG review station, ambulatory	NF		130	115	G1: See preamble text	-0.47
95X23	Eeg phy/qhp>84 hr w/veeg	EQ016	EEG review station, ambulatory	NF		160	145	G1: See preamble text	-0.47
97607	Neg press wnd tx </=50 sq cm	EF014	light, surgical	NF		23	20	E15: Refined equipment time to conform to changes in clinical labor time	-0.02

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97607	Neg press wnd tx </=50 sq cm	EF031	table, power	NF		23	20	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
97607	Neg press wnd tx </=50 sq cm	L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	L1: Refined time to standard for this clinical labor task	-1.11
97608	Neg press wound tx >50 cm	EF014	light, surgical	NF		31	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
97608	Neg press wound tx >50 cm	EF031	table, power	NF		31	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
97608	Neg press wound tx >50 cm	L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	L1: Refined time to standard for this clinical labor task	-1.11
G0124	Screen c/v thin layer by md	EP024	microscope, compound	NF		14	10	G1: See preamble text	-0.13
G0124	Screen c/v thin layer by md	L033A	Lab Technician	NF	File specimen, supplies,	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for	-0.33

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					and other materials			a particular service	
G0124	Screen c/v thin layer by md	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90
G0141	Scr c/v cyto,autosys and md	EP024	microscope, compound	NF		14	10	G1: See preamble text	-0.13
G0141	Scr c/v cyto,autosys and md	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
G0141	Scr c/v cyto,autosys and md	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90
P3001	Screening pap smear by phys	EP024	microscope, compound	NF		16	10	G1: See preamble text	-0.19
P3001	Screening pap smear by phys	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
P3001	Screening pap	L045A	Cytotechnolog	NF	Perform	7	5	G1: See preamble text	-0.90

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	smear by phys		ist		regulatory mandated quality assurance activity (service period)				

TABLE 22: Proposed CY 2020 Invoices Received for Existing Direct PE Inputs

CPT/ HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
52441, 52442	Urolift Implant and implantation device	SD291	$814.89	$875.00	7%	3	24,149
92546, 92548, 92XX0	CDP-computerized dynamic posturography system	EQ002	$68,842.62	$86,334.50	25%	6	80,359

TABLE 23: Proposed CY 2020 New Invoices

CPT/ HCPCS codes	Item Name	CMS code	Average price	Number of Invoices	NF Allowed Services
15X01, 15X03	Liposuction system	EQ395	$22,039.05	1	1,565
205X1, 205X2	needle, dry needling	SC107	$0.25	3	8
37765, 37766	tumescent tubing	SD333	$11.00	3	18,700
37765, 37766	tumescent pump	EQ393	$1,750.00	1	18,700
64430, 64435	pudendal block tray, sterile	SA129	$5.24	1	1,254
78459, 78491, 78492, 78X33	PET Refurbished Imaging Cardiac Configuration	ER110	$425,000.00	1	65,277
78491, 78492, 78X31, 78X32, 78X33, 78X34	IV line kit for Rb Generator	SA130	$16.98	7	130,539
78491, 78492, 78X31, 78X32, 78X33, 78X34, 78X35	PET Generator Infusion Cart	ER109	$47,052.80	5	130,585
78X29, 78X31, 78X32, 78X34, 78X35	PET/CT Imaging Camera Cardiac Configuration	ER111	$1,232,226.44	4	65,798
788X3	Software and hardware package for tumor and other distribution Quantitation	ER112	$40,535.75	4	23
95X01, 95X11, 95X12, 95X13	EEG, digital, prolonged testing system with remote video, for patients home use	EQ394	$26,410.95	2	251,218
97607, 97608	kit, negative pressure wound therapy, disposable	SA131	$100.00	0	759

TABLE 24: Proposed CY 2020 No PE Refinements

HCPCS	Description
11981	Insert drug implant device
11982	Remove drug implant device
11983	Remove/insert drug implant
15X00	grfg autol soft tiss dir exc
15X01	grfg autol fat lipo 50 cc/<
15X02	grfg autol fat lipo ea addl
15X03	grfg autol fat lipo 25 cc/<
15X04	gfrg autol fat lipo ea addl
20220	Bone biopsy trocar/needle
205X1	Ndl insj w/o njx 1 or 2 musc
205X2	Ndl insj w/o njx 3+ musc
206X0	Mnl prep&insj dp rx dlvr dev
206X1	Mnl prep&insj imed rx dev
206X2	Mnl prep&insj i-artic rx dev
206X3	Rmvl deep rx delivery device
206X4	Rmvl imed rx delivery device
206X5	Rmvl i-artic rx delivery dev
26020	Drain hand tendon sheath
27279	Arthrodesis sacroiliac joint
33020	Incision of heart sac
33025	Incision of heart sac
33361	Replace aortic valve perq
33362	Replace aortic valve open
33363	Replace aortic valve open
33364	Replace aortic valve open
33365	Replace aortic valve open
33366	Trcath replace aortic valve
33866	Aortic hemiarch graft
338XX	As-aort grf f/aortic dsj
34X00	Evasc rpr a-iliac ndgft
34X01	Evasc rpr n/a a-iliac ndgft
37252	Intrvasc us noncoronary 1st
37253	Intrvasc us noncoronary addl
37765	Stab phleb veins xtr 10-20
37766	Phleb veins - extrem 20+
3X000	Pericardiocentesis w/imaging
3X001	Prcrd drg 6yr+ w/o cgen car
3X002	Prcrd drg 0-5yr or w/anomly
3X003	Perq prcrd drg insj cath ct
46945	Int hrhc lig 1 hroid w/o img
46946	Int hrhc lig 2+hroid w/o img
46X48	Int hrhc tranal dartlzj 2+
490X1	Prpertl pel pack hemrrg trma
490X2	Reexploration pelvic wound
52441	Cystourethro w/implant
52442	Cystourethro w/addl implant

HCPCS	Description
54640	Orchiopexy ingun/scrot appr
62270	Dx lmbr spi pnxr
62272	Ther spi pnxr drg csf
622X0	Dx lmbr spi pnxr w/fluor/ct
622X1	Ther spi pnxr csf fluor/ct
62367	Analyze spine infus pump
62368	Analyze sp inf pump w/reprog
62369	Anal sp inf pmp w/reprg&fill
64421	Njx aa&/strd ntrcost nrv ea
64449	Njx aa&/strd lmbr plex nfs
64XX0	Njx aa&/strd gnclr nrv brnch
66711	Ecp ciliary body destruction
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
70210	X-ray exam of sinuses
70220	X-ray exam of sinuses
70250	X-ray exam of skull
70260	X-ray exam of skull
70360	X-ray exam of neck
70480	Ct orbit/ear/fossa w/o dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o&w/dye
72020	X-ray exam of spine 1 view
72040	X-ray exam neck spine 2-3 vw
72050	X-ray exam neck spine 4/5vws
72052	X-ray exam neck spine 6/>vws
72070	X-ray exam thorac spine 2vws
72072	X-ray exam thorac spine 3vws
72074	X-ray exam thorac spine4/>vw
72080	X-ray exam thoracolmb 2/> vw
72100	X-ray exam l-s spine 2/3 vws
72110	X-ray exam l-2 spine 4/>vws
72114	X-ray exam l-s spine bending
72120	X-ray bend only l-s spine
72125	Ct neck spine w/o dye
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72128	Ct chest spine w/o dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72131	Ct lumbar spine w/o dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72170	X-ray exam of pelvis
72190	X-ray exam of pelvis
72200	X-ray exam si joints

HCPCS	Description
72202	X-ray exam si joints 3/> vws
72220	X-ray exam sacrum tailbone
73000	X-ray exam of collar bone
73010	X-ray exam of shoulder blade
73020	X-ray exam of shoulder
73030	X-ray exam of shoulder
73050	X-ray exam of shoulders
73070	X-ray exam of elbow
73080	X-ray exam of elbow
73090	X-ray exam of forearm
73650	X-ray exam of heel
73660	X-ray exam of toe(s)
73700	Ct lower extremity w/o dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o&w/dye
74210	X-ray xm phrnx&/crv esoph c+
74220	X-ray xm esophagus 1cntrst
74240	X-ray xm upr gi trc 1cntrst
74246	X-ray xm upr gi trc 2cntrst
74251	X-ray exam of small bowel
74270	X-ray xm colon 1cntrst std
74280	X-ray xm colon 2cntrst std
74425	Contrst x-ray urinary tract
74X00	X-ray xm esophagus 2cntrst
74X01	X-ray sm int f-thru std
75625	Contrast exam abdominl aorta
75630	X-ray aorta leg arteries
75726	Artery x-rays abdomen
75774	Artery x-ray each vessel
76098	X-ray exam breast specimen
76376	3d render w/intrp postproces
76604	Us exam chest
77073	X-rays bone length studies
77074	X-rays bone survey limited
77075	X-rays bone survey complete
77076	X-rays bone survey infant
77077	Joint survey single view
788X3	Rp quan meas single area
909XX	Bfb training ea addl 15 min
92145	Corneal hysteresis deter
92548	Cdp-sot 6 cond w/i&r
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
92X18	Opscpy extnd rta draw uni/bi
92X19	Opscpy extnd on/mac draw
92XX0	Cdp-sot 6 cond w/i&r mct&adt
933X0	Myocrd strain img spckl trck
93784	Ambl bp mntr w/software
93786	Ambl bp mntr w/sw rec only
93788	Ambl bp mntr w/sw a/r
93790	Ambl bp mntr w/sw i&r
94200	Lung function test (mbc/mvv)
961X0	Hlth bhv assmt/reassessment
961X1	Hlth bhv ivntj indiv 1st 30
961X2	Hlth bhv ivntj indiv ea addl
961X3	Hlth bhv ivntj grp 1st 30
961X4	Hlth bhv ivntj grp ea addl
961X5	Hlth bhv ivntj fam 1st 30
961X6	Hlth bhv ivntj fam ea addl
961X7	Hlth bhv ivntj fam wo pt 1st
961X8	Hlth bhv ivntj fam w/o pt ea
971XX	Ther ivntj 1st 15 min
97597	Rmvl devital tis 20 cm/<
97598	Rmvl devital tis addl 20cm/<
97610	Low frequency non-thermal us
98X00	Qnhp ol dig e/m svc 5-10min
98X01	Qnhp ol dig em svc 11-20min
98X02	Qnhp ol dig e/m svc 21+ min
99281	Emergency dept visit
99282	Emergency dept visit
99283	Emergency dept visit
99284	Emergency dept visit
99285	Emergency dept visit
99495	Trans care mgmt 14 day disch
99496	Trans care mgmt 7 day disch
994X0	Rem physiol mntr ea addl 20
99X01	Self-meas bp pt educaj/train
99X02	Self-meas bp 2 readg bid 30d
9X0X1	Ol dig e/m svc 5-10 min
9X0X2	Ol dig e/m svc 11-20 min
9X0X3	Ol dig e/m svc 21+ min
9XXX0	Ther ivntj ea addl 15 min

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O. Comment Solicitation on Opportunities for Bundled Payments Under the PFS

Under the PFS, Medicare typically makes a separate payment for each individual service furnished to a beneficiary consistent with section 1848 of the Act, which requires CMS to establish payment for physicians' services based on the relative resources involved in furnishing the service. The statute defines ''services'' broadly, with reference to the uniform procedure coding system established by CMS for the purpose of Medicare FFS payments, called the Healthcare Common Procedure Coding System (HCPCS). There are sets of HCPCS codes that represent health care procedures, supplies, medical equipment, products, and services. The majority of physicians' services for which payment is made under the PFS are described using HCPCS Level I codes and descriptors that are the AMA's Current Procedural Terminology (CPT) code set. CPT codes generally describe an individual item or service, while some codes describe a combination of services (a procedure and imaging guidance, for example) bundled together. Some HCPCS codes explicitly encompass multiple services (global surgery codes, for example), and the PFS payment for some services is reduced when a combination of services is furnished to the same patient on the same day (through multiple procedure payment reduction policies). However, payment for most services under the PFS is made based on rates established for individual services, each described by a CPT code. Identifying and developing appropriate payment policies that aim to achieve better care and improved health for Medicare beneficiaries is a priority for CMS. Consistent with that goal, we are interested in exploring new options for establishing PFS payment rates or adjustments for services that are furnished together. For purposes of this discussion, we will refer to the circumstances where a set of services is grouped together for purposes of ratesetting and payment as ''bundled payment.''

One of the mechanisms through which we support innovative payment and service delivery models, for Medicare and other beneficiaries, is through CMS' Center for Medicare and Medicaid Innovation (the Innovation Center). The Innovation Center is currently testing models in which payment for physicians' services is bundled on a per-beneficiary population basis, or is based on episodes of care that usually begin with a triggering event and extend for a specified period of time thereafter. An example of a model in which payment is made on a per-beneficiary population basis is Comprehensive Primary Care Plus (CPC+), in which participating practices receive prospective per-beneficiary care management fees and Comprehensive Primary Care Payments for certain primary care services such as chronic care management and evaluation and management services. An example of an episode payment model is the Oncology Care Model (OCM), in which participating physician practices receive a per-beneficiary Monthly Enhanced Oncology Services payment for care management and care coordination surrounding chemotherapy administration to cancer patients. We are actively exploring the extent to which these basic principles of bundled payment, such as establishing per-beneficiary payments for multiple services or condition-specific episodes of care, can be applied within the statutory framework of the PFS.

We are seeking public comments on opportunities to expand the concept of bundling to recognize efficiencies among physicians' services paid under the PFS and better align Medicare payment policies with CMS's broader goal of achieving better care for patients, better health for our communities, and lower costs through improvement in our health care system. We believe that the statute, while requiring CMS to pay for physicians' services based on the relative resources involved in furnishing the service, allows considerable flexibility for developing payments under the PFS.

P. Payment for Evaluation and Management (E/M) Visits

1. Background

a. E/M Visits Coding Structure

Physicians and other practitioners who are paid under the PFS bill for common office visits for evaluation and management (E/M) services under a relatively generic set of CPT codes (Level I HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. These CPT codes are broadly referred to as E/M visit codes and have three key components within their code descriptors: History of present illness (History), physical examination (Exam), and medical decision-making (MDM).[80]

The CPT code descriptors recognize counseling, care coordination, and the nature of the presenting problem as additional service components, but these are contributory factors in determining which code to report.[81] Per the CPT code descriptors, counseling and/or care coordination are provided consistent with the nature of the problem and the patient's and/or family's needs. Counseling and care coordination are not required at every patient encounter and can be accounted for in separate coding.[82]

As finalized in the CY 2019 PFS final rule, the amount of time spent by the billing practitioner is not a determining factor in code level selection unless (1) counseling and care coordination dominate the visit, in which case time becomes the key factor in determining visit level; and/or (2) the service is a prolonged (or beginning in 2021, ''extended'') (83 FR 59630) E/M visit. Typical times for each level of E/M visit are included in each of the CPT code descriptors, are used for PFS rate setting purposes, and provide a reference point for the reporting of prolonged visits. Separate add-on codes describe, and can be reported for, visits that take prolonged (or beginning in 2021, ''extended'') (83 FR 59630) amounts of time.

There are 3 to 5 E/M visit code levels, depending upon site of service and the extent of the three components of history, exam, and MDM. For example, there are 3 to 4 levels of E/M visit codes in the inpatient hospital and nursing facility settings based on a relatively narrow range of complexity in those settings. In contrast, there are 5 levels of E/M visit codes in the office or other outpatient setting based on a broader range of complexity in those settings.

PFS payment rates for E/M visit codes generally increase with the level of visit billed, although in the CY 2019 PFS final rule (83 FR 59638), for reasons discussed below, we finalized the assignment of a single payment rate for levels 2 through 4 office/outpatient E/M visits beginning in CY 2021. As for all services under the PFS, the payment rates for E/M visits are based on the work (time and intensity), practice expense, and malpractice expense resources required to furnish the typical case of the service.

In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise

[80] 2019 CPT Codebook, Evaluation and Management, pp. 6–13.

[81] 2019 CPT Codebook, Evaluation and Management, pp. 6–13.

[82] 2019 CPT Codebook, Evaluation and Management, pp. 4–56.

approximately 20 percent of allowed charges for PFS services. Within the E/M services represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties. According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Generally, these practitioners include both primary care practitioners and certain specialists such as neurologists, endocrinologists and rheumatologists. Certain specialties, such as podiatry, tend to furnish lower level E/M visits more often than higher level E/M visits. Some specialties, such as dermatology and otolaryngology, tend to bill more E/M visits on the same day as they bill minor procedures.

b. E/M Documentation Guidelines

For CY 2019 and 2020, when coding and billing E/M visits to Medicare, practitioners may use one of two versions of the E/M Documentation Guidelines for a patient encounter, commonly referenced based on the year of their release: the ''1995'' or ''1997'' E/M Documentation Guidelines (hereafter, the 1995 and 1997 Guidelines).[83] These Guidelines specify the medical record information within each of the three key components (such as number of body systems reviewed) that serves as support for billing a given level of E/M visit. The 1995 and 1997 Guidelines are very similar to the guidelines for E/M visits that currently reside within the AMA's CPT codebook for E/M visits. For example, the core structure of what comprises or defines the different levels of history, exam, and medical decision-making in the 1995 and 1997 Guidelines are the same as those in the CPT codebook. However, the 1995 and 1997 Guidelines include extensive examples of clinical work that comprise different levels of medical decision-making that do not appear in the AMA's CPT codebook. Also, the 1995 and 1997 Guidelines do not contain references to preventive care that appear in the AMA's CPT codebook. We provide an example of how the 1995 and 1997 Guidelines distinguish between level 2 and level 3 E/M visits in Table 25.

TABLE 25—KEY COMPONENT DOCUMENTATION REQUIREMENTS FOR LEVEL 2 VS. 3 E/M VISIT

Key component *	Level 2 (1995)	Level 3 (1995)	Level 2 (1997)	Level 3 (1997)
History (History of Present Illness or HPI).	Review of Systems (ROS) n/a.	Problem Pertinent ROS: Inquires about the system directly related to the problem(s) identified in the HPI.	No change from 1995	No change from 1995.
Physical Examination (Exam).	A limited examination of the affected body area or organ system.	A limited examination of the affected body area or organ system and other symptomatic or related organ system(s).	General multi-system exam: Performance and documentation of one to five elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of one to five elements.	General multi-system exam: Performance and documentation of at least six elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of at least six elements.
Medical Decision Making (MDM). Measured by: **	Straightforward:	Low complexity:	No change from 1995.	
1. Problem—Number of diagnoses/treatment options.	1. Minimal	1. Limited.		
2. Data—Amount and/or complexity of data to be reviewed.	2. Minimal or no data review.	2. Limited data review.		
3. Risk—Risk of complications and/or morbidity or mortality.	3. Minimal risk	3. Low risk.		

* For certain settings and patient types, each of these three key components must be met or exceeded (for example, new patients; initial hospital visits). For others, only two of the three key components must be met or exceeded (for example, established patients, subsequent hospital or other visits).

** Two of three met or exceeded.

According to both Medicare claims processing manual instructions and CPT coding rules, when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time) the duration of the visit can be used as an alternative basis to select the appropriate E/M visit level (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.C available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf; see* also 2019 CPT Codebook Evaluation and Management Services Guidelines, page 10). Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.B states, ''Instruct physicians to select the code for the service based

[83] See *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf*; *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf*; and the Evaluation and Management Services guide at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf.*

upon the content of the service. The duration of the visit is an ancillary factor and does not control the level of the service to be billed unless more than 50 percent of the face-to-face time (for non-inpatient services) or more than 50 percent of the floor time (for inpatient services) is spent providing counseling or coordination of care as described in subsection C.'' Subsection C states that ''the physician may document time spent with the patient in conjunction with the medical decision-making involved and a description of the coordination of care or counseling provided. Documentation must be in sufficient detail to support the claim.'' The example included in subsection C further states, ''The code selection is based on the total time of the face-to-face encounter or floor time, not just the counseling time. The medical record must be documented in sufficient detail to justify the selection of the specific code if time is the basis for selection of the code.''

Both the 1995 and 1997 Guidelines address time, stating that, ''In the case where counseling and/or coordination of care dominates (more than 50 percent of) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), time is considered the key or controlling factor to qualify for a particular level of E/M services.'' The Guidelines go on to state that, ''If the physician elects to report the level of service based on counseling and/or coordination of care, the total length of time of the encounter (face-to-face or floor time, as appropriate) should be documented and the record should describe the counseling and/or activities to coordinate care.'' [84] Additional manual provisions regarding E/M visits are housed separately within Medicare's internet-Only Manuals, and are not contained within the 1995 or 1997 Guidelines.

In accordance with section 1862(a)(1)(A) of the Act, which requires services paid under Medicare Part B to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, medical necessity is a prerequisite to Medicare payment for E/M visits. Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.B states, ''Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported.''

c. Summary of Changes to Coding, Payment and Documentation of Office/Outpatient E/M Visits Finalized for CY 2021 in the CY 2019 PFS Final Rule

In the CY 2019 PFS final rule (83 FR 59452 through 60303), we finalized a number of coding, payment, and documentation changes under the PFS for office/outpatient E/M visits (CPT codes 99201–99215) to reduce administrative burden, improve payment accuracy, and update this code set to better reflect the current practice of medicine. In summary, we finalized the following policy changes for office/outpatient E/M visits under the PFS effective January 1, 2021:

- Reduction in the payment variation for office/outpatient E/M visit levels by paying a single rate (also referred to as a blended rate) for office/outpatient E/M visit levels 2 through 4 (one rate for established patients and another rate for new patients), while maintaining the payment rate for office/outpatient E/M visit level 5 in order to better account for the care and needs of complex patients. Practitioners will still report the appropriate code for the level of service they furnished, since we did not replace these CPT codes with HCPCS G codes and will continue to use typical times associated with each individual CPT code when time is used to document the office/outpatient E/M visit.
- Permitting practitioners to choose to document office/outpatient E/M level 2 through 5 visits using MDM or time, or the current framework based on the 1995 or 1997 Guidelines.
- As a corollary to the uniform payment rate for level 2–4 E/M visits, when using MDM or the current framework to document the office/outpatient E/M visit, a minimum supporting documentation standard associated with level 2 office/outpatient E/M visits will apply. For these cases, Medicare will require information to support a level 2 office/outpatient E/M visit code for history, exam, and/or MDM.
- When time is used to document, practitioners will document the medical necessity of the office/outpatient E/M visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary. The required face-to-face time will be the typical time for the reported code, except for extended or prolonged visits where extended or prolonged times will apply.
- Implementation of HCPCS add-on G codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care (HCPCS codes GPC1X and GCG0X, respectively). These codes were finalized in order to reflect the differential resource costs associated with performing certain types of office/outpatient E/M visits. These codes will only be reportable with office/outpatient E/M level 2 through 4 visits.
- Adoption of a new ''extended visit'' add-on G code (HCPCS code GPRO1) for use only with office/outpatient E/M level 2 through 4 visits, to account for the additional resources required when practitioners need to spend extended time with the patient for these visits. The existing prolonged E/M codes can continue to be used with levels 1 and 5 office/outpatient E/M visits.

We stated that we believed these policies would allow practitioners greater flexibility to exercise clinical judgment in documentation so they can focus on what is clinically relevant and medically necessary for the beneficiary. We believed these policies will reduce a substantial amount of administrative burden (83 FR 60068 through 60070) and result in limited specialty-level redistributive impacts (83 FR 60060). We stated our intent to continue engaging in further discussions with the public over the next several years to potentially further refine our policies for 2021. We finalized the coding, payment, and documentation changes to reduce administrative burden, improve payment accuracy, and update the code set to better reflect the current practice of medicine.

2. Continued Stakeholder Feedback

In January and February 2019, we hosted a series of structured listening sessions on the forthcoming changes that CMS finalized for office/outpatient E/M visit coding, documentation and payment for CY 2021. These sessions provided an opportunity for CMS to gain further input and information from the wide range of affected stakeholders on these important policy changes. Our goal was to continue to listen and consider perspectives from individual practicing clinicians, specialty associations, beneficiaries and their advocates, and other interested stakeholders to prepare for implementation of the office/outpatient

[84] Page 16 of the 1995 E/M guidelines and page 48 of the 1997 guidelines.

E/M visit policies that we finalized for CY 2021.

In these listening sessions, although stakeholders supported our intention to reduce burdensome, clinically outdated documentation requirements, they noted that in response to the office/outpatient E/M visit policies CMS finalized for CY 2021, the AMA/CPT established the Joint AMA CPT Workgroup on E/M to develop an alternative solution. This workgroup developed an alternative approach, similar to the one we finalized, for office/outpatient E/M coding and documentation. That approach was approved by the CPT Editorial Panel in February 2019, with an effective date of January 1, 2021 and is available on the AMA's website at *https://www.ama-assn.org/cpt-evaluation-and-management.*

Effective January 1, 2021, the CPT Editorial Panel adopted revisions to the office/outpatient E/M code descriptors, and substantially revised both the CPT prefatory language and the CPT interpretive guidelines that instruct practitioners on how to bill these codes. The AMA has approved an accompanying set of interpretive guidelines governing and updating what determines different levels of MDM for office/outpatient E/M visits. Some of the changes made by the CPT Editorial Panel parallel our finalized policies for CY 2021, such as the choice of time or MDM in determination of code level. Other aspects differ, such as the number of code levels retained, presumably for purposes of differential payment; the times, and inclusion of all time spent on the day of the visit; and elimination of options such as the use of history and exam or time in combination with MDM, to select code level.

Many stakeholders have continued to express objections to our assignment of a single payment rate to level 2–4 office/outpatient E/M visits stating that this inappropriately incentivizes multiple, shorter visits and seeing less complex patients. Many stakeholders also stated that the purpose and use of the HCPCS add-on G codes that we established for primary care and non-procedural specialized medical care remain ambiguous, expressed concern that the codes are potentially contrary to current law prohibiting specialty-specific payment, and asserted that Medicare's coding approach is unlikely to be adopted by other payers.

In meetings with stakeholders since we issued the CY 2019 PFS final rule, some stakeholders suggested that only time should be used to select the service level because time is easy to audit, simple to document, and better accounts for patient complexity, in comparison to the CPT Editorial Panel revised MDM interpretive guidance. These stakeholders stated that the implementation of the CPT Editorial Panel revised MDM interpretive guidance will result in the likely increase in the selection of levels 4 and 5, relative to current typical coding patterns. They suggested that to more accurately distinguish varying levels of patient complexity, either the visit levels should be recalibrated so that levels 4 and 5 no longer represent the most often billed visit, or a sixth level should be added. In these meetings, some stakeholders also stated that the office/outpatient E/M codes fail to capture the full range of services provided by certain specialties, particularly primary care and other specialties that rely heavily on office/outpatient E/M services rather than procedures, systematically undervaluing primary care visits and visits furnished in the context of non-procedural specialty care, thereby creating payment disparities that have contributed to workforce shortages and beneficiary access challenges across a range of specialties. They reiterated that office/outpatient E/M visit codes have not been extensively examined since the creation of the PFS and recommended that CMS conduct an extensive research effort to revise and revalue office/outpatient E/M services through a major research initiative akin to that undertaken when the PFS was first established.

The AMA believes its approach will accomplish greater burden reduction, is more clinically intuitive and reflects the current practice of medicine, and is more likely to be adopted by all payers than the policies CMS finalized for CY 2021. The AMA has posted an estimate of the burden reduction associated with the policies approved at CPT on the AMA's website, available at *https://www.ama-assn.org/cpt-evaluation-and-management.*

Given the CPT coding changes that will take effect in 2021, the AMA RUC has conducted a resurvey and revaluation of the office/outpatient E/M visit codes, and provided us with its recommendations. We discuss our proposal to adopt the CPT coding for office/outpatient E/M visits below, noting that the CPT coding changes will also necessitate some changes to CMS' policies for CY 2021, due to forthcoming changes in code descriptors. In addition, we address revaluation of the codes, proposing new values for the codes as revised by CPT. We propose to assign separate payment rather than a blended rate, to each of the office/outpatient E/M visit codes (except CPT code 99201, which CPT is deleting) and the new prolonged visit add-on CPT code (CPT code 99XXX). We propose to delete the HCPCS add-on code we finalized last year for CY 2021 for extended visits (GPRO1). We propose to simplify, consolidate and revalue the HCPCS add-on codes we finalized last year for CY 2021 for primary care (GPC1X) and non-procedural specialized medical care (GCG0X), and to allow the new code to be reported with all office/outpatient E/M visit levels (not just levels 2 through 4). All of these changes would be effective January 1, 2021. We believe our proposed policies will further our ongoing effort to reduce administrative burden, improve payment accuracy, and update the office/outpatient EM visit code set to better reflect the current practice of medicine.

3. Proposed Policies for CY 2021 for Office/Outpatient E/M Visits

a. Office/Outpatient E/M Visit Coding and Documentation

For CY 2021, for office/outpatient E/M visits (CPT codes 99201–99215) we are proposing to adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA/CPT (*see https://www.ama-assn.org/cpt-evaluation-and-management*) because we believe it would accomplish greater burden reduction than the policies we finalized for CY 2021 and would be more intuitive and consistent with the current practice of medicine. We note that this includes deletion of CPT code 99201 (Level 1 office/outpatient visit, new patient), which the CPT Editorial Panel decided to eliminate as CPT codes 99201 and 99202 are both straightforward MDM and only differentiated by history and exam elements.

Under this new framework, history and exam would no longer select the level of code selection for office/outpatient E/M visits. Instead, an office/outpatient E/M visit would include a medically appropriate history and exam, when performed. The clinically outdated system for number of body systems/areas reviewed and examined under history and exam would no longer apply, and these components would only be performed when, and to the extent medically necessary and clinically appropriate. Level 1 visits would only describe or include visits performed by clinical staff for established patients.

For levels 2 through 5 office/outpatient E/M visits, the code level reported would be decided based on

either the level of MDM (as redefined in the new AMA/CPT guidance framework) or the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time). Because we would no longer assign a blended payment rate (discussed below), we would no longer adopt the minimum supporting documentation associated with level 2 office/outpatient E/M visits, which we finalized as a corollary to the uniform payment rate for level 2–4 office/outpatient E/M visits when using MDM or the current framework to document the office/outpatient E/M visit.

We would adopt the new time ranges within the CPT codes as revised by the CPT Editorial Panel. We interpret the revised CPT prefatory language and reporting instructions to mean that there would be a single add-on CPT code for prolonged office/outpatient E/M visits (CPT code 99XXX) that would only be reported when time is used for code level selection and the time for a level 5 office/outpatient visit (the floor of the level 5 time range) is exceeded by 15 minutes or more on the date of service. The long descriptor for CPT code 99XXX is *Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*. We demonstrate below how prolonged office/outpatient E/M visit time would be reported:

TABLE 26—TOTAL PROPOSED PRACTITIONER TIMES FOR OFFICE/OUTPATIENT E/M VISITS WHEN TIME IS USED TO SELECT VISIT LEVEL

Established patient office/outpatient E/M visit (total practitioner time, when time is used to select code level) (minutes)	CPT code
40–54	99215.
55–69	99215x1 and 99XXXx1.
70–84	99215x1 and 99XXXx2.
85 or more	99215x1 and 99XXXx3 or more for each additional 15 mintues.
New patient office/outpatient E/M visit (total practitioner time, when time is used to select code level) (minutes)	**CPT code**
60–74	99205.
75–89	99205x1 and 99XXXx1.
90–104	99205x1 and 99XXXx2.
105 or more	99205x1 and 99XXXx3 or more for each additional 15 minutes.

We are proposing to adopt our interpretation of the revised CPT prefatory language and reporting instructions, that CPT codes 99358–9 (Prolonged E/M without Direct Patient Contact) would no longer be reportable in association or ''conjunction'' with office/outpatient E/M visits. In other words, when using time to select office/outpatient E/M visit level, any additional time spent by the reporting practitioner on a prior or subsequent date of service (such as reviewing medical records or test results) could not count towards the required times for reporting CPT codes 99202–99215 or 99XXX, or be reportable using CPT codes 99358–9. This interpretation would be consistent with the way the office/outpatient E/M visit codes were resurveyed, where the AMA/RUC instructed practitioners to consider all time spent 3 days prior to, or 7 days after, the office/outpatient E/M visit (*see* below for a discussion of revaluation proposals). Moreover we note that CPT codes 99358–9 describe time spent beyond the ''usual'' time (CPT prefatory language), and it is not clear what would comprise ''usual'' time given the new time ranges for the office/outpatient E/M visit codes and new CPT code 99XXX (prolonged office/outpatient E/M visit). New CPT prefatory language specifies, ''For prolonged services on a date other than the date of a face-to-face encounter, including office or other outpatient services (99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215), see 99358, 99359 . . . Do not report 99XXX in conjunction with . . . 99358, 99359''. We do not believe CPT code 99211 should be included in this list of base codes since it will only include clinical staff time. Also given that CPT codes 99358, 99359 can be used to report practitioner time spent on any date (the date of the visit or any other day), the CPT reporting instruction ''see 99358, 99359'' seems circular. The new prefatory language seems unclear regarding whether CPT codes 99358, 99359 could be reported instead of, or in addition to, CPT code 99XXX, and whether the prolonged time would have to be spent on the visit date, within 3 days prior or 7 days after the visit date, or outside of this new 10-day window relevant for the base code. We are seeking public input on this proposal and whether it would be appropriate to interpret the CPT reporting instructions for CPT codes 99358–9 as proposed, as well as how this interpretation may impact valuation. We believe CPT codes 99358 and 99359 may need to be redefined, resurveyed and revalued. After internal review, we believe that when time is used to select visit level, having one add-on code (CPT code 99XXX) instead of multiple add-on codes for additional time may be administratively simpler and most consistent with our goal of documentation burden reduction.

HCPCS code GPRO1 (extended office/outpatient E/M time) would no longer be needed because the time described by this code would instead be described by a level 3, 4 or 5 office/outpatient E/M visit base code and, if applicable, the single new add-on CPT code for prolonged office/outpatient E/M visits (CPT code 99XXX). Therefore, we propose to delete HCPCS code GPRO1 for CY 2021. We propose to adopt the AMA/CPT prefatory language that lists qualifying activities that could be included when time is used to select the visit level. Alternatively, if MDM is used to choose the visit level, time would not be relevant to code selection.

b. Office/Outpatient E/M Visit Revaluation (CPT Codes 99201 Through 99215)

We have received valuation recommendations from the AMA RUC for the revised office/outpatient E/M codes (CPT codes 99201 through 99215) following completion of its survey and revaluation process for these codes. Although these codes do not take effect until CY 2021, we believe that it is appropriate to follow our usual process of addressing the valuation of the revised office/outpatient E/M codes through rulemaking after we receive the RUC recommendations. Additionally, establishing values for the new codes through rulemaking this year will allow more time for clinicians to make any necessary process and systems adjustments before they begin using the codes. In recent years, we have considered how best to update and revalue the office/outpatient E/M codes as they represent a significant proportion of PFS expenditures.

MedPAC has had longstanding concerns that office/outpatient E/M services are undervalued in the PFS, and in its March 2019 Report to Congress, further asserted that the office/outpatient E/M code set has become passively devalued as values of these codes have remained unchanged, while the coding and valuation for other types of services under the fee schedule have been updated to reflect changes in medical practice (*see* pages 120 through 121 at *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch4_sec.pdf?sfvrsn=0*).

In April 2019, the RUC provided us the results of its review, and recommendations for work RVUs, practice expense inputs and physician time (number of minutes) for the revised office/outpatient E/M code set. Please note that these proposed changes in coding and values are for the revised office/outpatient E/M code set and a new 15-minute prolonged services code. That code set is effective beginning in CY 2021, and the proposed values would go into effect with those codes as of January 1, 2021.

We are proposing to adopt the RUC-recommended work RVUs for all of the office/outpatient E/M codes and the new prolonged services add-on code. Specifically, we are proposing a work RVU of 0.93 for CPT code 99202 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 15–29 minutes of total time is spent on the date of the encounter*), a work RVU of 1.6 for CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30–44 minutes of total time is spent on the date of the encounter*), a work RVU of 2.6 for CPT code 99204 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45–59 minutes of total time is spent on the date of the encounter*), a work RVU of 3.5 for CPT code 99205 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60–74 minutes of total time is spent on the date of the encounter. (For services 75 minutes or longer, see Prolonged Services 99XXX)*), a work RVU of 0.18 for CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal)*), a work RVU of 0.7 for CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter*), a work RVU of 1.3 for CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter),* a work RVU of 1.92 for CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter*), a work RVU of 2.8 for CPT code 99215 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40–54 minutes of total time is spent on the date of the encounter. (For services 55 minutes or longer, see Prolonged Services 99XXX)*) and a work RVU of 0.61 for CPT code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*).

Regarding the RUC recommendations for practice expense inputs for these codes, we are proposing to remove equipment item ED021 (computer, desktop, with monitor), as we do not believe that this item would be allocated to the use of an individual patient for an individual service; rather, we believe this item is better characterized as part of indirect costs similar to office rent or administrative expenses.

The information we reviewed on the RUC valuation exercise was based on an extensive survey the RUC conducted of over 50 specialty societies. For purposes of valuation, survey respondents were asked to consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a time frame of 3 days prior to the visit and 7 days after, respectively. This is different from the way codes are usually surveyed by the RUC for purposes of valuation, where pre-, intra-, and post-service time were surveyed, but not within a specific time frame. The RUC then separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the times associated with the three service periods does not match the RUC-recommended total time. The RUC's approach sometimes results in two conflicting sets of times: The component times as surveyed and the total time as surveyed. Although we are proposing to adopt the RUC-recommended times as explained below, we are seeking comment on how CMS should address the discrepancies in times, which have implications both for for valuation of individual codes and for PFS ratesetting in general, as the intra-service times and total times are used as references for valuing many other services under the PFS and that the programming used for PFS ratesetting requires that the

component times sum to the total time. Specifically, we request comment on which times should CMS use, and how we should resolve differences between the component and total times when they conflict. Table 27A illustrates the surveyed times for each service period and the surveyed total time. It also shows the actual total time if summed from the component times.

TABLE 27A—RUC-RECOMMENDED PRE-, INTRA-, POST-SERVICE TIMES, RUC-RECOMMENDED TOTAL TIMES FOR CPT CODES 99202–99215 AND ACTUAL TOTAL TIME

HCPCS	Pre-service time	Intra-service time	Immediate post-service time	Actual total time	RUC-recommended total time
99202	2	15	3	20	22
99203	5	25	5	35	40
99204	10	40	10	60	60
99205	14	59	15	88	85
99211	.....	5	2	7	7
99212	2	11	3	16	18
99213	5	20	5	30	30
99214	7	30	10	47	49
99215	10	45	15	70	70

Table 27B summarizes the current office/outpatient E/M services code set, and the new prolonged services code physician work RVUs and total time compared to what CMS finalized in CY 2019 for CY 2021, and the RUC-recommended work RVU and total time.

TABLE 27B—SIDE BY SIDE COMPARISON OF WORK RVUS AND PHYSICIAN TIME FOR THE OFFICE/OUTPATIENT E/M SERVICES CODE SET, AND THE NEW PROLONGED SERVICES CODE

[Current versus revised]

HCPCS code	Current total time (mins)	Current work RVU	CY 2021 total time (mins)	CY 2021 work RVU	RUC rec total time (mins)	RUC rec work RVU
99201	17	0.48	17	0.48	N/A	N/A
99202	22	0.93	22	1.76	22	0.93
99203	29	1.42	29	1.76	40	1.6
99204	45	2.43	45	1.76	60	2.6
99205	67	3.17	67	3.17	85	3.5
99211	7	0.18	7	0.18	7	0.18
99212	16	0.48	16	1.18	18	0.7
99213	23	0.97	23	1.18	30	1.3
99214	40	1.5	40	1.18	49	1.92
99215	55	2.11	55	2.11	70	2.8
99XXX	N/A	N/A	N/A	N/A	15	0.61

The RUC recommendations reflect a rigorous robust survey approach, including surveying over 50 specialty societies, demonstrate that office/outpatient E/M visits are generally more complex, for most clinicians. In the CY 2019 PFS final rule, we finalized for CY 2021 a significant reduction in the payment variation in office/outpatient E/M visit levels by paying a single blended rate for E/M office/outpatient visit levels 2 through 4 (one for established and another for new patients). We also maintained the separate payment rates for E/M office/outpatient level 5 visits in order to better account for the care and needs of particularly complex patients. We believed that the single blended payment rate for E/M office/outpatient visit levels 2–4 better accounted for the resources associated with the typical visit. After reviewing the RUC recommendations, in conjunction with the revised code descriptors and documentation guidelines for CPT codes 99202 through 99215, we believe codes and recommended values would more accurately account for the time and intensity of office/outpatient E/M visits than either the current codes and values or the values we finalized in the CY 2019 PFS final rule for CY 2021. Therefore, we are proposing to establish separate values for Levels 2–4 office/outpatient E/M visits for both new and established patients rather than continue with the blended rate. We are proposing to accept the RUC-recommended work and time values for the revised office/outpatient E/M codes without refinement for CY 2021. With regard to the RUC's recommendations for practice expense inputs, we are proposing to remove equipment item ED021 (computer, desktop, with monitor), as this item is included in the overhead costs. Note that these changes to codes and values would go into effect January 1, 2021.

c. Simplification, Consolidation and Revaluation of HCPCS Codes GCG0X and GPC1X

Although we believe that the RUC-recommended values for the revised office/outpatient E/M visit codes would more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, we believe that the revalued office/outpatient E/M code set itself still does not appropriately reflect differences in resource costs between certain types of office/outpatient E/M visits. In the CY 2019 PFS proposed rule we articulated that, based on stakeholder comments, clinical examples, and our review of the literature on office/outpatient E/M

services, there are three types of office/outpatient E/M visits that differ from the typical office/outpatient E/M visit and are not appropriately reflected in the current office/outpatient E/M code set and valuation. These three types of office/outpatient E/M visits can be distinguished by the mode of care provided and, as a result, have different resource costs. The three types of office/outpatient E/M visits that differ from the typical office/outpatient E/M service are (1) separately identifiable office/outpatient E/M visits furnished in conjunction with a global procedure, (2) primary care office/outpatient E/M visits for continuous patient care, and (3) certain types of specialist office/outpatient E/M visits. We proposed, but did not finalize, the application of an MPPR to the first category of visits, to account for overlapping resource costs when office/outpatient E/M visits were furnished on the same day as a 0-day global procedure. To address the shortcomings in the E/M code set in appropriately describing and reflecting resource costs for the other two types of office/outpatient E/M visits, we proposed and finalized the two HCPCS G codes: HCPCS code GCG0X (*Visit complexity inherent to evaluation and management associated with non-procedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established*) which describes the inherent complexity associated with certain types of specialist visits and GPC1X (*Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established*), which describes additional resources associated with primary care visits.

Although we finalized two separate codes, we valued both HCPCS codes GCG0X and GPC1X via a crosswalk to 75 percent of the work and time value of CPT code 90785 (*Interactive complexity (List separately in addition to the code for primary procedure*)). Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more work due to the complexity of the patient, and we believed that 75 percent of its work and time values accurately captured the additional resource costs of primary care office/outpatient visits and certain types of specialty office/outpatient visits when billed with the single, blended payment rate for office/outpatient E/M visit levels 2–4.

In the CY 2019 PFS final rule, we stated that, due to the variation among the types of visits performed by certain specialties, we did not believe that the broad office/outpatient E/M code set captured the resource costs associated with furnishing primary care and certain types of specialist visits (FR 83 59638). As we stated above, we believe that the revised office/outpatient E/M code set and RUC-recommended values more accurately reflect the resources associated with a typical visit. However, we believe the typical visit described by the revised code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits.

As such, we believe that there is still a need for add-on coding because the revised office/outpatient E/M code set does not recognize that there are additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits. However, based on previous public comments and ongoing engagement with stakeholders, we understand the need for the add-on code(s) and descriptor(s) to be easy to understand and report when appropriate, including in terms of medical record documentation and billing. We also want to make it clear that the add-on coding is not intended to reflect any difference in payment based on the billing practitioner's specialty, but rather the recognition of different per-visit resource costs based on the kinds of care the practitioner provides, regardless of their specialty. Therefore, we are proposing to simplify the coding by consolidating the two add-on codes into a single add-on code and revising the single code descriptor to better describe the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition.

We are proposing to revise the descriptor for HCPCS code GPC1X and delete HCPCS code GCG0X. The proposed descriptor for GPC1X appears in Table 28. We are seeking comment from the public and stakeholders regarding these proposed changes, particularly the proposed new code descriptor for GPC1X and whether or not more than one code, similar to the policy finalized last year, would be necessary or beneficial.

We have also reconsidered the appropriate valuation for this HCPCS add-on G-code in the context of the revised office/outpatient E/M service code set and proposed values. Upon further review and in light of the other proposed changes to the office/outpatient E/M service code set, we believe that valuing the add-on code at 75 percent of CPT code 90785 would understate the additional inherent intensity associated with furnishing primary care and certain types of specialty visits. As CPT code 90785 also describes additional work associated with certain psychotherapy or psychiatric services, we believe its work and time values are the most appropriate crosswalk for the revised HCPCS code GPC1X. Therefore, we are proposing to value HCPCS code GPC1X at 100 percent of the work and time values for CPT code 90785, and proposing a work RVU of 0.33 and a physician time of 11 minutes. We are also proposing that this HCPCS add-on G code could be billed as applicable with every level of office and outpatient E/M visit, and that we would revise the code descriptor to reflect that change. See Table 28 for the proposed changes to the code descriptor. We note that if the CPT Editorial Panel makes any further changes to the office and outpatient E/M codes and descriptors, or creates one or more CPT codes that duplicate this add-on code, or if the RUC and/or stakeholders or other public commenters recommend values for these or other related codes, we would consider them through subsequent rulemaking.

TABLE 28—PROPOSED REVALUATION OF HCPCS ADD-ON G CODE FINALIZED FOR CY 2021

HCPCS code	Proposed code descriptor revisions	FR 2019 total time (mins)	FR 2019 work RVU	Proposed total time (mins)	Proposed work RVU
GPC1X	*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).*	8.25	0.25	11	0.33

d. Valuation of CPT Code 99xxx (Prolonged Office/Outpatient E/M)

The RUC also provided a recommendation for new CPT code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services*). The RUC recommended 15 minutes of physician time and a work RVU of 0.61. We are proposing to delete to the HCPCS add-on code we finalized last year for CY 2021 for extended visits (GPRO1) and adopt the new CPT code 99XXX. Further, as discussed above we are proposing to accept the RUC recommended values for CPT code 99XXX without refinement.

We are seeking comment on these proposals, as well as any additional information stakeholders can provide on the appropriate valuation for these services.

e. Implementation Timeframe

We propose that these policy changes for office/outpatient E/M visits would be effective for services furnished starting January 1, 2021. We believe this would allow sufficient time for practitioner and provider education and further feedback; changes in clinical workflows, EHRs and any other impacted systems; and corresponding changes that may be made by other payers. In summary, we propose to adopt the following policies for office/outpatient E/M visits effective January 1, 2021:

- Separate payment for the five levels of office/outpatient E/M visit CPT codes, as revised by the CPT Editorial Panel effective January 1, 2021 and resurveyed by the AMA RUC, with minor refinement. This would include deletion of CPT code 99201 (Level 1 new patient office/outpatient E/M visit) and adoption of the revised CPT code descriptors for CPT codes 99202–99215;
- Elimination of the use of history and/or physical exam to select among code levels;
- Choice of time or medical decision making to decide the level of office/outpatient E/M visit (using the revised CPT interpretive guidelines for medical decision making);
- Payment for prolonged office/outpatient E/M visits using the revised CPT code for such services, including separate payment for new CPT code 99xxx and deletion of HCPCS code GPRO1 (extended office/outpatient E/M visit) that we previously finalized for 2021;
- Revise the descriptor for HCPCS code GPC1X and delete HCPCS code GCG0X; and
- Increase in value for HCPCS code GCG1X and allowing it to be reported with all office/outpatient E/M visit levels.

f. Global Surgical Packages

In addition to their recommendations regarding physician work, time, and practice expense for office/outpatient E/M visits, the AMA RUC also recommended adjusting the office/outpatient E/M visits for codes with a global period to reflect the changes made to the values for office/outpatient E/M visits. Procedures with a 10- and 90-day global period have post-operative visits included in their valuation. These post-operative visits are valued with reference to values for the E/M visits and each procedure has at least a half of an E/M visit included the global period. However, these visits are not directly included in the valuation. Rather, work RVUs for procedures with a global period are generally valued using magnitude estimation.

In the CY 2015 PFS final rule, we discussed the challenges of accurately accounting for the number of visits included in the valuation of 10- and 90-day global packages. (79 FR 67548, 67582.) We finalized a policy to change all global periods to 0-day global periods, and to allow separate payment for post-operative follow-up E/M visits. Our concerns were based on a number of key points including: The lack of sufficient data on the number of visits typically furnished during the global periods, questions about whether we will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and concerns about how our global payment policies could affect the services that are actually furnished. In finalizing a policy to transform all 10- and 90-day global codes to 0-day global codes in CY 2017 and CY 2018, respectively, to improve the accuracy of valuation and payment for the various components of global packages, including pre- and post-operative visits and the procedure itself, we stated that we were adopting this policy because it is critical that PFS payment rates be based upon RVUs that reflect the relative resources involved in furnishing the services. We also stated our belief that transforming all 10- and 90-day global codes to 0-day global packages would:

- Increase the accuracy of PFS payment by setting payment rates for individual services that more closely reflect the typical resources used in furnishing the procedures;
- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period;
- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global packages; and
- Facilitate the availability of more accurate data for new payment models and quality research.

Section 523(a) of MACRA added section 1848(c)(8)(A) of the Act, which

prohibited the Secretary from implementing the policy described above, which would have transformed all 10-day and 90-day global surgery packages to 0-day global packages. Section 1848(c)(8)(B) of the Act, which was also added by section 523(a) of the MACRA, required us to collect data to value surgical services. Section 1848(c)(8)(B)(i) of the Act requires us to develop a process to gather information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General shall audit a sample of the collected information to verify its accuracy. Section 1848(c)(8)(C) of the Act, which was also added by section 523(a) of the MACRA, requires that, beginning in CY 2019, we must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS.

Resource-based valuation of individual physicians' services is a critical foundation for Medicare payment to physicians. It is essential that the RVUs under the PFS be based as closely and accurately as possible on the actual resources used in furnishing specific services to make appropriate payment and preserve relativity among services. For global surgical packages, this requires using objective data on all of the resources used to furnish the services that are included in the package. Not having such data for some components may significantly skew relativity and create unwarranted payment disparities within the PFS. The current valuations for many services valued as global packages are based upon the total package as a unit rather than by determining the resources used in furnishing the procedure and each additional service/visit and summing the results. As a result, we do not have the same level of information about the components of global packages as we do for other services. To value global packages accurately and relative to other procedures, we need accurate information about the resources—work, PEs and malpractice—used in furnishing the procedure, similar to what is used to determine RVUs for all services. In addition, we need the same information on the postoperative services furnished in the global period (and pre-operative services the day before for 90-day global packages).

In response to the MACRA amendments to section 1848(c)(8 of the Act), CMS required practitioners who work in practices that include 10 or more practitioners in Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island to report using CPT 99024 on post-operative visits furnished during the global period for select procedures furnished on or after July 1, 2017. The specified procedures are those that are furnished by more than 100 practitioners and either are nationally furnished more than 10,000 times annually or have more than $10 million in annual allowed charges.

RAND analyzed the data collected from the post-operative visits through this claim-based reporting for the first year of reporting, July 1, 2017–June 30, 2018. They found that only 4 percent of procedures with 10-day global periods had any post-operative visits reported. While 71 percent of procedures with 90-day global periods had at least one associated post-operative visit, only 39 percent of the total post-operative visits expected for procedures with 90-day global periods were reported. (A complete report on this is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html*).

In addition to the claims-based data collection, RAND collected data on the level of visits. They began with an attempt to collect data via a survey from all specialties as described in the 2017 final rule. Given the low rate of response from practitioners, we shifted the study and focused on three high-volume procedures with global periods that were common enough to likely result in a robust sample size: (1) Cataract surgery; (2) hip arthroplasty; and (3) complex wound repair. A total of 725 physicians billing frequently for cataract surgery, hip arthroplasty, and complex wound repair reported on the time, activities, and staff involved in 3,469 visits. Our findings on physician time and work from the survey were broadly similar to what we expected based on the Time File for cataract surgery and hip replacement and somewhat different for complex wound repair. (For the complete report, *see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html*).

The third report in the series looks at ways we could consider revaluing procedures using the collected data. To provide us with estimates to frame a discussion, RAND modeled how valuation for procedures would change by adjusting work RVUs, physician time, and direct PE inputs based on the difference between the number of post-operative visits observed via claims-based reporting and the expected number of post-operative visits used during valuation. RAND looked at three types of changes: (1) Updated work RVUs based on the observed number of post-operative visits measured four ways (median, 75th percentile, mean, and modal observed visits); (2) Allocated PE RVUs reflecting direct PE inputs updated to reflect the median number of reported post-operative visits; and (3) Modeled total RVUs reflecting (a) updated work RVUs, (b) updated physician time, and (c) updated direct PE inputs, and including allocated PE and malpractice RVUs. This report is designed to inform further conversations about how to revalue global procedures. (For the complete report, *see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html*.) We will give the public and stakeholders time to study the reports we are making available along with this rule and consider an appropriate approach to revaluing global surgical procedures. We also note that the Office of the Inspector General (OIG) has published a number of reports on this topic. We will continue to study and consider alternative ways to address the values for these services.

g. Comment Solicitation on Revaluing the Office/Outpatient E/M Visit Within TCM, Cognitive Impairment Assessment/Care Planning and Similar Services

We recognize there are services other than the global surgical codes for which the values are closely tied to the values of the office/outpatient E/M visit codes, such as transitional care management services (CPT codes 99495, 99496); cognitive impairment assessment and care planning (CPT code 99483); certain ESRD monthly services (CPT codes 90951 through 90961); the Initial Preventive Physical Exam (G0438) and the Annual Wellness Visit (G0439). In future rulemaking, we may consider adjusting the RVUs for these services and are seeking public input on such a policy. We note that unlike the global surgical codes, these services always include an office/outpatient E/M visit(s) furnished by the reporting practitioner as part of the service, and it may therefore be appropriate to adjust their valuation commensurate with any

changes to the values for the revised codes for office/outpatient E/M visits. While some of these services do not involve an E/M visit, we valued them using a direct crosswalk to the RVUs assigned to an office/outpatient E/M visit(s) and for this reason they are closely tied to values for office/outpatient E/M visits.

We are also seeking comment on whether or not the public believes it would be necessary or beneficial to make systematic adjustments to other related PFS services to maintain relativity between these services and office/outpatient E/M visits. We are particularly interested in whether it would be beneficial or necessary to make corresponding adjustments to E/M codes describing visits in other settings, such as home visits, or to codes describing more specific kinds of visits, like counseling visits. For example, CPT code 99348 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family*) is commonly used to report home visits, and like CPT code 99214, the code describes approximately 45 minutes of time with the patient and has a work RVU of 1.56. Under the proposal to increase the work RVU of CPT code 99214 from 1.5 to 1.92, the proportional value of CPT code 99348 would decrease relative to the work RVU for CPT code 99214. To maintain the same proportional value to CPT code 99214, the work RVU for CPT code 99348 would need to increase from 1.56 to 2.00. We understand that certain other services, such as those that describe ophthalmological examination and evaluation, as well as psychotherapy visit codes, are used either in place of or in association with office/outpatient visit codes. For example, CPT code 92012 (*Ophthalmological services: Medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient*) currently has a work RVU of 0.92. Under the proposal to increase the work RVU of CPT code 99213 from 0.97 to 1.30, the proportional value of CPT code 92012 would decrease relative to the work RVU for CPT code 99213, as both codes describe around 30 minutes of work. To maintain the same proportional value to CPT code 99213, the work RVU for CPT code 92012 would need to increase from 0.92 to 1.23. Similarly, behavioral health professionals report several codes to describe psychiatric diagnostic evaluations and visits they furnish. When furnished with an evaluation and management service, practitioners report psychotherapy add-on codes instead of stand-alone psychotherapy codes that would otherwise be reported. Because the overall work RVUs for the combined service, including the value for the office/outpatient visit code, would increase under the proposal, we are interested in comments regarding whether or not it would be appropriate to reconsider the value of the psychotherapy codes, as well as the psychiatric diagnostic evaluations relative to the proposed values for the office/outpatient visit codes. Under the proposed revaluation of the office/outpatient E/M visits, the proportional value of CPT code 90834 (*Psychotherapy, 45 minutes with patient*) would decrease relative to work RVUs for CPT code 99214 plus CPT code 90836. The current work RVU for CPT code 99214 when reported with CPT code 90836 is 3.40 (1.90 + 1.50) and the current work RVU for CPT code 90834 is 2.0. Under the proposed revaluation of the office/outpatient E/M visits, the combined work RVU for CPT codes 99214 and 90836 would be 3.82 (1.90 + 1.92). In order to maintain the proportionate difference between these services, the work RVU for CPT code 90834 would increase from 2.00 to 2.25. Based on these three examples, we are seeking public comment on whether we should make similar adjustments to E/M codes in different settings, and other types of visits, such as counseling services.

III. Other Provisions of the Proposed Regulations

A. Changes to the Ambulance Physician Certification Statement Requirement

Under our ongoing initiative to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, we are proposing to revise §§ 410.40 and 410.41. Importantly, we first clarify that these requirements apply to ambulance providers, as well as suppliers. The proposed revisions would give certain clarity to ambulance providers and suppliers regarding the physician or non-physician certification statement and add staff who may sign certification statements when the ambulance provider or supplier is unable to obtain a signed statement from the attending physician.

1. Exceptions to Certification Statement Requirement

Under section 1861(s)(7) of the Act, ambulance services are covered where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Currently, § 410.40(d) specifies the medical necessity requirements for both nonemergency, scheduled, repetitive ambulance services and nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis. In the final rule with comment period that appeared in the January 25, 1999 **Federal Register** (64 FR 3637) (hereinafter referred to as the ''January 25, 1999 final rule with comment period''), we stated that a physician certification statement (PCS) must be obtained as evidence that the attending physician has determined that other means of transportation are contraindicated and that the transport is medically necessary (64 FR 3639). In the final rule with comment period that appeared in the February 27, 2002 **Federal Register** (67 FR 9100) (hereinafter referred to as the ''February 27, 2002 final rule with comment period'') we added that a certification statement (hereinafter referred to as non-physician certification statement) could be obtained from other authorized staff should the attending physician be unavailable. (67 FR 9111)

Currently there are no circumstances, other than those specified at § 410.40(d)(3)(ii) and (iv), granting exceptions to the need for a PCS or non-physician certification statement, and we have received feedback from ambulance providers, suppliers, and their industry representatives (''stakeholders'') that various situations exist where the need for a PCS or non-physician certification is excessive, or at least redundant to similar existing documentation requirements. Two of the most prominent circumstances identified by the stakeholders include interfacility transports (IFTs), commonly referred to as hospital to hospital transports and specialty care transports (SCTs), and it has been requested that we incorporate additional exceptions into the regulatory framework.

Upon reviewing the need for a PCS and non-physician certification

statement, stakeholders' concerns, and our commitment to reducing the burden placed on providers and suppliers, we have determined that instead of incorporating additional exceptions, our efforts would be better served by minorly altering the structure of the existing regulatory framework. These changes are intended to maximize flexibility for ambulance providers and suppliers to obtain the requisite certification statements and maintain the focus on the determination that other means of transportation are contraindicated and that the transport is medically necessary.

To accomplish this, we are proposing to add a new paragraph (a) in § 410.40 in which we would define both PSCs, as well as non-physician certification statements. Therefore, we are proposing to redesignate existing paragraph (a) ''Basic rules'' as paragraph (b) and redesignate the remaining paragraphs, respectively. Most significantly, paragraph (d) ''Medical necessity requirements'' will be redesignated as paragraph (e).

For new proposed paragraph (a), the two definitions, PCSs and non-physician certification statements, would clarify that: (1) The focus is on the certification of the medical necessity provisions contained in proposed newly redesignated paragraph (e)(1); and (2) the form of the certification statement is not prescribed, thus affording maximum flexibility to ambulance providers and suppliers. Since the two definitions incorporate the requirement to obtain a certification of medical necessity, we are proposing a conforming change to newly redesignated paragraph (e)(2) to remove the language requiring that an order certifying medical necessity be obtained.

We have repeatedly been told by stakeholders that there are ample opportunities for ambulance providers and suppliers to convey the information required in the certification statement. Stakeholders have mentioned, for example, that for transports such as IFTs and SCTs other requirements of federal, state, or local law require them to obtain other documentation, such as Emergency Medical Treatment & Labor Act (EMTALA) forms and medical transport forms, that can serve the same purpose as the PCS or non-physician certification statement. There is every likelihood that other ambulance transports require similarly styled documentation that likewise could serve the same purpose.

To be clear, our regulations have never prescribed the precise form or format of this required documentation. To satisfy the requirements of section 1861(s)(7) of the Act, ambulance providers' and suppliers' focus should be on clearly documenting the threshold determination that other means of transportation are contraindicated and that the transport is medically necessary. The precise form or format by which that information is conveyed has never been prescribed. We aim here to ensure that ambulance providers and suppliers understand they have flexibility in the form by which they convey the requirements of proposed § 410.40(e), so long as that threshold determination is clearly expressed.

The definition of non-physician certification statement in proposed § 410.40(a) would incorporate the existing requirements that apply when an ambulance provider or supplier is unable to obtain a signed PCS from the attending physician and, instead, obtains a non-physician certification statement, including: (1) That the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished; (2) the employment requirements; and (3) the specific staff that can sign in lieu of the attending physician. Included within the proposed definition of non-physician certification statement, and as further discussed below, is an expansion of the list of staff who may sign when the attending physician is unavailable. In light of the staff being listed as part of the definition of non-physician certification statement proposed at § 410.40(a), we are proposing a corresponding change to proposed and newly redesignated paragraph (e)(3)(iii) to remove the reference to the staff currently listed within the paragraph. Moreover, in paragraphs (e)(3)(i) and (iv) we have proposed changes to refer to the newly redesignated paragraph (e) and in paragraph (e)(3)(v) we have proposed changes to refer to the newly defined terms in paragraph (a), specifically the physician or non-physician certification statement. Lastly, we are also proposing a corresponding change to § 410.41(c)(1) to add that ambulance providers or suppliers must indicate on the claims form that, ''when applicable, a physician certification statement or non-physician certification statement is on file.''

In the CY 2013 PFS final rule with comment period (77 FR 69161), we stated that the Secretary is the final arbiter of whether a service is medically necessary for Medicare coverage. We believe that the proposed changes would better enable contractors to establish the medical necessity of these transports by focusing more on the threshold medical necessity determination as opposed to the form or format of the documentation used. We do not anticipate that this clarification will alter the frequency of claim denials.

2. Addition of Staff Authorized To Sign Non-Physician Certification Statements

In the January 25, 1999 final rule with comment period (64 FR 3637), we finalized language at § 410.40 to require ambulance providers or suppliers, in the case of nonemergency unscheduled ambulance services (§ 410.40(d)(3)) to obtain a PCS. In that rule, we explained that: (1) Nonemergency ambulance service is a Medicare service furnished to a beneficiary for whom a physician is responsible, therefore, the physician is responsible for the medical necessity determination; and (2) the PCS will help to ensure that the claims submitted for ambulance services are reasonable and necessary, because other methods of transportation are contraindicated (64 FR 3641). We further stated that we believed the requirement would help to avoid Medicare payment for unnecessary ambulance services that are not medically necessary even though they may be desirable to beneficiaries.

In that final rule with comment period, however, we also addressed the ability of ambulance providers or suppliers to obtain a written order from the beneficiary's attending physician within 48 hours after the transport to avoid unnecessary delays. We agreed with stakeholders that while it is reasonable to expect that an ambulance supplier could obtain a pretransport PCS for routine, scheduled trips, it is less reasonable to impose such a requirement on unscheduled transports, and that it was not necessary that the ambulance suppliers have the PCS in hand prior to furnishing the service. To avoid unnecessary delays for unscheduled transports, we therefore finalized the requirement that required documentation can be obtained within 48 hours after the ambulance transportation service has been furnished.

In the February 27, 2002 final rule with comment period (67 FR 9111), we noted that we had been made aware of instances in which ambulance suppliers, despite having provided ambulance transports, were, through no fault of their own, experiencing difficulty in obtaining the necessary PCS within the required 48-hour timeframe. We stated that the 48-hour period remained the appropriate period of time, but created alternatives for ambulance providers and suppliers unable to obtain a PCS. We finalized an alternative at § 410.40(d)(3)(iii) where ambulance providers and suppliers

unable to obtain a PCS from the attending physician could obtain a signed certification (*not* a physician certification statement) from certain other staff. At that time, we identified several staff members, including a physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), and a discharge planner as staff members able to sign such a non-physician certification statement. The only additional constraints are: (1) That the staff be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported; and (2) that the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished.

In the intervening years, we have received feedback from stakeholders that other staff, such as licensed practical nurses (LPNs), social workers, and case managers, should be included in the list of staff that can sign a certification statement. Similar to the currently designated staff, we now believe that LPNs, social workers, and case managers who have personal knowledge of a beneficiary's condition at the time ambulance transport is ordered and the service is furnished have a skill set largely equal or similar to the other staff members. Thus, we are proposing as part of the new proposed definition of non-physician certification statement at § 410.40(a)(2)(iii) to add LPNs, social workers, and case managers to the list of staff who may sign a certification statement when the ambulance provider or supplier is unable to obtain a signed PCS from the attending physician. As with the staff currently listed in § 410.40(d)(3)(iii), LPNs, social workers, and case managers would need to be employed by the beneficiary's attending physician or the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported, and have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. We also request comments on whether other staff should be included in this regulation, and request that commenters identify such staff's licensure and position and the reason it would be appropriate for such staff to sign a certification statement.

B. Proposal To Establish a Medicare Ground Ambulance Services Data Collection System

1. Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor, and other applicable adjustment factors as set forth at section 1834(l) of the Act and 42 CFR 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate. The two permanent add-on payments are: (1) A 50 percent increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles; and (2) a 50 percent increase to both the base and mileage rate for rural air ambulance transports. The three temporary add-on payments are: (1) A 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in ''super rural'' areas. Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Statutory Requirement for Ground Ambulance Providers and Suppliers To Submit Cost and Other Information

Section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Such system must be designed to collect information: (1) Needed to evaluate the extent to which reported costs relate to payment rates under the AFS; (2) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1121(a) of the Act; and (3) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in section 1834(l)(12) of the Act (super rural areas).

Section 1834(l)(17)(B)(i) of the Act requires the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system, including the representative sample defined at clause (ii).

Under section 1834(l)(17)(B)(ii) of the Act, not later than December 31, 2019, for the data collection for the first year and for each subsequent year through 2024, the Secretary must determine a representative sample to submit information under the data collection system. The sample must be representative of different types of ground ambulance providers and suppliers (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas), and not include an individual ground ambulance provider or supplier in the sample for 2 consecutive years, to the extent practicable.

Section 1834(l)(17)(C) of the Act requires that for each year, a ground ambulance provider or supplier identified by the Secretary in the representative sample as being required to submit information under the data collection system for a period for the year must submit to the Secretary the information specified under the system in a form and manner, and at a time specified by the Secretary.

Section 1834(l)(17)(D) of the Act requires that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not

sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. A hardship exemption to the payment reduction is authorized under section 1834(l)(17)(D)(iii) of the Act, which provides that the Secretary may exempt a ground ambulance provider or supplier from the payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the ground ambulance provider or supplier to submit such information in a timely manner for the specified period. Lastly, section 1834(l)(17)(D)(iv) of the Act requires the Secretary to establish an informal review process under which a ground ambulance provider or supplier may seek an informal review of a determination that the provider or supplier is subject to the payment reduction.

Section 1834(l)(17)(E)(i) allows the Secretary to revise the data collection system as appropriate and, if available, taking into consideration the report (or reports) that the Medicare Payment Advisory Commission (MedPAC) will submit to Congress. Section 1834(l)(17)(E)(ii) of the Act specifies that, to continue to evaluate the extent to which reported costs relate to payment rates under section 1834(l) of the Act and other purposes as the Secretary deems appropriate, the Secretary shall require ground ambulance providers and suppliers to submit information for years after 2024, but in no case less often than once every 3 years, as determined appropriate by the Secretary.

As required by section 1834(l)(17)(F) of the Act, not later than March 15, 2023, and as determined necessary by MedPAC, MedPAC must assess, and submit to Congress a report on, information submitted by providers and suppliers of ground ambulance services through the data collection system, the adequacy of payments for ground ambulance services and geographic variations in the cost of furnishing such services. The report must contain the following:

- An analysis of information submitted through the data collection system;
- An analysis of any burden on ground ambulance providers and suppliers associated with the data collection system;
- A recommendation as to whether information should continue to be submitted through such data collection system or if such system should be revised by the Secretary, as provided under section 1834(l)(17)(E)(i) of the Act; and
- Other information determined appropriate by MedPAC.

Section 1834(l)(17)(G) of the Act requires the Secretary to post information on the results of the data collection on the CMS website, as determined appropriate by the Secretary.

Section 1834(l)(17)(H) of the Act requires the Secretary to implement the provisions of section 1834(l)(17) of the Act through notice and comment rulemaking.

Section 1834(l)(17)(I) of the Act provides that the Paperwork Reduction Act (Title 44, Chapter 35 of the U.S. Code) does not apply to collection of information required under section 1834(l)(17) of the Act.

Section 1834(l)(17)(J) of the Act provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the data collection system or identification of respondents.

We note that while the requirements of section 1834(l)(17) of the Act are specific to ground ambulance organizations, many stakeholders have expressed interest to us in making this type of information available for other providers and suppliers of ambulance services. For example, air ambulance organizations have suggested they are interested in making this information available. We recognize that the regulation of air ambulances spans multiple federal agencies, and note that section 418 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254, enacted October 5, 2018) requires the Secretary of HHS, in consultation with the Secretary of Transportation, to establish an advisory committee that includes HHS, DOT, and others to review options to improve the disclosure of charges and fees for air medical services, better inform consumers of insurance options for those services, and better inform and protect consumers of these services. We welcome comments on the state of the air ambulance industry and how CMS can work within its statutory authority to ensure that appropriate payments are made to air ambulance organizations serving the Medicare population.

3. Research To Inform the Development of a Ground Ambulance Data Collection System

To inform the development of a ground ambulance data collection system, including a representative sampling plan, our contractor developed recommendations regarding the methodology for collecting cost, revenue, utilization and other information from ground ambulance providers and suppliers (collectively referred to in this proposed rule as ''ground ambulance organizations'') and a sampling plan consistent with sections 1834(l)(17)(A) and (B) of the Act. Our contractor also developed recommendations for the collection and reporting of data with the least amount of burden possible to ground ambulance organizations. The recommendations took into consideration the following:

- An environmental scan consisting of a review of existing peer-reviewed literature, government and association reports, and targeted web searches. The purpose of the environmental scan was to collect information on costs and revenues of ground ambulance transportation services, identify background information regarding the differences among ground ambulance organizations including state and local requirements that may impact the costs of providing ambulance services, and describe financial challenges facing the ambulance industry. Five previously fielded ambulance cost collection tools were also identified and analyzed and are described below.
- Interviews with ambulance providers and suppliers, billing companies, and other stakeholders to determine all major cost, revenue, and utilization components, and differences in these components across ground ambulance organizations. These discussions provided valuable information on the process for developing a data collection system, including how to best elicit valid responses and limit burden on respondents, as well as the timing of the data collection.
- Analyses of Medicare claims and enrollment data, including all fee-for-service (FFS) Medicare claims with dates of service in 2016, the most recent complete year of claims data for ground ambulance services.

Our contractor also analyzed the following five data collection tools that currently collect or have collected data from ground ambulance organizations:

- The Moran Company Statistical and Financial Data Survey (the ''Moran

survey'').[85] In 2012, American Ambulance Association (AAA) commissioned a study with the goal of developing a data collection instrument and making recommendations for collecting data to determine the costs of delivering ground ambulance services to Medicare beneficiaries. The result was the Moran survey, which is a two-step data collection method in which all ambulance providers and suppliers first complete a short survey with basic descriptive information on their characteristics, and second, a representative sample of ambulance providers and suppliers report more specific cost information.

- Ground Emergency Medical Transportation (GEMT) Cost Report form and instructions from California's Medicaid program.[86] The GEMT Cost Report form and instructions is used by some states to determine whether ambulance providers and suppliers should receive supplemental payments from state Medicaid programs to cover shortfalls between revenue and costs. This data collection instrument is geared toward government entities, as private ambulance providers and suppliers do not qualify for the supplemental payments.
- The Emergency Medical Services Cost Analysis Project (EMSCAP) framework.[87] The National Highway Traffic Safety Administration funded EMSCAP in 2007 to develop a framework for determining the cost for an EMS system at the community level. Subsequently, EMSCAP researchers used this framework to develop a cost workbook and pilot test the instrument on three communities representing rural, urban, and suburban areas. EMS services within the three communities included volunteer, paid, and combination EMS agencies, both fire department and third service-based. Third service-based refers to services provided by a local government that include a fire department, police department and a separate EMS, forming an emergency trio.
- A 2012 Government Accountability Office (GAO) ambulance survey.[88] To examine ground ambulance suppliers' costs for transports, in 2012 GAO administered a web-based survey to a random sample of 294 eligible ambulance suppliers. GAO collected data on their 2010 costs, revenues, transports, and organizational characteristics. Although the GAO survey collected data for each domain at the summary level, it also prompted respondents to take into account multiple factors when calculating their summary costs.
- The Rural Ambulance Service Budget Model.[89] This tool was developed by a task force of the Rural EMS and Trauma Technical Assistance Center with funds from the Health Resources and Services Administration (HRSA) in the early 2000s. The purpose was to provide assistance to rural ambulance entities in establishing an annual budget and to calculate the value of services donated by other entities, as well as services donated by the ambulance entity's staff to the community. The tool was last updated in 2010 and has been cited as a resource for rural ground ambulance organizations by state and national government agencies. However, use of the tool is not required by any of these agencies.

Our contractor's analysis of these tools revealed that while there was overlap of the broad cost categories collected (for example, labor, vehicles, and facilities costs) via these tools, there were significant differences in the more specific data collected within these broad categories. Overall, there was a large amount of variability regarding whether the tools allowed for detailed accounting of costs and whether the tools used respondent-defined or survey-defined categories for reporting. The five tools also differed in terms of their instructions, format, and design in terms of how a portion of organizations' total costs were allocated to ground ambulance costs, the time frame for reporting, and the flexibility of reporting.

Based on these activities, our contractor prepared a report entitled, ''Medicare Ground Ambulance Data Collection System—Sampling and Data Collection Instrument Considerations and Recommendations'' (referred to as ''the CAMH[90] report'') which is referenced throughout this proposed rule. It is available at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html* and provides more detail on the research, findings and recommendations concerning the data collection instrument and sampling. This report, in addition to other considerations we describe below, informed our proposals for the data collection instrument.

4. Proposals for the Data Collection Instrument

a. Proposed Format

We considered several options for collecting the data including a survey, a cost report spreadsheet like the GEMT, and the Medicare Cost Report (MCR). During interviews with ambulance providers and suppliers, some participants stated that they would prefer that data collection be done through a cost report spreadsheet, rather than a survey, such as the GEMT and other similar data collection tools utilized by state Medicaid programs. They noted that data cost collection spreadsheets such as the GEMT are used in some states where supplemental payments are made to ground ambulance organizations based on costs and revenue reported via a cost reporting template. Although these tools are valuable to the ambulance suppliers that utilize them for Medicaid payment purposes, we note that only a small number of states make use of these tools for the purpose of providing supplemental payments and that they are generally geared toward government run entities that provide a broad range of emergency medical services and not just ground ambulance services. For these reasons, we do not believe that these tools could be used by all ground ambulance organizations for Medicare payment purposes without significant revision.

Other ambulance providers and suppliers stated their preference for survey-based reporting, such as the Moran survey, because they believe survey reporting is less burdensome and allows more flexibility for reporting. We agree that survey reporting can be designed to provide greater flexibility of reporting with reduced reporting burden. However, the Moran survey recommended excluding small ground ambulance organizations with limited capacity or those which relied heavily

[85] The Moran Company (2014). Detailing ''Hybrid Data Collection Method'' for the Ambulance Industry: Beta Test Results of the Statistical & Financial Data Survey & Recommendations, [Online]. Available at *https://s3.amazonaws.com/americanambulance-advocacy/AAA+Final+Report+Detailing+Hybrid+Data+Collection+Method.pdf.*

[86] State of California—Health and Human Services Agency Department of Health Care Services Ground Emergency Medical Transportation (2013). Ground Emergency Medical Transportation Services Cost Report General Instructions for Completing Cost Report Forms, [Online]. Available at *http://www.dhcs.ca.gov/provgovpart/documents/gemt/gemt_cstrptinstr.pdf.*

[87] Lerner, E.B., Nichol, G., Spaite, D.W., Garrison, H.G., & Maio, R.F. (2007). A comprehensive framework for determining the cost of an emergency medical services system. Available at *https://www.mcw.edu/departments/emergency-medicine/research/emergency-medical-services-cost-analysis-project.*

[88] U.S. Government Accountability Office (2012). Survey of Ambulance Services. Available at *https://www.gao.gov/assets/650/649018.pdf.*

[89] Health Resources and Services Administration. The Rural Ambulance Service Budget Model, [Online]. Available at *https://www.ruralcenter.org/resource-library/rural-ambulance-service-budget-model.*

[90] CMS Alliance to Modernize Healthcare.

on volunteer services, which would exclude a large percentage of ground ambulance organizations from our sample. It would also not take into account the unique differences of government run ground ambulance entities, and specifically ground ambulance entities that provide other emergency services such as fire services, and could not be used by all ground ambulance organizations without significant revisions. Some ambulance organizations that favored using the Moran survey also recommended using cost reporting guidelines that are similar to the CMS requirements for the MCR. Although we agree that standardization is important for data analysis, many smaller ground ambulance organizations have said they would have difficulty complying with complex cost reporting guidelines. We believe that requiring ground ambulance organizations to complete and submit an MCR for the purpose of the data collection required in section 1834(l)(17) of the Act would be unnecessarily resource intensive and burdensome.

We also considered using multiple instruments or staged data collection as recommended in the Moran Report, where we would first collect organizational characteristic data from all ground ambulance organizations, use that information for sampling purposes, and then collect cost and revenue information from a sample of ambulance providers and suppliers. Using this approach, we would need 100 percent participation from all ground ambulance organizations in reporting the organizational characteristic data in order for the data to be used for sampling purposes. We are not proposing this approach because we believe multiple data collections would increase respondent burden and may not align with sections 1834(l)(17)(A) and (B) of the Act which requires CMS to collect data from a random sample and prohibits data collection from the same ground ambulance organizations in 2 consecutive years to the extent practicable. We will discuss this more in the options we considered for sampling section of this proposed rule.

Based on our analysis of the existing or previously used data collection instruments described above, we do not believe that any of them would be sufficient to adequately capture the data required by section 1834(l) of the Act. Therefore, we are proposing to collect ground ambulance organization data using a survey that we developed specifically for this purpose, which we will refer to from this point forward in this proposed rule as the data collection instrument, and which we would make available via a secure web-based system. We believe that the data collection instrument should be usable by all ground ambulance organizations, regardless of their size, scope of operations and services offered, and structure. The proposed data collection instrument includes screening questions and skip patterns that direct ground ambulance organizations to only view and respond to questions that apply to their specific type of organization. We also believe that the proposed data collection instrument is easier to navigate and less time consuming to complete than a cost report spreadsheet. The proposed secure web-based survey would be available before the start of the first data reporting period to allow time for users to register, receive their secure login information, and receive training from CMS on how to use the system. We are also proposing to codify these policies at § 414.626.

b. Proposed Scope of Cost, Revenue, and Utilization Data

Section 1834(l)(17)(A) of the Act requires CMS to develop a data collection system to collect data related to cost, revenue, utilization, and other information determined appropriate by the Secretary for ground ambulance organizations. Section 1834(1)(17)(A)(i) of the Act further specifies that the information collected through the system should be sufficient to evaluate the extent to which reported costs relate to payment rates.

We considered several options regarding the scope of collecting data on ground ambulance cost, revenue, and utilization. One option would be to require ground ambulance organizations to report on their: (1) Total costs related to ground ambulance services; (2) total revenue from ground ambulance services; and (3) total ground ambulance service utilization. This approach would consider all ground ambulance costs, revenue, and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary. The advantage of this approach is that ground ambulance organizations already track information at their organizational level on total costs, revenue, and utilization for their own internal budgeting and planning. This method was also used to calculate an organization-level average cost per transport in two previous studies described below:

In a 2012 study entitled, ''Ambulance Providers: Costs and Medicare Margins Varied Widely; Transports of Beneficiaries has Increased'',[91] the GAO performed an analysis to assess how Medicare payments, including the temporary add-on payments, compared to costs reported using a survey. The GAO collected information via a survey on organizations' total costs, including operating and capital costs, without restriction to costs associated with Medicare transports or costs incurred in responding to calls for service from Medicare beneficiaries. GAO then divided reported total costs by the reported number of transports (regardless of whether Medicare paid for the transport) to calculate an average cost per transport for each organization, and reported summary statistics across these averages, including a median cost per transport of $429. However, to simplify data collection and analysis, the analysis was limited to ambulance suppliers that did not share operational costs with a fire department, hospital, or other entity. GAO stated that its calculations assumed that this average cost per transport was constant for all of an organization's transports regardless of whether or not the patient transported was a Medicare beneficiary. This approach implicitly loads the costs associated with activities that did not result in a transport, such as responses by a ground ambulance where the patient could not be located, refused transport, or was treated on the scene, into the estimated cost per transport.

The second study, ''Report to Congress Evaluation of Hospitals' Ambulance Data on Medicare Cost Reports and Feasibility of Obtaining Cost Data from All Ambulance Providers and Suppliers,'' [92] was conducted by HHS as required under the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013). This report used data from Medicare cost reports as its data source, rather than a survey, and included only ambulance providers, rather than ambulance providers and suppliers. It described substantially higher costs per transports for ambulance providers compared to the estimate from GAO, with a median of approximately $1,750 per transport. It did not compare reported total costs to Medicare revenue tallied in claims data with and without the temporary add-on payments. Neither the GAO nor the HHS report compared costs and AFS payment rates for specific Healthcare Common Procedure Coding System

[91] This report is available at *https://www.gao.gov/assets/650/649018.pdf.*

[92] This report is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf.*

(HCPCS) codes because the available cost data in both studies did not support that level of analysis.

Another option would be to consider only those costs that are relevant to ground ambulance services furnished to Medicare beneficiaries. Collecting costs associated with specific services (such as Medicare transports) and excluding other services (such as Medicaid transports or responses that did not result in transport) would require either a much more intensive and costly data collection approach (such as time and motion studies) or assumptions on which portions of total costs were related to the specific activity. We believe this approach would be overly burdensome and complex for ground ambulance organizations, especially those who provide other services in addition to ground ambulance services.

A third option would be to consider only those costs that are related to the specific ground ambulance transport services that are paid under the AFS. This would require ground ambulance organizations to report costs, revenue, and utilization related to specific levels of services reported with HCPCS codes, but not costs, revenue, and utilization for other services such as responses that did not result in a transport (which is not covered under the AFS). We believe this option would also be overly burdensome and complex.

In discussions with ambulance providers and suppliers, we were informed that ground ambulance organizations most often track organization-level total costs, revenue, and utilization across all activities and services furnished to all patients, and that most would find it difficult to report costs, revenue, and utilization associated with services furnished exclusively to Medicare beneficiaries or associated with Medicare services covered under the AFS.

Therefore, we propose the first option as discussed above, which would require ground ambulance organizations to report on their: (1) Total costs related to ground ambulance services; (2) total revenue from ground ambulance services; and (3) total ground ambulance service utilization. This approach would consider all ground ambulance costs, revenue, and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary to collect total cost, total revenue, and total utilization data.

Although we are proposing to collect a ground ambulance organization's total costs and total revenues, we are aware that many ground ambulance organizations share operational costs with fire departments, other public service organizations, air ambulance services, hospitals, and other entities. For these organizations, only a portion of certain capital and operational costs contribute to total ground ambulance costs, and only a portion of revenue is from ground ambulance services. We are also aware that some ground ambulance suppliers deploy emergency medical technicians (EMTs) in fire trucks, which would make it difficult to determine whether the fire truck costs should be factored into the total ground ambulance costs, and if so, how that would be calculated.

One option to address these challenges is to limit data collection to ground ambulance organizations that do not share operational costs with fire departments, hospitals, or other entities, as GAO did for their 2012 report. However, we do not believe this approach meets the requirement in section 1834(l)(17)(B)(ii) of the Act for a representative sample because many ambulance suppliers and all ambulance providers share operational costs with fire, police, health care delivery or other activities. We also considered including providers' and suppliers' total costs and revenues across all activities. While this would simplify cost and revenue data reporting, the resulting data would not be limited to ground ambulance activities, and therefore, would result in biased estimates of ground ambulance costs or require significant assumptions to estimate ground ambulance costs alone.

To more accurately define total costs and total revenues related to ground ambulance services for those ground ambulance organizations that provide other services in addition to ground ambulance services, we are proposing an approach where the data collection instrument instructions would separately address three further refined proposed categories of total ground ambulance costs and revenues:

- *Cost and revenue components completely unrelated to ground ambulance services.* These costs and revenues would be unrelated to this data collection and not reported. Examples include administrative staff without ground ambulance responsibilities, health care delivery outside of ground ambulance, community paramedicine, community education and outreach, and fire and police public safety response.
- *Cost and revenue components partially related to ground ambulance services.* These costs and revenue would be reported in full, but respondents would report additional information that can be used to allocate a portion of the costs to ground ambulance services. Depending on how the data would be utilized, certain costs could be included or excluded from an analysis after data are collected. Examples include EMTs who are also firefighters and facilities with both ground ambulance and fire department functions. (We considered an alternative where respondents would allocate costs and report only costs associated with ground ambulance services but believe that would pose an additional burden on the respondent to calculate allocated amounts, and would result in an allocation process that is less transparent and standardized).
- *Cost and revenue components entirely related to ground ambulance services.* These costs are reported in full. Examples include EMTs with only ground ambulance responsibilities and ground ambulance vehicles.

We believe that this approach would enable us to collect the data necessary to evaluate the adequacy of payments for ground ambulance services, the utilization of capital equipment and ambulance capacity, and the geographic variation in the cost of furnishing such services. The data could be analyzed in the same manner as the data in the GAO report, for example, calculating an average per-transport cost for each organization and calculating Medicare margins with and without add-on payments, or could provide the basis for other analyses to link reported costs to AFS rates. For example, an analysis could use reported total costs and information on the volume of transports by levels of services to estimate a cost for each HCPCS code reported for the AFS, or regression-based approaches to estimate the marginal cost of furnishing each HCPCS code on the AFS. We believe that under our proposed approach, the collected data would be available to estimate total costs and revenue relevant to ground ambulance services.

c. Proposed Data Collection Elements

The draft data collection instrument is available on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.* An overview of the elements of the data collection instrument we are proposing is in Table 29, including information on costs, revenues, utilization (which we define for the purposes of the instrument as service volume and service mix), as well as the characteristics of ground ambulance organizations.

To help structure the data collection instrument, we organized costs by category (for example, labor, vehicles, and facilities), which is the approach

used in the GEMT and the AAA/Moran survey.

TABLE 29—PROPOSED COMPONENTS FOR THE DATA COLLECTION INSTRUMENT

Component (data collection instrument section)	Broad description
Ground ambulance organization characteristics (2–4).	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions.
Utilization: Ground ambulance service volume and service mix (5 and 6).	Number of responses and transports, level of services reported by HCPCS code.
Costs (7–12)	Information on all costs partially or entirely related to ground ambulance services.
• Staffing and Labor Costs (7)	Number and costs associated with EMTs administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; rent and mortgage payments, insurance, maintenance, and utility costs.
• Vehicle Costs (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual depreciation; total fuel, maintenance, and insurance costs.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (11)	All other costs not reported elsewhere.
• Total Cost (12)	Total costs for the ground ambulance organization included as a way to cross-check costs reported in the instrument.
Revenue (13)	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

The following sections describe our proposed approach for data collection in each of these categories.

(1) Collecting Data on Ground Ambulance Provider and Supplier Characteristics

CMS is required to collect information regarding the geographic location of ground ambulance organizations to meet the requirement at section 1834(l)(17)(A)(iii) of the Act that the collected data include information on services furnished in different geographic locations, including rural areas and low population density areas. We also recognize that there are differences between and among ground ambulance organizations on several key characteristics, including geographic location; ownership (for-profit or non-profit, government or non-government, etc.); service volume, organization type (including whether costs are shared with fire or police response or health care delivery operations); EMS responsibilities; and staffing models. Research conducted for this proposal indicates that:

- There are differences in costs per transport by ground ambulance organizations with a different ownership status;
- EMS level of service and staffing models often have an important impact on costs, with higher EMS levels of service (for example, quicker response times) and static staffing models (that is, mainatining a constant response capability 24 hours a day, 7 days a week, 365 days a year) involving higher fixed costs; and
- Utilization varies significantly across ambulance providers and suppliers of different characteristics.

Due to this variation in characteristics and the effect it has on costs and revenues, we believe it is important for ground ambulance organizations to report additional characterictics, as described below, to adequately analyze the differences in costs and revenue among different types of ambulance providers and suppliers. We also believe collecting this information directly through the proposed data collection instrument will improve data quality with minimal burden on the respondents because the proposed data collection instrument is designed to tailor later sections and questions based on respondents' characteristics through programmed ''skip patterns''. We considered relying exclusively on the Medicare enrollment form CMS 855A for ground ambulance providers or CMS 855B for ground ambulance suppliers to capture this information, but believe that data accuracy would be more robust if reported directly by respondents for the specific purpose of this data collection.

The proposed data collection questions related to organizational characteristics and service area are in sections 2, 3, and 4 of the data collection instrument. We are proposing to collect information on ownership and organization type through a sequence of questions in section 2 of the data collection instrument. Some of the questions in this section are adapted in part from prior surveys (such as the GAO and Moran surveys) with changes as necessary to fit scenarios reported during interviews with ground ambulance organizations. The first question related to organizational characteristics, question 6, asks about the organizations' ownership status. This item aligns closely with a similar question on the Medicare enrollment form CMS 855B for ambulance suppliers. Question 7 asks whether the respondent's organization uses any volunteer labor. While this question could have been asked later in the data collection instrument around the collection of labor data, we opted to include it here because many ground ambulance organizations informed CMS that they view the use of volunteer labor as a defining organizational characteristic, on par with ownership status, and that a volunteer labor question was expected by respondents at this early point in the data collection instrument. Question 8 asks respondents to select a category that best describes their ambulance organization. The response options for this item are mutually exclusive and align with the ambulance provider and supplier taxonomy described in the CAMH report. The next two questions, 9 and 10, more directly ask whether the respondent has shared operational costs with an entity of another type, including a fire department, hospital, or other entity. We are proposing these questions in addition to the organization type question to account for situations where a respondent might primarily identify as an organization of one type (with implications for shared operational costs) but then might have shared

operational costs with another entity type. Responses to questions 9 and 10 play an important role in skip logic later in the data collection instrument regarding questions and response options relevant only to ground ambulance organizations with shared operational costs with an entity of another type.

Other proposed questions regarding organizational characteristics are necessary to tailor later parts of the data collection instrument to the respondent. These include proposed questions in section 2 of the data collection instrument on whether the respondent's ambulance organization:

- Is part of a broader corporation or other entity billing under multiple National Provider Identifiers (NPIs) (question 2).
- Routinely responds to emergency calls for service (question 11).
- Operates land, water, and air ambulances (questions 12–14).
- Has a staffing model that is static (that is, consistent staffing over the course of a day/week) or dynamic (that is, staffing varies over the course of a day/week) or combined deployment (certain times of the day have a fixed number of units, and other times are dynamic depending on need) (question 15).
- Provides continuous (also known as ''24/7/365'') emergency services) (question 16).
- Provides paramedic or other emergency response staff to meet ambulances from other organizations in the course of a response (questions 17 and 18).

In our interviews with ambulance providers and suppliers, some participants indicated that their staffing model is an organizational characteristic that would likely be associated with costs per transport. Organizations that need to maintain fixed staffing levels over time (for example, to maintain an emergency response capability to serve a community) would likely have higher costs than those that do not.

Section 1834(l)(17)(A)(iii) of the Act requires collecting data from ambulance providers and suppliers in different geographic locations, including rural areas and low population density areas. The area served by ambulance providers and suppliers is an important characteristic and we are proposing to collect information on the geographic area served by each ambulance provider and supplier in section 3 of the data collection instrument.

Many ground ambulance organizations have a primary service area in which they are responsible for a certain type of service (for example, ALS–1 emergency response within the borders of a county, town, or other municipality) and may have secondary services areas for a variety reasons, such as providing mutual or auto aid, or providing a different service in a secondary area (for example, non-emergency transports state-wide). We considered several alternatives to collect information on service area. One option would be to utilize Medicare claims data, but this would limit the information to Medicare billed transports only and would also not differentiate between primary and other service areas. Another option would be to allow respondents to write in a description of their primary and other service areas, but this would require converting written responses to a format that can be used for analysis. A third option would be for respondents to report the ZIP codes that constitute their primary and other service area. This approach aligns with the Medicare enrollment process requirement to submit ZIP codes where the ground ambulance organization operates. It would also collect ZIP code-based information on service area that can be easily linked to the ZIP Code to Carrier Locality file [93] that lists each ZIP code and its designation as urban; rural; or super-rural. This file is used by the MACs to determine if the temporary add-on payments should apply to a transport under the AFS. The main limitation of this approach is that ZIP codes would not always align to service areas, because ZIP codes routinely cross town, county, and other boundaries that are likely relevant for defining ground ambulance organizations' service areas.

We are proposing to require ground ambulance organizations that are selected during sampling to identify their primary service area by either: (1) Providing a list of ZIP codes that constitute their primary service area; or (2) selecting a primary service area using pre-populated drop-down menus at the county and municipality level in question 1, section 3 of the data collection instrument. We are also proposing to require respondents to specify whether they have a ''secondary'' service area, which are areas where services are regularly provided under mutual aid, auto-aid, or other agreements in section 3, question 4 of the data collection instrument and if so, to identify the secondary service area using ZIP codes or other regions as described above for the primary service area (section 3, question 5). Mutual aid agreements are joint agreements with neighboring areas in which they can ask each other for assistance. Auto-aid arrangements allow a central dispatch to send the closest ambulance to the scene. We are not proposing to collect information on areas served only in exceptional circumstances, such as areas rarely served under mutual or auto-aid agreements or deployments in response to natural disasters or mass casualty events because we believe reporting on rarely-served areas would involve significant additional burden and would add to instrument complexity without generating data that would be useful for analysis.

The proposed approach distinguishes between primary and secondary service areas. This would allow subsequent questions on the balance of transports in a respondent's primary versus secondary service area and whether average trip time and response times are substantively longer in the secondary versus primary service area. We believe this approach results in data that can be easily analyzed and eliminates the need to ask certain other questions (such as the population and square mileage of the respondent's service area) because this information can be inferred using the reported geographic service area boundaries.

We are proposing to ask the following questions in sections 3 and 4 of the of the data collection instrument, service area and subsequent emergency response time, because the responses to these questions are closely related to the area served by the organization:

- Whether the respondent is the primary emergency ambulance organization for at least one type of service in their primary service area (section 3, question 2).
- Average trip time in primary and secondary service areas (section 3, questions 3 and 6).
- Average response time (for organizations responding to emergency calls for service) for primary and secondary service areas (section 4, questions 1–2).
- Whether the organization is required or incentivized to meet response time targets by contract or other arrangement (for organizations responding to emergency calls for service) (section 4, question 3).

Average trip and response time are necessary to understand how geographic distance between the ground ambulance organization's facilities and patients affects costs. In interviews, ground ambulance organizations recommended the collection of average trip time in addition to mileage because some rural and remote areas may have relatively

[93] Available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html.*

long average trip times even though mileage may be more modest due to terrain, the quality of roads, and other factors. We believe that collecting information on average response time would allow the analysis of whether communities with different response time expectations and targets have systematically different costs.

(2) Collecting Data on Ground Ambulance Utilization

CMS is required to collect information on the utilization of ground ambulance services. While we could collect information on the volume of ground ambulance services that can be billed to Medicare, this approach would not provide information needed to determine total utilization of ground ambulance organizations. Another option would be to utilize Medicare claims data for estimates of ground ambulance transport volume and separately collect information on services not payable by Medicare (such as responses that did not result in a transport). This approach would also not provide complete information on total transport volume, since other services, such as responses that do not result in a transport, would not be included.

Based on information provided during interviews with ground ambulance organizations, we identified several distinct utilization categories, such as total responses and ground ambulance responses. This is particularly important for fire-based and police-based organizations that may have a significant volume of fire and police responses that do not involve a ground ambulance. The number of responses that did not result in a transport can be separately tallied. Other important utilization categories are ground ambulance transports (that is, responses during which a patient is loaded in a ground ambulance), which can be measured in terms of total transports (that is, all ground ambulance transports regardless of payor) or paid transports (that is, transports for which the ambulance provider or supplier was paid in part or in full). Another utilization category would include information on ambulance providers and suppliers that furnish paramedic intercept services or provide paramedic-level staff in the course of a BLS response where another organization provides the ground ambulance transport.

We believe it is important to collect utilization data related to all services, not just transports, because other services that contribute to the total volume of responses have direct implications for costs. Collecting utilization information related to transports but not other services could omit important cost information. Some utilization measures, such as the ratio of ground ambulance to total responses, may be one basis for allocating certain costs reported elsewhere in the data collection instrument. Another example would be the difference between total and paid transport, as this would provide information on services that were provided to patients but for which no payment is received.

To best capture the full range of utilization data, we are proposing a two-pronged approach to collect data on the volume and the mix of services. First, we are proposing to collect total volume of services for each of the categories listed below in section 5 of the proposed data collection instrument:

- Total responses, including those where a ground ambulance was not deployed (question 1).
- Ground ambulance responses, that is, responses where a ground ambulance was deployed (question 2).
- Ground ambulance responses that did not result in a transport (question 4).
- Ground ambulance transports (question 5).
- Paid ground ambulance transports, that is, ground ambulance transports where the ambulance provider or supplier was paid for a billed amount in part or in full (question 6).
- Standby events (question 7).
- Paramedic intercept services as defined by Medicare (question 8).
- Other situations where paramedic staff contributes to a response where another organization provides the ground ambulance transport (question 9).

The CAMH report describes several cases where an ambulance provider or suppliers' mix of services within one of the utilization categories described above could affect costs or revenue. Most importantly, within billed transports, variation in the mix of specific ground ambulance services (for example, ALS versus BLS services) will affect both costs (because ALS transports require more and more costly inputs) and revenue (because ALS services are generally paid at a higher rate). Ground ambulance organizations with a higher share of responses that are emergency responses may also face higher fixed costs, and that the costs for organizations furnishing larger shares of water ambulance transports are likely different than costs from organizations that do not furnish water ambulance transports. There is a subset of ground ambulance organizations that specialize in non-emergency transports or inter-facility transports, which suggests that this business model may result in different per-transport costs compared to EMS-focused ambulance providers and suppliers.

Second, to account for this significant variation, we are proposing to collect the following information related to service mix:

- The share of responses that were emergency versus non-emergency (section 6 question 1).
- The share of transports that were land versus water (asked only of organizations reporting that they operate water ambulances; section 6 question 2).
- The share of transports by service level (section 6 question 3).
- The share of transports that were inter-facility transports (section 6 question 4).

We are not proposing that respondents report on their mix of services in primary and secondary service areas (as defined above) separately because this would double the length of this section of the data collection instrument and require complex calculations or use of assumptions by respondents that do not separately track services by area. Instead, we are proposing that respondents report the share of total ground ambulance responses that were in a secondary rather than primary service area in a single item (section 5 question 3). We also are not proposing to collect detailed information regarding the mix of services for total transports (versus paid transports) and paid transports (versus total transports) because collecting information on the mix of services for total and paid transports separately would double the reporting burden in this section and because we believe, based on discussions with stakeholders, that it is reasonable to assume that the distribution of transports across categories would be the same.

(3) Collecting Data on Costs

Section 1834(l)(17)(A) of the Act requires CMS to collect cost information from ground ambulance organizations, and we previously discussed our proposal to collect data on a ground ambulance organization's total costs. This part of the proposed rule describes the data in each cost category that we are proposing to collect, as well as alternatives that we considered.

The costs reported separately in the categories of costs we are proposing to collect would sum to an organization's total ground ambulance costs. In addition to ground ambulance costs, we are proposing to ask all respondents in the proposed data collection instrument

to report their total annual costs (that is, operating and capital expenses), inclusive of costs unrelated to ground ambulance services, in a single survey item (section 12, question 1). For ground ambulance organizations that do not have costs from other activities (such as from operating a fire or police department), the reported total costs are a way to cross-check costs reported in individual cost categories throughout the instrument, and we can compare the reported total to the sum of costs across categories. Such a cross-check may also be appropriate for ground ambulance organizations with costs from other activities, as the sum of costs across ground ambulance cost categories should always be less than the ground ambulance organization's reported total costs. We believe that this cross-check will improve data quality and is consistent with existing survey-based data collection tools. This approach will also provide a better understanding of the overall size and scope of ground ambulance organizations, including activities other than providing ground ambulance services. Relatively larger organizations may have lower ground ambulance costs due to due to economies of scale and scope.

To avoid reporting the same costs multiple times, there are instructions and reminders throughout the proposed data collection instrument to avoid double-counting of costs. From a design perspective, we believe it is less important where a particular cost is reported on the survey data collection instrument and more important that the cost is reported only once.

We are making two proposals that have important implications for reporting in all cost sections in the proposed data collection instrument. First, in the case where a sampled organization is part of a broader organization (such as when a single parent company operates different ground ambulance suppliers), we propose to ask the respondents to report an allocated portion of the relevant ground ambulance labor, facilities, vehicle, supply/equipment, and other costs from the broader parent organization level in separate questions in several places in the cost sections of the data collection instrument (section 7.2 question 3, section 8.2 question 2, section 8.3 question 2, section 9.2 question 5, section 9.3 question 6, section 10.2 question 4, and section 11 questions 2 and 5). This scenario is discussed in more detail in the sampling section below. In exploratory analyses, we found that a small share of NPIs were part of broader parent organizations. Due to the rarity of this scenario and the complexity of calculations required, we are proposing to allow the respondent to report an allocated amount directly for these questions using an allocation approach they regularly use for this purpose. We believe that while proposing a specific allocation approach would yield more uniform and transparent data, we believe that these benefits are not worth the additional respondent burden.

Second, we are proposing to include a general instruction stating that in cases where costs are paid by another entity with which the respondent has an ongoing business relationship, the respondent must collect and report these costs to ensure that the data reported reflects all costs relevant to ground ambulance services. Examples include when a municipality pays rent, utilities, or benefits directly for a government or non-profit ambulance organization, or when hospitals provide supplies and/or medications to ground ambulance operations at no cost. During interviews with ground ambulance organizations, we were told that there are many nuanced arrangements that fit this broad scenario. Although we recognize this would be an additional step for some ground ambulance organizations, we are concerned that the lack of reported cost data in one of these major categories could significantly affect calculated total cost.

Because some ambulances, other vehicles, and buildings are donated to ground ambulance organizations, we considered asking respondents to report fair market values for these vehicles and buildings. However, we are aware that while the lack of reported cost data in one of these major categories could affect calculated total cost, it is not always clear what cost is appropriate to report. To avoid the subjectivity and burden involved in asking respondents to report fair market value, we propose instead that respondents report which ambulances, other vehicles, and buildings have been donated, but not an estimate of the fair market value of those donations. We believe fair market values could be imputed using publicly available sources of data to facilitate comparison of data between organizations that have donations and those that do not. For the same reasons, we are also proposing not to collect an estimate of fair market value for donated equipment, supplies, and costs collected in the ''other costs'' section of the instrument. As noted above, for those organizations with costs that were paid by another entity with which the respondent has an ongoing business relationship, such as a ground ambulance organization that is part of or owned by a government entity, respondents would obtain the cost information directly from that entity since we would not consider these to be donated items.

The following sections describe each cost category, alternative for data collection, and our proposals related to each category of costs separately.

(i.) Collecting Data on Staffing and Labor Costs

In interviews with ambulance providers and suppliers, they stated that labor is one the largest contributors to total ground ambulance costs (especially medical staff such as EMTs, paramedics, and medical directors) and that they use a broad mix of labor types and hiring arrangements. There is also significant variation in tracking staffing and labor cost inputs that are needed to calculate costs. We were also informed by ambulance providers and suppliers that data on the number of ground ambulance staff and associated labor costs were often available at one of three levels: The individual employee level; aggregated by category such as EMT-Basic or Medical Director; or aggregated across all staff. Additionally, we were told by ambulance providers and suppliers that ground ambulance organizations typically face challenges in tracking ground ambulance staff and costs by category when staff had multiple ground ambulance responsibilities (for example, EMTs with supervisory responsibilities, EMTs who are also firefighters, etc.).

We agree that labor costs are an important component of total costs and believe that it is necessary to collect information on both staffing levels, that is, the quantity of labor used, and the labor costs resulting from these labor inputs. Without information on staffing levels, we would not be able to gauge whether differences in labor costs are due to compensation or different levels of staffing. Collecting information on staffing levels also allows the use of imputed labor rates from other sources (such as the Bureau of Labor Statistics). We also acknowledge the practical need to balance the burden involved in reporting extremely detailed staffing and labor costs information against the usefulness of detailed data for explaining variation in ground ambulance costs. Therefore, we are proposing to collect information in the proposed data collection instrument on the number of staff and labor costs for several detailed categories of response staff (for example, EMT-basic, EMT-intermediate, and EMT-paramedic) (section 7.1), and for a single category for paid administrative and facilities

staff (for example, executives, billing staff, and maintenance staff) (section 7.2), and (c) separately for medical directors (section 7.2). We believe this approach involves less respondent burden compared to reporting on each individual staff member. If more detailed categories were used for reporting staffing levels and costs, we believe the burden involved in assigning paid administrative and facilities staff with multiple roles to individual categories or apportioning their labor and costs to separate categories would increase.

The main limitation of the proposed approach is that we would not collect detailed information on specific paid administration and facilities labor categories. Therefore, we are also proposing to collect some information that would help explain variation in labor costs by asking whether the ground ambulance organization has some staff in more specific paid administration and facilities categories such as billing, dispatch, and maintenance staff (section 7, question 1). This question also serves as a screening question to determine which response options appear to the respondent in several other questions in this section of the proposed data collection instrument. We also propose to ask for information on why individual labor categories are not used (section 7, question 1) and if there is at least one individual with 20 hours a week or more of effort devoted to specific activities such as training and quality assurance (section 7.2, question 2).

Reporting Staffing Levels

In reporting staffing levels in the proposed data collection instrument, we considered several approaches. One approach we considered was asking the respondent to report only the number of staff (that is, counts of people). Under this approach, a part-time employee would count as ''1'' to the number of staff even if they worked a small number of hours per week. We believe this approach would result in less accurate reporting of labor inputs, especially from organizations relying heavily on part-time staff or staff with responsibilities unrelated to ground ambulance services. We also considered allowing respondents to report full-time-equivalent (FTE) staff on a 40-hour per week basis, but ground ambulance organizations informed us that reporting FTEs would be burdensome. As a third approach, we considered asking respondents to report ground ambulance staffing levels in terms of hours over a reporting year. Reporting labor hours over the entire reporting year allows for more accurate reporting of staff working part-time and may involve less burden for respondents that already tally annual labor hours (for example, via payroll records), but would likely be difficult for those who do not already track labor hours in this manner. As a fourth approach, we considered asking respondents to report ground ambulance staffing levels in terms of hours worked during a typical week. Reporting staffing levels in terms of hours worked either over a reporting year or during a typical week allows detailed accounting of part-time staff and staff with ground ambulance and other responsibilities and involves fewer calculations and adjustments than reporting FTEs. Reporting in terms of hours over a typical week has the additional advantage of simplifying reporting for staff that start or stop work during the 12-month reporting period. The main limitation of reporting staffing levels in terms of hours over a typical week is that the week that the respondent selects for reporting may not be generalizable to other weeks in the reporting period.

In the interest of minimizing reporting burden, we are proposing to collect information on the number of staff in terms of hours worked over a typical week (sections 7.1 and 7.2). The instructions in the proposed data collection instrument ask respondents to ''select a week for reporting that is typical, in terms of seasonality, in the volume of services that you offer (if any) and staffing levels during the reporting year.''

Scope of Reported Labor Costs

For the purposes of collecting information on labor costs, we are proposing to define labor costs to include compensation, benefits (for example, healthcare, paid time off, retirement contributions, etc.), stipends, overtime pay, and all other compensation to staff. We refer to these costs as fully-burdened costs. Some ambulance providers and suppliers track compensation but not benefits because another entity, such as a municipality, pays for benefits, and that the ability of these ambulance providers and suppliers to report fully burdened costs may be limited. Despite this limitation, due to the importance of labor costs as a component of total ground ambulance costs, we believe that information on fully burdened costs (sections 7.1 and 7.2) must be reported so that all relevant ground ambulance transport costs are collected. Ambulance providers and suppliers selected to report data may need to implement new tracking systems or request information from other entities (such as municipalities) to be able to report fully-burdened labor costs.

Volunteer Labor

Ground ambulance organizations have also informed CMS that a significant share of ambulance providers and suppliers rely in part or entirely on volunteer labor and that the systems and data available to track the number of volunteers and the time that they devote to ground ambulance services varies. We are proposing to collect information on the total number of volunteers and the total volunteer hours in a typical week using the same EMT/response staff and administrative and facilities staff categories used elsewhere in the proposed data collection instrument (section 7.3, questions 1–5). Although some suggested that assigning a value to volunteer labor hours may be important, the proposed data collection instrument collects information only on the amount of volunteer labor (measured in hours in a typical week) and not a market value for that labor. We believe reported hours can be converted, if necessary, to market rates using data from other sources. We are also proposing to collect the total realized costs associated with volunteer labor such as stipends, honorariums, and other benefits to ensure all costs associated with ground ambulance transport are collected (section 7.3, question 6).

Allocation and Reporting Staff With Other Non-Ground Ambulance Responsibilities

Since firefighter/EMTs are common in many ambulance suppliers, we are proposing to ask respondents that share costs with a fire or police department to report total hours in a typical week for paid EMT/response staff with fire/police duties only (section 7.1). We believe this information can be used to subtract a portion of associated labor costs when calculating ground ambulance labor costs. We believe our proposed approach is more consistent and involves less burden than asking respondents to perform their own allocation calculations necessary to report only the hours or full-time equivalents related to ground ambulance services.

As already noted, many ground ambulance organizations have staff with responsibilities beyond ground ambulance and fire/police response. To account for these scenarios, we are proposing to ask respondents to report the total hours in a typical week unrelated to ground ambulance or fire/police response duties (which are

addressed separately as described in section 7.1), as the costs associated with this labor can be subtracted by those analyzing the data when calculating ground ambulance labor costs. We believe this proposed approach provides both transparency and consistency in the data with minimal burden, and may avoid scenarios where all of the costs associated with staff with limited ground ambulance responsibilities contribute to total ground ambulance costs.

(ii.) Collecting Data on Facility Costs

Facility costs may include rent, mortgage payments, depreciation, property taxes, utilities, insurance, and maintenance, and the associated costs vary widely across ambulance providers and suppliers. Some ground ambulance organizations own facilities while for others, rent, mortgage, or leasing is an important component of total operational costs. Some ground ambulance organizations share facilities with other operations (such as fire and rescue services), and individual ground ambulance organizations often operate out of several facilities of different types, sizes, and share of space related to ground ambulance operations.

We considered proposing to require respondents to report facilities costs aggregated across all facilities. We believe this approach would minimize burden on the respondent by eliminating the need to break costs down by facility; however, it may also increase the risk for inconsistencies in how respondents report total facilities costs. Under this approach, respondents whose ground ambulance organizations share operational costs with a fire department or other entity would need to calculate and report an estimate of facilities costs that was relevant only to ground ambulance services.

We also considered proposing to require respondents to report all costs on a per-facility basis. We believe this approach would allow the most flexibility in reporting complex facility arrangements from ground ambulance organizations operating out of multiple facilities. However, this approach may also involve more burden, particularly for larger organizations, to report costs on a facility-by-facility basis, and many organizations do not track costs such as maintenance or utilities on a per-facility basis.

We are proposing a hybrid approach involving both per-facility and aggregate reporting of different information. First, respondents report the total number of facilities (section 8., questions 1–2) and then indicate for each facility whether they paid rent, mortgage, or neither during the reporting period, total square footage, and share of square footage related to ground ambulance services (section 8.1, question 3). Second, respondents report their per-facility rent, mortgage, or annual depreciation (section 8.2). Third, respondents report facilities-related insurance, maintenance, utilities, and property taxes aggregated across all facilities (section 8.3).

We believe this proposed approach allows for the collection of the information needed to calculate a total facilities cost related to ground ambulance services while avoiding a burden on respondents to calculate allocated facility costs. Total insurance, maintenance, utility, and property tax costs can be allocated using reported square footage and shares of square footage related to ground ambulance services. The proposed approach requires respondents to provide both the square footage of each facility, and the share of square footage for the facility that is related to ground ambulance operations. We expect that some ground ambulance organizations would have this information available and others would need to collect this square footage information to report along with facilities costs, but do not believe this information would be difficult to collect.

(iii.) Collecting Data on Vehicle Costs

Section 1834(l)(17)(A)(ii) of the Act requires CMS to collect information on ''the utilization of capital equipment and ambulance capacity.'' We are proposing to collect information on the number of ground ambulances and other vehicles related to providing ground ambulance services, as well as the costs associated with these vehicles to meet these requirements.

Ambulance providers and suppliers operate ground ambulances, as well as other vehicles to support their ground ambulance operation, and some may have a variety of other vehicles that are associated with ground ambulance responses. For example, a fire truck staffed with fire personnel cross-trained as EMTs may respond with a ground ambulance to an emergency call. Other vehicles might be used in responses and may be referred to as a non-transporting EMS vehicle, a quick response vehicle, a fly-car, or an SUV that carries a paramedic to meet a BLS ambulance from another organization during the course of a response.

We considered two alternatives for collecting vehicle costs. One alternative would be to only include the costs for ambulances and exclude other certain non-ambulance response vehicles from reported costs. We believe that excluding other certain non-ambulance response vehicles from reported costs could potentially result in underreporting of total ground ambulance costs, particularly among those providers or suppliers that rely heavily on these vehicles to support their ground ambulance services. Another alternative would be to include the costs of all vehicles that are used as part of ambulance services, such as quick response vehicles that are used to supplement ambulances.

For all vehicles, vehicle costs can be reported either in aggregate or on a per-vehicle basis. We believe that while reporting vehicle costs in aggregate may involve less burden for some respondents, those respondents that do not track aggregated costs would still require a tool to enter information on per-vehicle basis. Furthermore, we believe that aggregated costs for vehicles other than ground ambulances offer analysts with fewer alternatives to allocate a share of vehicle costs to ground ambulance services.

We are proposing to collect data on vehicle costs in the proposed data collection instrument in two parts: Ground ambulance vehicles (section 9.1); and all other vehicles related to ground ambulance operations (section 9.2). For ground ambulance vehicles, we are proposing to collect information on the number of vehicles, total miles traveled, and per-vehicle information on annual depreciated value (and remounting costs if applicable) for owned vehicles, and annual lease payments for rented vehicles (section 9.1, questions 1–4). We considered proposing to collect the necessary information to calculate annual depreciated value using a standardized approach. However, we are proposing to allow respondents with owned vehicles to use their own accounting approach to calculate annual depreciated value per vehicle. We believe that allowing flexibility for respondents to use their standard approach for this calculation would result in more accurate data and less reporting burden.

We are also proposing to use a similar approach to collect per-vehicle information for owned and leased vehicles of any other type that contribute to ground ambulance operations, including fire trucks, quick response vehicles, all-terrain vehicles, etc. (section 9.2, questions 1–5). The proposed instructions in section 9.2 of the data collection instrument specify that reported vehicles must support ground ambulance services. We are proposing to collect the type of each vehicle in broad categories in addition

to the annual depreciated value or lease payment amount for each vehicle.

In addition to the above costs, we also are proposing to collect aggregate costs associated with licensing, registration, maintenance, fuel, insurance costs for all vehicles combined (ambulance and non-ambulance) (section 9.3, questions 1–5). We believe that these costs are often aggregated within providers' and suppliers' records and that reporting in aggregate form may reduce respondent burden with minimum risk for reporting error.

When estimating total ground ambulance vehicle costs for ground ambulance organizations that share operational costs with fire and police response or other non-ground ambulance activities, a share of vehicle costs reported via the instrument will need to be allocated as vehicle costs related to ground ambulance services. One alternative we considered to do this was simply to ask respondents about the share of costs associated with ground ambulance services as we thought this would be the least burdensome approach; however, we believe data collected in this manner would not allow for estimation of costs associated with non-ground ambulance vehicles that support ambulance services. We considered another alternative where (1) the ratio of ground ambulance to total responses would be used to allocate costs associated with non-ambulance vehicles, (2) the total number of vehicles would be used to allocate aggregate costs associated with licensing, registration, maintenance, and fuel costs, and (3) depreciated annual costs and/or lease payment amounts would be used to allocate insurance costs. The main limitation of this approach is that maintenance and fuel costs could vary significantly across vehicle categories. For example, maintenance and fuel costs may be significantly different for ground ambulance than for other types of vehicles. As a result, we are proposing a modification of this alternative where we also ask respondents to list percent of total maintenance and fuel costs attributable to each type of vehicle (that is, ground ambulances, fire trucks, land rescue vehicles, water rescue vehicle, other vehicles that respond to emergencies such as quick response vehicles, and other vehicles; section 9.3, questions 4 and 5). We propose to also ask respondents to report total mileage for ground ambulance (land and water separately) and total mileage for other vehicles related to ground ambulance responses (land and water separately) as a potential alternative means to allocate fuel and maintenance costs.

(iv.) Collecting Data on Equipment and Supply Costs

In our interviews with ground ambulance organizations, we were told that not all ground ambulance organizations would be able to report detailed item-by-item equipment and supply information, and that some organizations have far more sophisticated inventory tracking systems than others that would allow them to report detailed information within a category.

We considered alternative approaches related to reporting equipment and supply costs that varied primarily on the level of detail for reporting. We considered extremely detailed data reporting as it would be potentially useful to identify variability in costs across organizations. However, as noted above, many ground ambulance organizations may not keep detailed records of all their individual equipment and supply costs. Taking those factors into account, we are proposing to request total costs in a small number of equipment and supply categories rather than itemized information for all equipment and supply categories (section 10). These would include:

- Capital medical equipment.
- Medications.
- All other medical equipment, supplies, and consumables.
- Capital non-medical equipment.
- Uniforms.
- All other non-medical equipment and supplies.

We also considered whether to have respondents report both medical and non-medical equipment and supplies together. We believe that the majority of medical supplies are more likely to be related to ground ambulance services than non-medical supplies for organizations with shared services, and therefore, we are proposing to collect this information separately.

Reporting of Capital Versus Non-Capital Equipment

To meet the requirement in section 1834(l)(17)(A)(ii) of the Act to collect information to facilitate the analysis of ''the utilization of capital equipment,'' we are proposing to separately collect information on capital equipment expenses (rather than equipment-related operating expenses). Capital equipment (both medical and non-medical) yield utility over time, which can vary depending on the expected service life of the specific good. In addition to the cost of purchasing or leasing durable goods equipment, depreciation and maintenance costs must be considered in the total cost calculations. Since ground ambulance organizations often track capital equipment on an itemized level, separating items of significantly different age and cost is necessary to calculate depreciation. Therefore, to minimize burden by aligning reporting with the accounting approaches used by respondents, we are proposing to ask for capital (section 10.1, question 1; section 10.2, question 1) and non-capital costs (section 10.1, questions 2–3; section 10.2, questions 2–3) separately so that respondents can report annual depreciated costs for capital equipment and total annual costs otherwise. We also are proposing to allow respondents to report annual maintenance and service costs for capital equipment because ground ambulance organizations have stated during interviews that these costs can be significant compared to purchase costs or annual depreciated costs. Finally, we are proposing to allow respondents to use their own standard accounting practice to categorize equipment as capital or non-capital. While we believe it would be possible to ask respondents to use a standard approach, we believe this would require respondents with another practice to recalculate annual depreciated cost and potentially increase respondent burden and reporting errors.

Allocation of Shared Costs

During interviews with ground ambulance organizations, it was noted that although the vast majority of equipment and supplies are for ground ambulance services, some costs are shared with hospitals or clinics. We believe separate reporting on medical and non-medical equipment and supplies would facilitate allocation (section 10.1, versus section 10.2). For organizations that indicate the use of shared services, we are proposing to ask separately what share of medical and non-medical equipment and supply costs are related to ground ambulance services (section 10.1, questions 1c, 2a; section 10.2, questions 1c, 2a, 3a). The share of non-medical equipment and supplies used for ambulance services may vary for respondents with operations beyond ambulance services. While other allocation methods (such as the share of responses that are ground ambulance responses) may be appropriate to allocate equipment and supply costs, asking respondents to provide their estimate of the share of equipment and supply costs related to ambulance services reduces assumptions made about how best to apply allocation across the various equipment and supplies reported.

(v.) Collecting Data on Other Costs

In addition to core costs for ambulance providers and suppliers that are associated with labor, vehicles, facilities, and equipment or supplies, ground ambulance organizations have indicated that these entities incur costs associated with contracted services (for example, for billing, vehicle maintenance, accounting, dispatch or call center services, facilities maintenance, and IT support), as well as other miscellaneous costs (for example, administrative expenses, fees and taxes) to support ground ambulance services.

We considered including contracted services as part of the labor section, since many of the contracted services related to costs that would otherwise be labor-related if the tasks were performed by employed staff. However, we were concerned that ground ambulance organizations might report this information in multiple instrument sections (for example, both labor and miscellaneous costs). As a result, we separated contracted services into their own categories. While we considered allowing respondents to report in the aggregate any other miscellaneous costs associated with ground ambulance services because we believed this approach may be less burdensome for organizations that track miscellaneous costs in aggregate, we believe this would introduce a large amount of reporting bias and inconsistency in reporting across organizations. Our proposals related to reporting contracted services and miscellaneous costs are described below.

Reporting Contracted Services

For contracted services, we are proposing that respondents indicate whether their organization utilizes contracted services to support a variety of tasks (section 11, question 1), the associated total annual cost for these services, and the percentage of costs attributable to ground ambulance services. The proposed data collection instrument would provide instructions to ensure that respondents do not report on contracted costs multiple times.

Reporting of Miscellaneous Costs

For other miscellaneous costs not otherwise captured in prior sections of the data collection instrument, we are proposing that respondents be able to report additional costs first using an extensive list of other potential cost categories (section 11, question 2) and then use write-in fields if necessary. Providing a pre-populated check list would help ensure the consistency and completeness of reporting across respondents.

Allocation of Miscellaneous Shared Costs

Information from ground ambulance organizations indicates that there are a number of miscellaneous costs associated with the overall operation of organizations that are shared across services. To account for these shared costs, we are proposing that respondents report an allocation factor for each contracted service, (section 11, question 1), as well as for each reported miscellaneous expense (section 11, questions 3–4) as described in the data collection instrument. We considered the alternative of asking for an overall share of miscellaneous costs associated with ground ambulance services or utilizing information gathered about the share of ground ambulance responses versus total responses to determine an overall allocation factor. While this would present less burden on respondents, the share of miscellaneous costs and share of contracted services varies widely across organizations with shared services.

d. Proposed Data Collection on Revenue

Section 1834(l)(17)(A) of the Act requires the development of a data collection system to collect revenue information for ground ambulance provider and suppliers. Payments from Medicare and other health care payers are important components of total revenue for some ambulance providers and suppliers. Most ambulance providers and suppliers also have other sources of revenue in addition to payments for billed services. Based on review of existing literature and discussions with ground ambulance organizations, these primary sources of revenue include, but are not limited to: Patient out-of-pocket payments; direct public financing of fire, EMS, or other agencies; subsidies, grants, and other revenue from local, state, or federal government sources; revenue from providing services under contract; and fundraising and donations. We view total revenue as the sum of payments from health care payers and all other sources of revenue, including those listed above.

While collecting information on total revenue is essential to understanding variations in how EMS services are financed across the country, this information is not collected by Medicare or by any other entity of which we are aware. Similar to other sections of the data collection instrument, we also considered what level of data to request in this section. We are proposing to ask for total revenue in aggregate (section 13, question 1) and total revenue from paid ground ambulance transports for Medicare and, if possible, broken down by payer category for other payers (section 13, questions 2–5). We are proposing this level of detail because we believe understanding payer mix would be helpful to assess Medicare's contributions to total revenue. Based on information provided by ambulance providers and suppliers, there is variation in how patient-paid amounts were recorded in ambulance billing systems. We are proposing to ask respondents whether revenue by payer includes corresponding patient cost sharing or whether cost-sharing amounts are included in a self-pay category. For other revenue (for example, contracts from facilities and membership fees (such as those associated with community members that enroll in ambulance clubs), we are proposing to request information on additional revenue in predetermined categories and using write-in fields if necessary (section 13, question 5).

Allocation of Shared Revenues. Ground ambulance organizations vary widely in the types of other revenue sources (as noted in section 13, question 6) they receive and their share of allocated costs. For this reason, we are proposing to have respondents report the share of revenue for each category that is attributable to ground ambulance services (section 13). Similar to miscellaneous costs, we considered the alternative of asking for an overall share of other revenue sources associated with ground ambulance services or utilizing information gathered about the share of ground ambulance responses versus total responses to determine an overall allocation factor. While this would present less burden on respondents, we do not believe it would not adequately capture the revenue only associated with ground ambulance services, especially for organization with shared services.

To collect information on uncompensated care, including charity care and bad debt, we are proposing to collect information on both total and paid transports. These two measures of volume can be used to provide insight into the share of transports that are not paid. The proposed data collection instrument broadly collects information on total costs (including costs incurred in furnishing services that are ultimately paid and not paid) and total transports (again including transports that are both paid and not paid). The collected data could be used to estimate per-transport costs that can be estimated by dividing total costs by total transports, so we do

not believe it is necessary to directly collect information on uncompensated care in the revenue section of the data collection instrument.

We invite comments regarding all the proposals for data collection described in this section, including our proposals on the format, scope, elements (characteristics, utilization, and costs), collection of equipment and supply costs, and other costs.

5. Proposals for Sampling

Section 1834(l)(17)(B)(i) of the Act requires that CMS identify the ground ambulance providers and suppliers organizations that would be required to submit information under the data collection system, including the representative sample. Section 1834(l)(17)(B)(ii)(II) of the Act requires the representative sample must be representative of the different types of providers and suppliers of ground ambulance services (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas). Under section 1834(l)(17)(B)(ii)(III) of the Act, the Secretary cannot include an individual ambulance provider and supplier in 2 consecutive years, to the extent practicable. In addition to meeting the requirements set forth in the statute, including developing a representative sample, our proposals around sampling aim to balance our need for statistical precision with reporting burden. Our proposals to meet these statutory requirements are described below, and were developed with the intention of obtaining statistical precision with the least amount of reporting burden.

Eligible Organizations. A sampling frame drawing on all ground ambulance organizations in the United States and its territories that provide ground ambulance services (that is, not just those enrolled in Medicare or billing Medicare in a given year) may be of interest conceptually, but we have not identified a data source listing all ambulance providers and suppliers that could be used as the source for a broader sampling frame. Since sections 1834(l)(17)(A) of the Act requires the Secretary to collect cost, revenue, and utilization information from providers of services and suppliers of ground ambulance services (which are Medicare specific terms with specific meaning) with the purpose of determining the adequacy of payment rates and section 1834(l)(17)(D) of the Act requires the Secretary to reduce payments to ground ambulance organizations that do not sufficiently report, we believe that the intent of the statute is to collect information under the data collection system from ground ambulance organizations that bill Medicare. Therefore, we are proposing to sample ground ambulance organizations that are enrolled in Medicare and that billed for at least one Medicare ambulance transport in the most recent year for which we have a full year of claims data prior to sampling. Since ground ambulance organizations have a full year to submit their claims to Medicare after the date of service, claims data for a calendar year are generally not considered complete until the end of the following calendar year. As a result, we would use 2017 Medicare claims and enrollment data to determine the sample for the 2020 data collection period because 2018 Medicare claims data could not be considered complete in late 2019 when the sample for the 2020 data collection period would be selected.

Sampling at the NPI level: Section 1834(l)(17) of the Act prohibits, to the extent practicable, sampling the same ambulance provider or supplier in 2 consecutive years. Although we considered sampling at a broader parent organization level for those that bill Medicare under more than one NPI, we found it was difficult to tease out of the Medicare enrollment data all the complexities of the business relationships and identify all NPIs that may be affiliated with the same parent organization. Therefore, we are proposing to select the sample at the NPI level and to include the specific NPI selected to report information. Furthermore, we propose to collect the name of the ground ambulance organization and the name and contact information of the person responsible for completing the data collection instrument for the purposes of confirming that the data submitted aligns with the intended NPI (section 2, questions 3 and 4).

Organizations using volunteer labor: Some stakeholders have suggested that ground ambulance organizations relying on volunteer labor above a certain threshold (for example, more than 10 percent of volunteer labor) should be exempt from sampling. Others have suggested that ground ambulance organizations using volunteer labor should not be excluded because those organizations that use volunteer labor are likely to be smaller and that a large share of ambulance suppliers (particularly those in rural and super rural areas) would be exempt from sampling, and therefore, our sample would not be representative as required by section 1834(l)(17)(B)(ii) of the Act. We acknowledge that analysis of the data may require additional steps to combine data submitted from ground ambulance organzations that do and do not rely on volunteers since reported labor costs would be significantly lower for ground ambulance organizations that use volunteer labor compared to those that do not. Ground ambulance organizations that use volunteer labor might have some costs related to their volunteer labor, such as stipends, but may not have others, such as an hourly wage. Therefore, we are proposing to collect information on paid and unpaid volunteer hours during a typical week using the same EMT/response staff categories used elsewhere in the data collection instrument. We believe reported hours can be converted to market rates using data from other sources, such as the Bureau of Labor Statistics' wage data. Ambulance providers and supplies that rely on volunteer labor report that it is becoming increasingly difficult to find volunteers and they are having to hire paid staff in their place, especially for the more costly labor categories, such as paramedics. Therefore, we are proposing that ambulance providers and suppliers that use any amount of volunteer labor be included in sampling. We invite comments as to whether organanizations that rely on volunteer labor should be exempt from sampling.

Sampling file. The organizational characteristics being proposed for the specific strata (volume of Medicare billed transports, service area population density, ownership, provider versus supplier status, and the share of transports that are non-emergency) can be obtained from available Medicare data. We are proposing to develop sampling files using the most recent full year of data available. For the first sample notified in 2019 and reporting in 2020, we are proposing to use 2017 claims and enrollment data. Another alternative we considered was using 2018 data, however we are not proposing this because such data may not be complete for all 2018 service dates at the time the sample for the initial year of data reporting is selected. We invite comments on our proposal to use the most recent full year of available Medicare data for sampling purposes, as described above.

Implications of historical sampling files. We expect there may be instances in which some ground ambulance organizations that were in operation at the time they were selected for the sample may cease operations by the

time data reporting begins. Similarily, we expect that some new ground ambulance organizations would start operating between the time the sample was pulled and when reporting begins. Since we propose to collect a full 12 continous months of data, these organizations would not have the data we are proposing to collect. Therefore, we are proposing that ground ambulance providers and suppliers organizations selected for the sample that were not in business for the full 12 continuous months of the data collection period would be exempt from reporting for the applicable data collection period; however, for newer ground ambulance organizations, they would be eligible for sampling and reporting in future years when they did have a full continuous 12 months of data.

We believe the above scenerios are inevitable given the significant amount of time between sampling and data reporting and invite comments on our proposed approach regarding exempting ground ambulance organizations who do not have a full 12-month continuous period of data.

Sampling rate: We are also proposing that 25 percent of ground ambulance organizations be sampled from all strata (as described below) in each of the first 4 years of reporting without replacement; that is, if an organization is sampled in Year 1, it would not be eligible for sampling again in the subsequent 3 years of data collection. We are proposing a 25 percent sampling rate because if a lower sampling rate is used, estimates of cost, revenue, and utilization from the data collected via the instrument for subgroups of ground ambulance suppliers would be of inadequate precision as described in the following section. Furthermore, our analyses illustrated that using 50 percent sampling rate yielded only marginal gains in precision over a corresponding strategy that involves sampling NPIs at a 25 percent rate while doubling the response burden. In our view, these gains are not sufficient to merit the increased burden that would be imposed by implementing a higher sampling rate. Our proposal was informed by analyses regarding the alternative sampling rates in Chapter 7 of the CAMH report. We invite comments on the proposed sampling rate of 25 percent each year.

We are also proposing to notify ground ambulance organizations that have been selected for the representative sample by listing such ground ambulance organizations on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html* and providing written notification to each selected ground ambulance organization via email or U.S. mail. Notification on the CMS website would be provided at least 30 days prior to the time the selected ambulance organization would be required to begin collecting data. For purposes of CY 2020, we will post such information on the website when the CY 2020 PFS final rule is issued. A discussion of the proposed collection and reporting requirements can be found in the next section. We are also proposing to codify the representative sample requirements in § 414.626(c).

Approach for Sampling: We considered several alternatives for developing a stratified sampling approach to facilitate data collection from specific types of ground ambulance oragnizations. Section 1834(l)(17)(B)(ii)(II) of the Act requires that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organization and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). One approach we considered was to sample ground ambulance organizations in proportion to their volume of Medicare-billed ground ambulance services. Under this approach, organizations with more billed Medicare ground ambulance transports would be more likely to be sampled than organizations with fewer billed Medicare ground ambulance transports. The analysis of our 2016 data described in the CAMH report shows that a small number of ground ambulance organizations provided a large share of total Medicare transports. Specifically, the top 10 percent of ground ambulance organizations by volume accounted for nearly 70 percent of total Medicare ground ambulance transports. In contrast, the bottom 50 percent of ambulance providers and suppliers by volume accounted for only 3 percent of total Medicare ground ambulance transports. Under this approach, the ambulance providers and suppliers in the top 10 percent by volume would therefore be much more likely to be sampled compared to those in the bottom 50 percent by volume. While this approach would efficiently collect data on the majority of Medicare ground ambulance transports, we do not believe that this approach would comport with the requirements in section 1834(l)(17)(B)(ii)(II) of the Act to develop a representative sample of ground ambulance organizations based on the characteristics (such as ownership and geographic location) of ambulance providers and suppliers. Therefore, we do not believe that data we would be collecting using this approach would meet the requirements in section 1834(l)(17)(B)(ii)(II) of the Act.

Other alternatives for a sampling methodology include simple and stratified random samples of ground ambulance organizations. A simple random sample would include a fixed share of all ground ambulance organizations, regardless of any differences in characteristics, in each year's sample. Unlike sampling in proportion to Medicare-billed ground ambulance services, a simple random sample by definition provides a representative sample. A stratified random sample first stratifies all ground ambulance organizations based on selected characteristics and then a sample is seleced at random from the strata. The rate at which these organizations are sampled would be the same for organizations in the same stratum; however, the sampling rate may vary across strata. So long as the sampling rate is not zero within any stratum and so long as appropriate weighting adjustments are used, the sample can be considered representative.

Stratified random sampling has several advantages in that it is easy to implement and it meets the requirement that the sample be representative. It also can be used to target sampling of ambulance organziations with specific characteristics, such as ownership and geographic location, to specifically meet the requirements in section 1834(l)(17)(B)(ii)(II) of the Act that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organziation and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). It is also possible to oversample from less prevelant strata using this approach in order to facilitate more precise estimates for certain groups or comparisons between subgroups. Furthermore, unlike a simple random sample, the flexibility to vary sampling rates across strata allows the ability to account for anticipated and unanticipated rates of nonresponse.

We believe that use of a stratified random sample would comport with the statutory requirements. Therefore, we are proposing a stratified random

sample approach. Specifically, we are proposing to sample from each strata at the same rate (25 percent, as described above). We believe that data collected from a sample of this type can be adjusted via statistical weighting to be representative of all ground ambulance organizations billing Medicare for ground ambulance services even if response rates vary across the characteristics used for stratification.

For the purposes of estimating the number of responses from the sampled ground ambulance organizations, we assumed that all ground ambulance providers and suppliers organizations sampled will report, because: (1) Reporting is a requirement; (2) there is a 10 percent payment reduction for failure to sufficiently report; and (3) we believe every ground ambulance organization would want its data accounted for in the evaluation of the extent to which reported costs relate to payment rates.

Variables for Stratification: Section 1834(l)(17)(B)(ii)(II) of the Act requires that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organization, and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). As discussed above, we are proposing a stratified sampling approach under which we would first sample based on a set of characterícistcs of ground ambulance organizations that are described below (that is, strata) and then assess response rates based on those characteristics. Based on our analysis of information provided by ground ambulance organizations, we believe there are several important characteristics that vary among ground ambulance organizations that have implications for their costs and revenues and that could serve as strata for the purposes of sampling:

- *Provider versus supplier status.* The GAO (2012) [94] and HHS (2015) [95] reports found much higher per-transport costs for ambulance providers than those of ambulance suppliers. This suggests that the ground ambulance cost structures for ambulance providers and suppliers are fundamentally different.
- *Service area population density.* Ground ambulance organizations operate in urban, rural, and super-rural settings. As described in the CAMH report, rural and super-rural organizations tend to be smaller, transport patients at greater distances, are more likely to be government owned, and rely more heavily on volunteer labor. The population density of the area in which a ground ambulance organization is operating is expected to affect costs and revenues in a number of ways. Organizations serving rural and super-rural areas generally are likely to face lower demand for services, and thus, deliver a smaller number of transports. In addition, in rural and super-rural areas the average distance traveled per transport tends to be greater. Payment rates will also differentially impact revenue by population density because the Medicare AFS accounts for mileage and, in addition, rural and super-rural providers and suppliers receive higher temporary add-on payments.
- *Volume of transports.* If there are economies of scale, organizations providing a larger volume of services typically would face lower per-transport costs. Our analysis found that the volume distribution is highly skewed. In other words, the majority of ground ambulance organizations have a low volume of transports, but there are a small number of organizations with a very high volume of transports. Suppliers providing a large volume of transports are more likely to be for-profit organizations.
- *Ownership.* For-profit (non-government), non-profit (non-government), and government ground ambulance organizations have different business models and mixes of services, leading to different costs. Conceptually, for-profit organizations maximize profit and operate only in markets and service lines with positive margins. Non-profit and government ground ambulance organizations more broadly provide emergency service to communities and may be organized and operated in a way that does not maximize profits. The 2012 GAO report found ground ambulance organizations with more limited government support are more likely to have incentives to keep costs lower. They found that for each 2 percent decline in the average length of government subsidy there was a 2 percent decline in the average cost per transport. As a result, we expect that costs will differ based on ownership.
- *Types of services provided.* One key distinction in the types of services provided is between emergency transports and non-emergency (for example, scheduled or inter-facility) transports. For-profit suppliers are more likely than others to specialize in non-emergency scheduled transports. Another key distinction is between the level of service provided (for example BLS versus ALS).
- *Staffing.* The level of staff training (for example, EMTs versus paramedics) and the number of staff deployed is driven in part by the type and volume of calls, the availability and proximity of the nearest providers, and resources available in that community. Some suppliers use static staffing models that use set staff schedules, whereas others use a dynamic, or flexible, staffing model that calls upon staff if there is a surge in demand.
- *Use of volunteer labor.* Volunteer labor tends to be more common among small, government-based ambulance suppliers operating in rural and super-rural settings.
- *Response times.* In many cases, response times are related to the population density of the area in which they operate, with rural areas having response times more than double those of urban areas. Rural and super-rural ambulance providers and suppliers generally travel greater distances to get to patients and transport them to a hospital or the nearest appropriate facility. Variation in response times within urban areas might also occur, for example if there is significant emergency department crowding, or in extreme cases diversion that requires the ambulance to travel further to another hospital or wait with the patient until a bed is available. This extra time affects the availability of the ambulance and the staff for subsequent trips, potentially increasing response times.

As previously discussed, we are not aware of any existing data source that lists all ground ambulance organzations or one that encompasses all the characteristics that impact costs and revenues described above. Medicare claims and enrollment data is the only source of data for which we are aware that has all the providers and suppliers that bill Medicare in a given year. Several of the organizational characteristics we discuss above (including provider versus supplier status, ownership, service area population density, Medicare billed transport volume, and type of services provided) are available from Medicare data while others, such as the use of volunteer labor, staffing model, and response times are not.

We are proposing to stratify the sample based on provider versus supplier status, ownership (for-profit, non-profit, and government), service area population density (transports originating in primarily urban, rural,

[94] This report is available at *https://www.gao.gov/assets/650/649018.pdf.*

[95] This report is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf.*

and super rural zip codes), and Medicare billed transport volume categories. Based on our analysis of the number and distribution of ground ambulance organizations' transports in 2016, we are proposing volume categories of 1 to 200, 201 to 800, 801 to 2,500, and 2,501 or more paid Medicare transports. The proposed volume categories aim to divide ground ambulance organizations into roughly similar-sized groups, while separating ground ambulance organizations with very high volume (that is, greater than 2,500 Medicare transports per year) into a separate category. We would expect that these highest-volume ground ambulance organizations may face different costs than lower-volume organizations due to economies of scale.

We are proposing to focus on these four characteristics due to data availability, and our analyses that show these to be key defining characteristics of ground ambulance organizations (which are also described in the CAMH report). Also, service area population density and Medicare billed transport volume have a direct impact on ground ambulance revenue, which is one of the categories of data that we are required to collect by section 1834(l)(17)(A) of the Act. Through Medicare claims and enrollment data, we believe we have enough information to stratify ground ambulance organizations on these four characteristics. This stratification approach results in 36 groupings of ground ambulance suppliers (defined by combinations of the three ownership categories, three service area population density categories, and four Medicare billed transport volume categories) and the same number of groupings for ambulance providers.

In some of these groupings, there are only a handful of ground ambulance organizations providing ground ambulance services with a specific set of the four characteristics. This could result in situations where few or no ground ambulance organizations with the specific set of characteristics were sampled. To minimize this risk and avoid situations where we are sampling from strata that contain only a few ambulance providers and suppliers in the entire population, we propose to stratify ground ambulance providers, which account for only 6 percent of ground ambulance organizations combined, based on service area population density only. We are proposing to use this characteristic to stratify providers rather than another characteristic because section 1834(l)(17)(A) of the Act specifically requires the Secretary to develop a data collection system to collect information on ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in section 1834(l)(12) of the Act (super rural areas).

We are also proposing to collapse the two highest Medicare ground ambulance transport volume categories (801–2500 and 2501 and more transports) into a single category (801 and more transports) for for-profit ground ambulance suppliers that primarily service super-rural areas due to the small number of ground ambulance organizations in these two volume categories. The proposed sampling rate of 25 percent aims to meet a threshold that will provide an adequate degree of precision for estimates within each strata subgroup (that is, provider versus supplier status, ownership (for-profit, non-profit, and government), service area population density (transports originating in primarily urban, rural, and super rural zip codes), and Medicare billed transport volume categories). The specific threshold is 200 expected responses in each subgroup. This number of expected responses will ensure that small to medium differences in means between groups (that is, affect size) can be detected.

A 25 percent sampling rate is expected to result in more than 200 responses in each subgroup except for ground ambulance providers (where we expect 153 responses with a 25 percent sampling rate). A 25 percent sampling rate will also result in more than 200 expected responses for other organizations not represented in the strata, including organizations providing primarily non-emergency transports and transports to and from dialysis facilities. We also expect that a 25 percent sampling rate will result in more than 200 responses for organizations that rely primarily on volunteer labor, as well as for those who do not.

We invite comments on all our proposals for sampling as described in this section, including our proposals on eligible organizations, methods for sampling, sampling at the NPI level, sampling of organizations using volunteer labor, sampling files, and sampling rates. We also invite comments on our proposals to collect data from ground ambulance organizations that bill Medicare, and the use of a stratified random sample.

6. Proposals for Collecting and Reporting of Information Under the Data Collection System

For each data collection year, section 1834(l)(17)(C) of the Act requires ground ambulance organizations identified as part of the representative sample to submit information specified under the system, with respect to a period for the year (referred to as the ''data collection period''), in a form and manner and at a time (referred to as the ''data reporting period'') specified by the Secretary. In this section, we are proposing to define the data collection period and the data reporting period. In determining when the proposed data collection and reporting periods should fall, our objectives were to: (1) Allow selected ground ambulance organizations sufficient time to collect and report the required information; and (2) collect the data for analysis in the least burdensome manner.

We considered annual (that is, 12-month) data collection periods and shorter data collection periods (for example, a 6-month period). We are proposing a 12-month data collection period because a shorter period could result in biased data due to seasonality in costs, revenue, or utilization among ground ambulance organizations.

As we stated previously, ambulance providers and suppliers constitute a diverse group of organizations with varied annual accounting practices. Accordingly, we are proposing to define the data collection period as a continuous 12-month period of time, which is either the calendar year aligning with the data collection year, or when an organization uses another fiscal year for accounting purposes and the organization elects to collect and report data over this period rather than the calendar year, the 12-month period that is their fiscal year that begins during the data collection year. We are proposing this data collection period based on feedback from ground ambulance organizations that stated that they prefer to collect data based on an annual accounting period (either calendar year or fiscal year) already used by the organization, and that requiring all organizations to report on the same 12-month period (for example, calendar year) could involve significant additional burden in terms of data collection and reporting. We believe that providing flexibility in collecting information under the data collection system would reduce the burden on ground ambulance organizations.

Therefore, we are proposing that the first data collection period be January 1, 2020 through December 31, 2021, with

organizations reporting on a calendar year basis collecting data from January 1, 2020 through December 31, 2021, and organizations reporting on a fiscal year basis collecting data over a continuous 12-month period of time from the start of the fiscal year beginning in calendar year 2020. Upon being notified that they are selected as part of the sample, ground ambulance organizations must notify CMS of their annual accounting period within 30 days according to the instructions in the notification letter, so that CMS is aware of when their data collection and data reporting periods would begin. We propose that respondents would additionally confirm the data collection period when reporting data via the data collection instrument (section 2, question 5).

We also propose that ground ambulance organizations would have up to 5 months to report to CMS (data reporting period) the data following the end of its 12-month data collection period. For example, if a ground ambulance organization is selected as part of the representative sample for the CY 2020 data collection year, and notifies CMS that its annual accounting period is based on a calendar year, the data collection period for this ground ambulance organization would begin on January 1, 2020 and end on December 31, 2020, and the data reporting period would be January 1, 2021 through May 31, 2021. A ground ambulance organization selected for CY 2020 that notifies CMS that its annual accounting period is based on a fiscal year basis with a fiscal year beginning on June 1, 2020 would have a data collection period from June 1, 2020 through May 31, 2021 and a data reporting period from June 1, 2021 through October 1, 2021. Since a 5-month reporting period is enough time for entities that file cost reports with Medicare to complete and submit their data, we believe it should also provide adequate time for ground ambulance organizations to report information under the data collection system to CMS. This proposal will allow providers and suppliers time to validate the information and certify the accuracy of their data required under the data collection before reporting it to CMS.

We propose to codify the data collection and reporting requirements for selected ground organizations at § 414.626(b).

Tables 30 and 31 illustrate various examples of data collection periods and the data reporting periods under our proposal. Please note that an individual ground ambulance organization would only be selected to participate in one data collection and reporting period, and that the specific data collection and reporting period dates might vary for each organization and be different than the dates noted in the tables.

TABLE 30—EXAMPLE OF A DATA COLLECTION AND REPORTING PERIOD FOR A GROUND AMBULANCE ORGANIZATION WITH A CALENDAR YEAR ACCOUNTING PERIOD

Year	Data collection period	Data reporting period
1	01/01/2020–12/31/2020	01/01/2021–05/31/2021
2	01/01/2021–12/31/2021	01/01/2022–05/31/2022
3	01/01/2022–12/31/2022	01/01/2023–05/31/2023
4	01/01/2023–12/31/2023	01/01/2024–05/31/2024

TABLE 31—EXAMPLE OF A DATA COLLECTION AND REPORTING PERIOD FOR A GROUND AMBULANCE ORGANIZATION WITH AN ACCOUNTING PERIOD NOT BASED ON A CALENDAR YEAR

Year	Data collection period	Data reporting period
1	06/01/2020–05/31/2021	06/01/2021–10/31/2021
2	06/01/2021–05/31/2022	06/01/2022–10/31/2022
3	06/01/2022–05/31/2023	06/01/2023–10/31/2023
4	06/01/2023–05/31/2024	06/01/2024–10/31/2024

We invite comments on our proposal to use a 12-month data collection period. We also invite comments on our proposal to give sampled ground ambulances the flexibility to collect data on either a calendar year basis or on the basis of the ground ambulance organization's fiscal year. In addition, we invite comments on our proposal to allow a ground ambulance organization 5 months to report the data collected during data collection period to CMS through the data collection system. We plan on addressing section 1834(l)(17)(E) of the Act, ongoing data collection, in future rulemaking.

7. Proposed Payment Reduction for Failure To Report

a. General Information and Applicable Period

Section 1834(l)(17)(D)(i) of the Act requires that beginning January 1, 2022, subject to clause (ii), the Secretary reduce the payments made to a ground ambulance organization under section 1834(l)(17) of the Act for the applicable period by 10 percent if the ground ambulance organization is required to submit data under the data collection system with respect to a data collection period and does not sufficiently submit such data. Section 1834(l)(17)(D)(ii) of the Act defines the applicable period as a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier failed to sufficiently submit information under the data collection system.

As previously discussed, we are proposing to define the data collection and data reporting periods based on the ground ambulance organization's annual accounting period (either calendar year or fiscal year). The timeline for the determination of the 10 percent reduction to payments would depend on: (1) The 12-month data collection period based on the organization's accounting period; (2) the end of the data reporting period that corresponds with the selected data collection period; and (3) the time it would take CMS to review the data to determine whether it had been sufficiently submitted. We are proposing that we would make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than the date that is 3 months following the date that the ambulance organization's data reporting period ends. This timeframe will allow CMS to assess whether the required data was sufficiently submitted.

For example, if a ground ambulance organization is selected in the first sampling year and it reports to CMS that its annual accounting period is an October 1 through September 30th fiscal year, then its data collection period would be October 1, 2020 through September 30, 2021, and the data reporting period that would apply to the ground ambulance organization would be from October 1, 2021–February 28 (or 29, if a leap year), 2022. We would make a determination regarding the sufficiency of that ground ambulance organization's reporting no later than June 1, 2022. With this timeframe, we would propose to apply the 10 percent reduction in payments, if applicable, for ambulance services provided by that ground ambulance organization between January 1, 2023 and December 31, 2023, because under section 1834(l)(17)(D)(iii) of the Act, the applicable period must be one year in length. As another example, if a ground ambulance organization's annual accounting period is the calendar year, its data collection period would be January 1, 2020 through December 31, 2020, the data reporting period that would apply to the ground ambulance organization would be from January 1, 2021–May 31, 2021,

and we would make a determination regarding the sufficiency of that ambulance organization's reporting no later than August 31, 2021. With this timeframe, we would propose to apply the 10 percent reduction in payments, if applicable, for ambulance services provided between January 1, 2022 and December 31, 2022. The payment reduction would always be applied to ground ambulance transports provided during the calendar year that begins following the date that we determine that the ground ambulance organization is subject to the payment reduction.

We propose that if we find the data reported is not sufficient, we would notify the ground ambulance organization that it will be subject to the 10 percent payment reduction for ambulance services provided during the next calendar year. We would interpret ''sufficient'' to mean that the data reported by the ground ambulance organization is accurate and includes all required data requested on the data collection instrument.

We are proposing to apply the 10 percent payment reduction for the appropriate calendar year as described above to ambulance fee schedule payments as described in § 414.610. The payment reduction would apply to claims for dates of service during the applicable calendar year and would be applied to the final ambulance fee schedule payment, after all other adjustments have been applied under § 414.610(c). We are proposing to codify the payment reduction by adding a new paragraph (c)(9) in § 414.610.

b. Proposed Hardship Exemption

Section 1834(l)(17)(A)(D)(iii) of the Act authorizes the Secretary to exempt a ground ambulance provider or supplier from the 10 percent payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the ground ambulance provider or supplier to submit such information in a timely manner for the specified period.

We recognize that there may be some ground ambulance organizations that have limited resources that affect their ability to report the required information, and that for these ground ambulance organizations, a 10 percent payment reduction in Medicare payments could result in significant financial hardship.

An example of this situation could be a ground ambulance organization that is located in a super rural area with such limited resources that it cannot report the required information without significantly increasing the possibility that it would need to file for bankruptcy.

Another example could be a ground ambulance organization that is located in an area that had recently experienced a natural disaster such as widespread flooding that caused the closure of a local emergency room or other facilities. Due to the increased demand for services and rerouting of patients, this ground ambulance organization might be unable to collect and report information in a timely manner.

We are proposing that ground ambulance organizations in these or other similar situations could request that CMS grant a hardship exemption, and CMS could consider granting an exemption if the ground ambulance organization could demonstrate that the significant hardship interfered with its ability to submit the required data under the data collection system.

To request a hardship exemption, we propose that a ground ambulance organization submit to CMS a completed request form, which can be found on the Ambulance Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*), and that the following information be included:

- Ambulance Provider or Supplier Name;
- NPI Number;
- Ambulance Provider or Supplier Location Address;
- CEO and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable);
- Reason for requesting a hardship exemption;
- Evidence of the impact of the hardship exemption (such as photographs, newspaper, other media articles, financial data, bankruptcy filing, etc.); and
- Date when the ground ambulance organization would be able to begin submitting information under the data collection system.

We are proposing that the completed hardship exemption request form be signed and dated by the Chief Executive Officer (CEO) or designee of the ambulance company, and be submitted as soon as possible, and not later than 90 calendar days of the date that the ground ambulance organization was notified that it will be subject to the 10 percent payment reduction as a result of not sufficiently submitting information under the data collection system. We propose that the request form be submitted to the Ambulance ODF mailbox at *AMBULANCEODF@cms.hhs.gov*. Following receipt of the request form, we are proposing to provide: (1) A written acknowledgement that the request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days of the date that we received the request. We are also proposing to codify the hardship exemption requirement at § 414.626(d).

c. Informal Review

Section 1834(l)(17)(D)(iv) of the Act requires the Secretary to establish a process under which a sampled ground organization may seek an informal review of a determination that it is subject to the 10 percent reduction. To request an informal review, we propose that a ground ambulance organization must submit the following information:

- Ground Ambulance Organization Name;
- NPI Number;
- CEO and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable);
- Ground ambulance organization's selected data collection period and data reporting period; and
- A statement of the reasons why the ground ambulance organization does not agree with CMS's determination and any supporting documentation.

We propose that the informal review request must be signed by the CEO/designee of the ground ambulance organization and be submitted within 90 calendar days of the date that the ground ambulance organization received notice regarding the 10 percent reduction in payments. We are proposing 90 calendar days to submit an informal review request to allow time for the ground ambulance organization to gather the information needed to support the request for informal review. We are proposing that the request be submitted to the Ambulance ODF mailbox at *AMBULANCEODF@cms.hhs.gov*. Following receipt of the request for informal review, we would provide: (1) A written acknowledgement using the contact information provided in the request, to the CEO and any additional designated personnel, notifying them that the ambulance provider or supplier's request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days. We are seeking comments on our proposed

informal review process. We are also proposing to codify the informal review process in § 414.610(e).

We invite comments regarding all the proposals on the payment reduction for failure to report, including the applicable period, hardship exemption, and informal review.

8. Public Availability

Section 1834(l)(17)(G) of the Act requires that the results of the data collection be posted on the CMS website, as determined appropriate by the Secretary. We are proposing to post on our website a report that includes summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable.

We are also proposing that the data proposed above will be made available to the public through posting on our website at least every 2 years. The 2-year timeframe would allow CMS time to analyze the data that is being reported, factoring in the various accounting periods of the first group of sampled ground ambulance organizations (which have early accounting periods in the CY 2020 data collection year).

We are proposing to post summary results by the last quarter of 2022, because we believe we may have most or all of the data requested by then. We invite comments on our proposals regarding the type of information that should be posted from the data collected and the timeline in which the results of the data collection should be posted on our website.

We invite comments regarding our proposals for public availability of the data.

9. Limitations on Review

Section 1834(l)(17)(J) of the Act provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the data collection system or identification of respondents. We are proposing to codify the limitations on review at § 414.626(g).

C. Expanded Access to Medicare Intensive Cardiac Rehabilitation (ICR)

Section 51004 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, enacted February 9, 2018) amended section 1861(eee)(4)(B) of the Act directing CMS to add covered conditions for intensive cardiac rehabilitation (ICR). This proposed rule includes our proposals for implementing this expansion of coverage through revisions to § 410.49(b)(1).

1. Background

Cardiac rehabilitation (CR) was developed in the 1950s from the concept of early mobilization after acute myocardial infarction (heart attack).[96] The standard of care prior to the widespread adoption of CR was bed-rest and inactivity after acute myocardial infarction.[97] In the 1970s, cardiac rehabilitation developed into highly structured, physician supervised, electrocardiographically-monitored exercise programs. However, the programs consisted almost solely of exercise alone.[98] Referencing 1998 guidelines [99] from the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), Forman (2000) stated that ''over subsequent years the objectives of cardiac rehabilitation broadened beyond exercise into a composite of cardiac risk modification. Lipid, blood pressure, and stress reduction, smoking cessation, diet change, and weight loss were coupled to goals of exercise training.''

ICR, also commonly referred to as a ''lifestyle modification'' program, typically involves the same elements as traditional CR programs, but are furnished in highly structured environments in which sessions of the various components may be combined for longer periods of CR and also may be more rigorous.

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted July 15, 2008) amended Title XVIII to add new section 1861(eee) of the Act to provide coverage of CR and ICR under Medicare part B. The statute specified certain conditions for these services and an effective date of January 1, 2010, for coverage of these services. Conditions of coverage for CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in § 410.49 through the CY 2010 PFS final rule with comment period (74 FR 61872–61879 and 62004–62005). These programs were designed to improve the health care of Medicare beneficiaries with cardiovascular disease.

Under § 410.49(b), Medicare part B covers CR and ICR program services for beneficiaries who have experienced one or more of the following: (1) An acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or (6) a heart or heart-lung transplant. For CR only, other cardiac conditions may be added as specified through a national coverage determination (NCD). Effective February 18, 2014, we expanded coverage of CR in NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100–03 20.10.1), to beneficiaries with stable, chronic heart failure, defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. Stable patients are defined as patients who have not had recent (≤6 weeks) or planned (≤6 months) major cardiovascular hospitalizations or procedures.

2. Statutory Authority

Section 51004 of the BBA of 2018, entitled ''Expanded Access to Medicare Intensive Cardiac Rehabilitation Programs,'' amended section 1861(eee)(4)(B) of the Act. The amendment directs us to expand the list of covered conditions for ICR beyond the 6 conditions specified in section 144(a) of the MIPPA and codified in § 410.49(b)(1).

3. Discussion of Statutory Requirements

Section 1861(eee)(4)(B) of the Act requires that, in addition to the 6 conditions specified in section 144(a) of the MIPPA, ICR be covered for beneficiaries with (1) stable, chronic heart failure (defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks); or (2) any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

The statute explicitly states *cardiac* rehabilitation; therefore, this proposed

[96] Pashkow, FJ. Issues in Contemporary Cardiac Rehabilitation: A Historical Perspective. JACC 1993 Mar 1;21(3):822–34.

[97] Forman DE. Cardiac rehabilitation and secondary prevention programs for elderly cardiac patients. Clin Geriatr Med. 2000 Aug;16(3):619–29.

[98] Ades PA. A controlled trial of cardiac rehabilitation in the home setting using electrocardiographic and voice transtelephonic monitoring. Am Heart J. 2000 Mar;139(3):543–8.

[99] AACWR Guidelines for Cardiac Rehabilitation and Secondary Prevention Programs, ed 3. Windsor, ON, Human Kinetics, 1998.

rule is specific to CR and ICR for cardiac conditions. As such, this proposed rule could not exceed the limits of the statute to apply CR and ICR other conditions (for example, cancer, metabolic syndrome, diabetes, peripheral artery disease, etc.).

4. Proposals for Implementation

We propose to amend § 410.49(b) to expand the covered conditions for ICR. We propose to amend § 410.49(b)(vii) to add coverage of ICR for patients with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. We also propose to specify in § 410.49(b)(vii) that coverage for CR was effective February 18, 2014 as per the NCD for Cardiac Rehabilitation for Chronic Heart Failure (Pub. 100–03 20.10.1) which was finalized on February 18, 2014 as discussed above, and that coverage for ICR was effective on enactment of the BBA of 2018 (February 9, 2018).

We also propose to add new § 410.49(b)(viii) to include coverage of ICR, in addition to CR, for other cardiac conditions as specified through an NCD. Under the existing § 410.49(b)(vii), coverage for CR may be established for other cardiac conditions through an NCD, and our proposal would extend this criterion to ICR, as well unless coverage for ICR is not supported by clinical evidence. As such, NCDs modifying the covered conditions would apply to both CR and ICR so long as clinical evidence supports coverage for CR and coverage for ICR.

It is important to note that conditions that may be considered for expanded coverage are limited to cardiac conditions and may not include other conditions (for example, cancer, metabolic syndrome, diabetes, peripheral artery disease, etc.).

5. Summary

In summary, we are proposing modifications to existing requirements under § 410.49(b) to implement the coverage changes specific to ICR. The proposals involve expanding coverage of ICR to beneficiaries with chronic heart failure as discussed above and providing for modifications to covered cardiac conditions for ICR, in addition to CR, as specified through an NCD. We invite the public to provide comments on these proposals.

D. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the incentive payments made to Medicaid EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of Certified EHR Technology (CEHRT). We have implemented these statutory provisions in prior rulemakings to establish the Medicaid Promoting Interoperability Program.

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act, and the definition of ''meaningful EHR user'' in regulations at 42 CFR 495.4, one of the requirements of being a meaningful EHR user is to successfully report the clinical quality measures selected by CMS to CMS or a state, as applicable, in the form and manner specified by CMS or the state, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting electronic clinical quality measures (eCQMs) for EPs to report under the Promoting Interoperability Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. We have taken steps to align various quality reporting and payment programs that include the submission of eCQMs.

In the CY 2019 PFS final rule (83 FR 59452, 59703 through 59704), we established for 2019 that Medicaid EPs are required to report on any 6 eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. We also adopted the Merit-based Incentive Payment System (MIPS) requirement that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). We explained that if no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, the EP may report on any 6 eCQMs that are relevant.

2. eCQM Reporting Requirements for EPs Under the Medicaid Promoting Interoperability Program for 2020

We annually review and revise the list of eCQMs for each MIPS performance year to reflect updated clinical standards and guidelines. In section III.I.3.h.(2)(b)(i) of this proposed rule, we propose to amend the list of available eCQMs for the CY 2020 performance period. To keep eCQM specifications current and minimize complexity, we propose to align the eCQMs available for Medicaid EPs in 2020 with those available for MIPS eligible clinicians for the CY 2020 performance period. Specifically, we propose that the eCQMs available for Medicaid EPs in 2020 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2020 performance period.

In previous years, CMS proposals to align the list of eCQMs for MIPS and the Medicaid Promoting Interoperability Program for EPs received positive comments that indicated that alignment between these two programs would help reduce health care provider reporting burden (83 FR 59702). These comments thus suggest that aligning the eCQM lists might encourage EP participation in the Medicaid Promoting Interoperability Program by giving Medicaid EPs that are also MIPS eligible clinicians the ability to report the same eCQMs as they report for MIPS. Not aligning the eCQM lists could lead to increased burden, because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program if they opt to report on newly added eCQMs for MIPS. In addition, we believe that aligning the eCQMs available in each program would help to ensure the most uniform application of up-to-date clinical standards and guidelines possible.

We anticipate that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, particularly in light of our belief that many EPs would report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on the available eCQMs for 2020. We expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2020 to maintain current eCQM lists and specifications.

For 2020, we propose to again require (as we did for 2019) that Medicaid EPs report on any 6 eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically. This policy of allowing Medicaid EPs to report on any 6 measures relevant to their scope of practice would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established at § 414.1335(a)(1). MIPS

eligible clinicians who elect to submit eCQMs must generally submit data on at least 6 quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure). We refer readers to § 414.1335(a) for the data submission criteria that apply to individual MIPS eligible clinicians and groups that elect to submit data with other collection types.

In addition, as we did for 2019, we propose that for 2020, EPs in the Medicaid Promoting Interoperability Program would be required to report on at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure). This policy would improve alignment with the requirements for the MIPS quality performance category for eligible clinicians using the eCQM collection type. We also propose that if no outcome or high priority measures are relevant to a Medicaid EP's scope of practice, the clinician may report on any 6 eCQMs that are relevant, as was the policy in 2019.

In the CY 2019 PFS final rule (83 FR 59702 and 59704), we established the following three methods to identify which of the available measures are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program. We propose to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2020:

- The same set of measures that are identified as high priority measures for reporting on the quality performance category for eligible clinicians participating in MIPS.
- All e-specified measures from the previous year's core set of quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (Child Core Set) or the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set) (hereinafter together referred to as ''Core Sets'') that are also included on the MIPS list of eCQMs.

Sections 1139A and 1139B of the Act require the Secretary to identify and publish core sets of health care quality measures for child Medicaid and CHIP beneficiaries and adult Medicaid beneficiaries. These measure sets are required by statute to be updated annually and are voluntarily reported by states to CMS. These Core Sets are composed of measures that specifically focus on populations served by the Medicaid and CHIP programs and are of particular importance to their care. The MIPS eCQM list includes several, but not all, of the measures in the Core Sets. Because the Core Sets are released at the beginning of each year, it is not possible to update the list of high-priority eCQMs with those added to the current year's Core Sets.

The eCQMs that would be available for Medicaid EPs to report in 2020, that are both part of the Core Sets and on the MIPS list of eCQMs, and that would be considered high priority measures under our proposal are: CMS2, ''Preventive Care and Screening: Screening for Depression and Follow-Up Plan''; CMS122, ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)''; CMS125, ''Breast Cancer Screening''; CMS128, ''Anti-depressant Medication Management''; CMS136, ''Follow-Up Care for Children Prescribed ADHD Medication (ADD)''; CMS137, ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment''; CMS153, ''Chlamydia Screening for Women''; CMS155, ''Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents''; and CMS165, ''Controlling High Blood Pressure.''

- Through an amendment to § 495.332(f), we gave each state the flexibility to identify which of the eCQMs available for reporting in the Medicaid Promoting Interoperability Program are high priority measures for Medicaid EPs in that state, with review and approval by CMS, through the State Medicaid HIT Plan (SMHP). States are thus able to identify high priority measures that align with their state health goals or other programs within the state.

All eCQMs identified via any of these three methods are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program for 2019. As noted above, we propose to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2020. We invite comments as to whether any of these methods should be altered or removed, or whether any additional methods should be considered for 2021.

We also propose that the 2020 eCQM reporting period for Medicaid EPs who have demonstrated meaningful use in a prior year be a minimum of any continuous 274-day period within CY 2020. This 274-day eCQM reporting period corresponds to the 9-month period from January 1, 2020 to September 30, 2020. Medicaid EPs would not be required to use that exact reporting period, but would be able to use any continuous 274-day period within CY 2020. Medicaid EPs could also use a longer eCQM reporting period in CY 2020, up to the full calendar year. In addition, states would be required to allow sufficient time for EPs to attest for program year 2020 beyond January 1, 2021 so that EPs may, should they choose to do so, select EHR and eCQM reporting periods that take place at any time within the 2020 calendar year through December 31, 2020.

We are proposing this eCQM reporting period for 2020 to improve state flexibility in the penultimate year of the Medicaid Promoting Interoperability Program, and to facilitate an orderly end of the program in 2021. In the CY 2019 PFS final rule, we established that the eCQM reporting period for Medicaid EPs in 2021 will be a minimum of any continuous 90-day period within CY 2021, and also established that the end date for this period must fall before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability payments to EPs by the December 31, 2021 statutory deadline (83 FR 59704 through 59706). When proposing that policy, we received comments that asked us to consider an eCQM reporting period shorter than a full year in 2020. Commenters stated that a full-year reporting period may create significant backlogs of 2020 and 2021 attestations in 2021 that may create difficulty for states to issue payments by the statutory deadline (83 FR 59705). We continue to believe that longer reporting periods create more useful data for quality measurement and improvement because they give states a broader picture of a health care provider's care and patient outcomes. However, we agree that a full-year eCQM reporting period in 2020 might unnecessarily burden states as they would need to issue incentive payments and implement systems changes for 2021 in a timely manner.

This proposal would allow states to accept attestations for program year 2020 as early as October 1, 2020 from Medicaid EPs who choose to use an eCQM reporting period early in the year, and thus could give states additional time to prepare for 2021 and the end of the Medicaid Promoting Interoperability Program. Even though states would also still have to allow EPs to submit attestations for 2020 in 2021, we believe that allowing some EPs to attest sooner could accelerate states' pre-payment verification and payment process. We considered whether to propose a Medicaid EP eCQM reporting period for 2020 from January 1, 2020 through September 30, 2020, with no flexibility for EPs to select an alternative 274-day eCQM reporting period. We also

considered whether to propose a date prior to December 31, 2020 by which all Medicaid EP EHR and eCQM reporting periods for 2020 must end. While either of these alternatives might have further helped to ensure that all states would have additional time to prepare for 2021, we decided not to propose either of them because we wanted to preserve as much flexibility as possible for Medicaid EPs. However, we seek comment, especially from states and Medicaid EPs, about whether either of these alternatives might be preferable to our proposal.

We note that states submit their attestation deadlines to CMS each year as part of their SMHPs. We do not believe that this proposal would create any additional burden on EPs or CEHRT vendors, as CEHRT should be able to report eCQM data from any length of time.

We propose that, in 2020, the eCQM reporting period for Medicaid EPs demonstrating meaningful use for the first time, which was established in the final rule entitled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017'' (80 FR 62762, 62892) (hereinafter known as the ''Stage 3 final rule''), would remain any continuous 90-day period within the calendar year, as in previous years.

3. Objective 1: Protect Patient Health Information in 2021

In the Stage 3 final rule (80 FR 62762, 62832), we established Meaningful Use Objective 1 as ''Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.'' As specified at § 495.24(d)(1)(i)(B), to meet that objective, EPs must meet the associated measure to conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

In the Stage 3 final rule, we explained that this measure must be completed in the same calendar year as the EHR reporting period. This may occur before, during, or after the EHR reporting period, though if it occurs after the EHR reporting period it must occur before the provider attests to meaningful use of CEHRT or before the end of the calendar year, whichever comes first (80 FR 62831). In practice, this means that EPs do not attest to meaningful use of CEHRT before completing this measure.

As discussed above, states must issue all Medicaid Promoting Interoperability Program incentive payments by the statutory deadline of December 31, 2021. States can establish state-specific deadlines for Medicaid EPs to attest to the state regarding meaningful use of CEHRT in CY 2021. However, due to changes CMS made in prior rulemaking to the Medicaid Promoting Interoperability Program EHR and eCQM reporting periods for 2021, all states must set attestation deadlines on or before October 31, 2021. *See* 42 CFR 495.4 (definition of ''EHR reporting period'') and 495.332(f)(3) and (4), and 83 FR 59704 through 59705. Because all EPs are therefore expected to attest to meaningful use of CEHRT before the end of CY 2021, Medicaid EPs would no longer have the option of completing the security risk analysis at the end of the calendar year, and would likely have to complete it well before December 2021. For example, in a state with an attestation deadline of October 1, 2021, a Medicaid EP would have to conduct the security risk analysis by September 30, 2021. Stakeholders have given us feedback that most security risk analyses are conducted on a clinic or practice level, which may include EPs and non-EPs. As we noted in the Stage 3 final rule, ''[a]n organization may conduct one security risk analysis or review which is applicable to all EPs within the organization, provided it is within the same calendar year and prior to any EP attestation for that calendar year. However, each EP is individually responsible for their own attestation and for independently meeting the objective. Therefore, it is incumbent on each individual EP to ensure that any security risk analysis or review conducted for the group is relevant to and fully inclusive of any unique implementation or use of CEHRT relevant to their individual practice'' (80 FR 62794).

If an EP or practice typically conducts the security risk analysis at the end of each year, the CY 2021 timeline for attesting to meaningful use of CEHRT may create burden for all Medicaid EPs and for non-EP health care providers within the same organization as Medicaid EPs, and may not be optimal for protecting information security, because it could disrupt the intervals between security risk analyses. As we explained in the Stage 3 final rule, a security risk analysis is not a discrete item in time, but a comprehensive analysis covering the full period of time for which it is applicable; and the annual review of such an analysis is similarly comprehensive. In other words, the analysis and review, no matter when they are conducted, should *not* be just a ''point in time'' exercise, and instead should cover a span of the entire year, including a review planning for future system changes within the year or a review of prior system changes within the year (80 FR 62831). However, EPs that typically conduct the security risk analysis in December of each calendar year might conduct one security risk analysis in December 2020, and then have to conduct another one well before December 2021, if the analysis must be completed before the EP attests to meaningful use of CEHRT for CY 2021. We believe that security risk analyses are most effective for data security when conducted on a regular schedule. In addition, practice locations may have ongoing contracts or processes in place to perform a security risk analysis at the same time each year. We do not wish to create burden for EPs and non-EPs related to changing those processes to meet the CY 2021 Medicaid Promoting Interoperability Program attestation timelines.

Therefore, we are proposing to allow Medicaid EPs to conduct a security risk analysis at any time during CY 2021, even if the EP conducts the analysis after the EP attests to meaningful use of CEHRT to the state. A Medicaid EP who has not completed a security risk analysis for CY 2021 by the time he or she attests to meaningful use of CEHRT for CY 2021 would be required to attest that he or she will complete the required analysis by December 31, 2021. Under this proposal, states could require Medicaid EPs to submit evidence that the security risk analysis has been completed as promised, even after the incentive payment has been issued. In addition, states could require EPs to attest that if a security risk analysis is not completed by December 31, 2021, they will voluntarily rescind their attestation to meaningful use of CEHRT and return the incentive payment. If this proposal is finalized as proposed, we would work with states to develop post-payment verification and audit processes that meet CMS due diligence requirements, including those in §§ 495.318 and 495.368, and generally to ensure that incentive payments are made properly. We remind states that as a condition of receiving enhanced federal financial participation (FFP), they are required to demonstrate to the satisfaction of HHS that they are conducting adequate

oversight of the program, including routine tracking of meaningful use attestations (*See* § 495.318(b)). States are also reminded that they must submit a description of the methodology used to verify that EPs have meaningfully used CEHRT for CMS approval as part of their SMHP. (*See* § 495.332(c)). In the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'' (75 FR 44313), CMS explained that states are expected to ''look behind'' provider attestations, and that this would require audits both pre- and post-payment (75 FR 44515). These requirements and expectations would not change under this proposal.

4. Clarification

In the CY 2019 PFS final rule (83 FR 59702), in the list of high priority eCQMs that are available for Medicaid EPs to report in 2019 because they are both part of the Core Sets and on the MIPS list of eCQMs, we inadvertently listed ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment'' as ''CMS4.'' It should have read ''CMS137, 'Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.' ''

E. Medicare Shared Savings Program

As required under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 9, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies including redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. In the CY 2019 PFS final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in selecting their primary care provider and in the use of that selection for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715). In the CY 2018 PFS final rule (82 FR 53209 through 53226), we finalized revisions to several different policies under the Shared Savings Program, including the assignment methodology, quality measure validation audit process, use of the skilled nursing facility (SNF) 3-day waiver, and handling of demonstration payments for purposes of financial reconciliation and establishing historical benchmarks. In addition, in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77255 through 77260, and 82 FR 53688 through 53706, respectively), we finalized policies related to the Alternative Payment Model (APM) scoring standard under the Merit-Based Incentive Payment System (MIPS), which reduced the reporting burden for MIPS eligible clinicians who participate in MIPS APMs, such as the Shared Savings Program.

As a general summary, in this CY 2020 PFS proposed rule, we:

- Discuss aligning the Shared Savings Program quality measure set with proposed changes to the Web Interface measure set under MIPS per previously-finalized policy;
- Propose a change to the claims-based measures;
- Solicit comment on aligning the Shared Savings Program quality score with the MIPS quality performance category score; and
- Propose a technical change to correct a cross-reference within a provision of the Shared Savings Program's regulations on the skilled nursing facility (SNF) 3-day rule waiver, to conform with amendments to § 425.612 that were adopted in the December 2018 final rule;

1. Quality Measurement

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule, we established a quality measure set spanning four domains: Patient experience of care, care coordination/patient safety, preventive health, and at-risk population (76 FR 67872 through 67891). Since the Shared Savings Program was established, we have updated the measures that comprise the quality performance measure set for the Shared Savings Program through the annual rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, and 83 FR 59707 through 59715 respectively).

As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. For performance year 2019, 23 quality measures will be used to determine ACO quality performance (83 FR 59707 through

59715). The information used to determine ACO performance on these quality measures will be submitted by the ACO through the CMS Web Interface, calculated by us from administrative claims data, and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey.

Eligible clinicians who are participating in an ACO and who are subject to MIPS (MIPS eligible clinicians) will be scored under the APM scoring standard under MIPS (81 FR 77260). These MIPS eligible clinicians include any eligible clinicians who are participating in an ACO in a track (or payment model within a track, such as Levels A–D of the BASIC Track) of the Shared Savings Program that is not an Advanced APM, as well as those participating in an ACO in a track (or payment model within a track) that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS.

b. Proposed Changes to the CMS Web Interface and Claims-Based Measures

Since the Shared Savings Program was first established in 2012, we have updated the quality measure set to reduce reporting burden and focus on more meaningful, outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2019 PFS final rule (83 FR 59711). In the CY 2019 PFS final rule, we explained that in developing the proposed changes to the quality measure set for 2019, we had considered the agency's efforts to streamline quality measures, reduce regulatory burden and promote innovation as part of the agency's Meaningful Measures initiative (*see* CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html*). We also noted that under the Meaningful Measures initiative, we have committed to assessing only those core issues that are most vital to providing high-quality care and improving patient outcomes, with the aim of focusing on high-priority measures, reducing unnecessary burden on providers, and putting patients first. The changes made in the CY 2019 PFS final rule reduced the Shared Savings Program quality measure set from 31 to 23 measures. Currently, more than half of the 23 Shared Savings Program quality measures are outcome and high-priority measures, including:

- Patient-experience of care measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience.
- Outcome measures supporting effective communication and care coordination, such as unplanned admission and readmission measures.
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes.

As we stated in the CY 2019 PFS final rule (83 FR 59713), we seek to align the Shared Savings Program measure set with changes made to the CMS Web Interface measures under the Quality Payment Program. In the 2017 PFS final rule, we stated that we do not believe it is beneficial to propose CMS Web interface measures for ACO quality reporting separately (81 FR 80499). Therefore, to avoid confusion and duplicative rulemaking, we adopted a policy that any future changes to the CMS Web interface measures would be proposed and finalized through rulemaking for the Quality Payment Program, and that such changes would be applicable to ACO quality reporting under the Shared Savings Program. In accordance with the policy adopted in the CY 2017 PFS final rule (81 FR 80501), we are not making any specific proposals related to changes in CMS Web Interface measures reported under the Shared Savings Program. Rather, we refer readers to Appendix 1, Table C (Existing Quality Measures Proposed for Removal Beginning with the 2022 MIPS Payment Year) and Table Group A (New Quality Measures Proposed for Addition Beginning with the 2022 MIPS Payment Year) of this proposed rule for a complete discussion of the proposed changes to the CMS Web Interface measures for performance year 2020 (2022 MIPS Payment Year). Based on the changes being proposed in Appendix 1, Table C of this proposed rule, ACOs would no longer be responsible for reporting the following measure for purposes of the Shared Savings Program starting with reporting for performance year 2020:

- ACO–14 Preventive Care and Screening Influenza Immunization

In the event we do not finalize the removal of this measure, we would maintain the measure with the ''substantive'' change described in Appendix 1, Table C (Previously Finalized Quality Measures Proposed for Removal in the 2022 Payment Year and Future Years) of this proposed rule. We have reviewed the proposed ''substantive'' change and we do not believe that this change to the measure would require that we revert the measure to pay-for-reporting for the 2020 performance year as we could create a historical benchmark.

Additionally, in section III.I.3.B.(1) of this proposed rule, we are proposing to add the following measure to the CMS Web Interface for purposes of the Quality Payment Program:

- ACO–47 Adult Immunization Status

Based on the policies being proposed for purposes of MIPS in Appendix 1, Table Group A of this proposed rule, Shared Savings Program ACOs would be responsible for reporting the Adult Immunization Status measure (ACO–47) starting with quality reporting for performance year 2020. Consistent with our existing policy regarding the scoring of newly introduced quality measures, this measure would be pay-for-reporting for all ACOs for 2 years (performance years 2020 and performance year 2021). The measure would then phase into pay-for-performance beginning in performance year 2022 (§ 425.502(a)(4)).

In section III.J.3.c.(1)(d) of this rule, we note that as discussed in Table DD (Previously Finalized Quality Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year), we have determined based on extensive stakeholder feedback that the 2018 CMS Web Interface measure numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (ACO–17) measure is inconsistent with the intent of the CMS Web Interface version of this measure as modified in the CY 2018 Quality Payment Program final rule (82 FR 54164) and is unduly burdensome on clinicians. Moreover, due to the current guidance, we are unable to rely on historical data to benchmark the measure. Therefore, for the 2018 performance year we are designating the measure pay-for-reporting in accordance with § 425.502(a)(5). Additionally, in section III.J.3.c.(1)(d) of this proposed rule, we are proposing to update the CMS Web Interface measure numerator guidance for purposes of the Quality Payment Program. To the extent that this proposed change constitutes a change to the Shared Savings Program measure set after the start of the 2019 performance period, we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to modify the measure as proposed in Table DD because the current guidance is inconsistent with the intent of the CMS Web Interface version of this measure,

as modified in the CY 2018 QPP final rule, and unduly burdensome on clinicians. If this modification is finalized as proposed, consistent with our discussion in the CY 2018 PFS final rule, we expect we would be able to use historical data reported on the measure to establish an appropriate 2019 benchmark that aligns with the updated specifications (82 FR 53214 and 53215) and the measure would be pay-for-performance for performance year 2019 and subsequent year.

In addition, we note that AHRQ, which is the measure steward for ACO–43—Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment), made an update to the measure that will require a change to the measure specifications for performance year 2020.[100] Currently, ACO–43 assesses the risk adjusted rate of hospital discharges for acute PQI conditions with a principal diagnosis of dehydration, bacterial pneumonia, and urinary tract infection. The updated measure will only include two conditions, bacterial pneumonia and urinary tract infection. This measure is a composite measure and the rate of hospital discharges is approximately equal to the sum of the rates of hospital discharges for each of its components. Therefore, the removal of dehydration will likely decrease the composite rate by approximately the rate of dehydration discharges. Based on this substantive change, we propose to redesignate ACO–43 as pay-for-reporting for 2020 and 2021 consistent with our policy under § 425.502(a)(4), which provides that a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods the measure is required. However, we also considered creating a benchmark using historical data for bacterial pneumonia and urinary tract infection and keeping the measure pay-for-performance. As this is a claims-based measure, we have access to historical data for both bacterial pneumonia and urinary tract infection so we would be able to create a historical benchmark for the revised measure. However, we believe that changes to measures impact how ACOs, their ACO participants, and ACO provider/suppliers allocate their resources and redesign their care process to improve quality of care for their beneficiaries. As a result, our proposal to revert the measure to pay-for-reporting for 2 years will give ACOs time to refine care processes and educate clinicians while also gaining experience with the refined composite measure and understanding of performance under revised benchmarks prior to the start of a pay for performance year.

We seek comment on this proposal and the alternative approach considered.

Table 32 shows the Shared Savings Program quality measure set for performance year 2020 and subsequent performance years that would result if the proposals in section III.I.3.B.(1) of this proposed rule are finalized, including the phase-in schedule for the proposed Adult Immunization Status measure (ACO–47).

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[100] *https://www.qualityindicators.ahrq.gov/News/Retirement%20Notice_v2019_Indicators.pdf.*

TABLE 32: Measure Set for Use in Establishing the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2020

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF N/A AHRQ	Survey	R	P	P
	ACO - 2	CAHPS: How Well Your Providers Communicate		NQF N/A AHRQ	Survey	R	P	P
	ACO - 3	CAHPS: Patients' Rating of Provider		NQF N/A AHRQ	Survey	R	P	P
	ACO - 4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 5	CAHPS: Health Promotion and Education		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 6	CAHPS: Shared Decision Making		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 7	CAHPS: Health Status/Functional Status		NQF #N/A AHRQ	Survey	R	R	R
	ACO - 34	CAHPS: Stewardship of Patient Resources		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 45	CAHPS: Courteous and Helpful Office Staff		NQF #N/A AHRQ	Survey	R	R	P
	ACO - 46	CAHPS: Care Coordination		NQF #N/A AHRQ	Survey	R	R	P
Care Coordination/ Patient Safety	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	P
	ACO - 38	Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions		NQF#2888 CMS	Claims	R	R	P
	ACO - 43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment)		AHRQ	Claims	R	R	P
	ACO - 13	Falls: Screening for Future Falls		NQF #0101 NCQA	CMS Web Interface	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO-47	Adult Immunization Status	✓	NQF #N/A NCQA	CMS Web Interface	R	R	P
	ACO - 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 18	Preventive Care and Screening: Screening for Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	P	P
	ACO - 19	Colorectal Cancer Screening		NQF #0034 NCQA	CMS Web Interface	R	R	P
	ACO - 20	Breast Cancer Screening		NQF #2372 NCQA	CMS Web Interface	R	R	P
	ACO - 42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease		NQF #N/A CMS	CMS Web Interface	R	R	R
Clinical Care for	ACO - 40	Depression Remission at Twelve		NQF #0710	CMS Web	R	R	R

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
At Risk Population - Depression		Months		MNCM	Interface			
Clinical Care for At Risk Population - Diabetes	ACO-27	Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%))		NQF #0059 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension : Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	P	P

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The net result, if the proposals in section III.I.3.b.(1) of this proposed rule are finalized, would be a set of 23 measures on which ACOs' quality performance would be assessed for performance year 2020 and subsequent performance years. The 4 domains would include the following numbers of quality measures (See Table 33):

- Patient/Caregiver Experience of Care-10 measures.
- Care Coordination/Patient Safety-4 measures.
- Preventive Health-6 measures.
- At Risk Populations-3 measures.

Table 33 provides a summary of the number of measures by domain and the total points and domain weights that would be used for scoring purposes.

TABLE 33: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2019

Domain	Number of Individual Measures	Total Measures for Scoring Purposes	Total Possible Points	Domain Weight
Patient/Caregiver Experience	10	10 individual survey module measures	20	25%
Care Coordination/ Patient Safety	4	4 measures	8	25%
Preventive Health	6	6 measures	12	25%
At-Risk Population	3	3 individual measures	6	25%
Total in all Domains	23	23	46	100%

c. Seeking Comment on Aligning the Shared Savings Program Quality Score With the MIPS Quality Score

As discussed above, our principal goal in selecting quality measures for the Shared Savings Program has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. The Shared Savings Program quality measure set currently consists of 23 measures spanning four domains that are submitted by the ACO through the CMS Web Interface, calculated by us for ACOs from administrative claims data, and collected via a patient experience of care survey referred to as the CAHPS for ACOs Survey. The number of measures within the four domains has changed over time to reflect changes in clinical practice, move towards more outcome and high-priority measures, align with other quality reporting programs, and reduce burden; however, the overall structure of four equally weighted measure domains has remained consistent in determining ACOs' quality performance since the Shared Savings Program was established in 2012. As provided in section 1899(d)(2) of the Act and § 425.502(a) of the Shared Savings Program regulations, ACOs must meet a quality performance standard to qualify to share in savings. Currently, the quality performance standard is based on an ACO's performance year rather than financial track. The quality performance standard is defined at the level of full and complete reporting (pay-for-reporting (P4R)) for the first performance year of an ACO's first agreement period. In the second or subsequent years of the first agreement period and all years of subsequent agreement periods, quality measures are scored as pay-for-performance (P4P) according to the phase-in schedule for the specific measure and the ACO's performance year in the Shared Savings Program:

- For all performance years, ACOs must completely and accurately report all quality data used to calculate and assess their quality performance.
- CMS designates a performance benchmark and minimum attainment level for each P4P measure and establishes a point scale for the measure. An ACO's quality performance for a measure is evaluated using the appropriate point scale, and these measure specific scores are used to calculate the final quality score for the ACO.
- ACOs must meet minimum attainment (defined as the 30th percentile benchmark for P4P measures) on at least one measure in each domain

to be eligible to share in any savings generated (§ 425.502(d)(2)(iii)(A)).

ACOs are rewarded for their quality performance on a sliding scale on which higher levels of quality performance translate to higher rates of shared savings and, depending on the track under which an ACO is participating, may result in lower rates of shared losses. In addition, ACOs that demonstrate significant quality improvement on measures in a domain are eligible to receive a quality improvement reward (§ 425.502(e)(4)). Specifically, for each domain, ACOs can be awarded up to four additional points for quality performance improvement on the quality measures within the domain. These bonus points are added to the total points that an ACO achieves for the quality measures within that domain, but the total number of points cannot exceed the maximum total points for the domain.

In the CY 2018 Quality Payment Program final rule, we finalized a policy for the 2018 performance period and subsequent performance periods that the quality performance category under the MIPS APM Scoring Standard for MIPS eligible clinicians participating in a Shared Savings Program ACO will be assessed based on measures collected through the CMS Web Interface and the CAHPS for ACOs survey measures (82 FR 53688 through 53706). We assign the same MIPS quality performance category score to each Tax Identification Number (TIN)/National Provider Identifier (NPI) in a Shared Savings Program ACO based on the ACO's total quality score derived from the measures reported via the CMS Web Interface and the CAHPS for ACOs survey. Eligible clinicians in a Shared Savings Program ACO will receive full credit for the improvement activities performance category in 2020 based on their performance of improvement activities required under the Shared Savings Program. In addition, ACO participants report on the Promoting Interoperability performance category at the group or solo practice level for eligible clinicians subject to Promoting Interoperability performance category. Data for the Promoting Interoperability performance category is reported by ACO participants at the TIN level and is then weighted and aggregated to get a single ACO score for the performance category that applies to all eligible clinicians participating in the ACO. These three categories in the APM scoring standard are weighted as follows: Quality is 50 percent, Improvement Activities is 20 percent, and Promoting Interoperability is 30 percent. Eligible Clinicians participating in the Shared Savings Program are not assessed under the MIPS cost performance category as these eligible clinicians are already subject to cost and utilization performance assessments as part of the Shared Savings Program. Therefore, the cost performance category is weighted at zero percent.

Eligible clinicians who reassign their billing rights to an ACO Participant TIN in an Advanced APM (Track 2, Track 1+ ACO Model, BASIC Track Level E, and ENHANCED Track) and who are included on the Advanced APM Participation List on at least one of three snapshot dates (March 31, June 30, and August 31) during the performance year may become Qualifying APM Participants (QPs) for the year, if they meet payment or patient count thresholds. If these eligible clinicians attain QP status for the performance year via their participation in the Shared Savings Program ACO, they would receive an APM incentive payment and would not be subject to the MIPS reporting requirements or payment adjustment for the related payment year. However, they would be required to report quality for purposes of the Shared Savings Program financial reconciliation.

We recognize that ACOs and their participating providers and suppliers have finite resources to dedicate to engaging in efforts to improve quality and reduce costs for their assigned beneficiary population. Although CMS has worked to align policies under the Shared Savings Program with the Quality Payment Program, we recognize that some differences in program methodologies for the Shared Savings Program and MIPS remain and could potentially create conflicts for MIPS eligible clinicians in an ACO who are attempting to strategically transform their respective practices to earn shared savings under the terms of the Shared Savings Program and a positive payment adjustment under MIPS. Currently, under the Shared Savings Program, ACOs in performance years other than the first performance year of their first agreement period are allocated up to two points for quality measures that are pay-for-performance, according to where their performance falls, relative to benchmark deciles. Incomplete reporting of any CMS Web Interface measure will result in zero points for all CMS Web Interface measures and the ACO will fail to meet the quality performance standard for the performance year. Similarly, if a CAHPS for ACOs Survey is not administered and/or no data is transmitted to CMS, zero points will be earned for all Patient/Caregiver Experience measures and the ACO will fail to meet the quality standard for the performance year. The quality measure set for the Shared Savings Program also includes certain claims-based measures that are not part of the MIPS quality performance category, and we currently calculate performance rates on these claims-based measures for purposes of determining an ACO's overall quality score under the Shared Savings Program.

In contrast, when a group submits measures for the MIPS quality performance category via the CMS Web Interface, each measure is assessed against its benchmark to determine how many points the measure earns. For the 2019 MIPS performance period, a group can receive between 3 and 10 points for each MIPS measure (not including bonus points) that meets the data completeness and case minimum requirements by comparing measure performance to established benchmarks. If a group fails to meet the data completeness requirement on one of the CMS Web Interface measures, it receives zero points for that measure; however, all other CMS Web Interface measures that meet the data completeness requirement are assessed against the measure benchmarks, and the points earned across all measures are included in the quality performance category score. Currently, the only administrative claims-based measure used in MIPS is the All-Cause Readmission measure, which is only calculated for groups with 16 or more eligible clinicians. These differences between the Shared Savings Program quality measure set and the MIPS quality measure set highlight the different quality measurement approaches for which Shared Savings Program ACOs must simultaneously evaluate, prioritize, and target resources that may be better directed toward patient care if the quality measurement approaches under the Shared Savings Program and MIPS were more closely aligned.

We believe that using a single methodology to measure quality performance under both the Shared Savings Program and the MIPS would allow ACOs to better focus on increasing the value of healthcare, improving care, and engaging patients, and reduce burden as ACOs would be able to track to a smaller measure set under a unified scoring methodology. Accordingly, we are soliciting comment on how to potentially align the Shared Savings Program quality reporting requirements and scoring methodology more closely with the MIPS quality reporting requirements and scoring methodology.

First, we are requesting comments on replacing the Shared Savings Program quality score with the MIPS quality performance category score, for ACOs in Shared Savings Program tracks (or payment models within a track) that do not meet the definition of an Advanced APM (currently, Track 1 and BASIC Track Levels A, B, C and D). Allowing for a single quality performance score for both programs would eliminate the need for ACOs to focus their resources for quality improvement on maximizing performance under two separate quality reporting requirements with distinct scoring methodologies. Currently, for ACOs in tracks (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. For Shared Savings Program quality scoring purposes, we could utilize the MIPS quality performance category score, converted to a percentage of points earned out of the total points available, as the ACO's quality score for purposes of financial reconciliation under the Shared Savings Program. We note that for performance year 2017 (the only year from which we have complete data available), the weighted mean MIPS quality performance category score for ACOs in Shared Savings Program tracks (or payment models within a track) that do not meet the definition of an Advanced APM) was 45.01 and the weighted median MIPS quality performance score for these ACOs was 46.8, out of a possible 50 points assigned for the quality performance category.

ACOs in tracks (or payment models within a track) that meet the definition of an Advanced APM whose eligible clinicians are QPs for the year and thus are excluded from the MIPS reporting requirements, do not receive a quality performance category score under MIPS. Instead the quality data the ACO reports to the CMS Web Interface is used along with the ACO's CAHPS data and the administrative claims-based measures calculated by us, solely for the purpose of scoring the quality performance of the ACO under the Shared Savings Program quality scoring methodology. As an alternative, given that we currently collect the necessary data from these ACOs, we could also calculate a quality score for these ACOs under the MIPS scoring methodology, and use this score to assess the quality performance of the ACO for purposes of the Shared Savings Program. Using this score would also inform eligible clinicians participating in these ACOs of their MIPS quality score in the event that they lose QP status and are scored under the MIPS APM scoring standard.

Utilizing a MIPS quality performance category score to assess the quality performance for purposes of the Shared Savings Program ACOs in tracks (or payment models within a track) that qualify as an Advanced APM would not change whether eligible clinicians participating in the ACO obtain QP status and are excluded from MIPS, nor would it change the ACO participant TINs' eligibility to receive Advanced APM incentive payments. Rather, under this approach we would utilize the same scoring methodology to determine the quality performance, for Shared Savings Program ACOs that are participating in Advanced APMs as would be used to assess the quality performance of ACOs in Shared Savings Program tracks (or payment models within a track) that do not meet the definition of an Advanced APM, creating further alignment of performance results and further synergies between the Shared Savings Program and MIPS. We welcome comment on the approach of using the MIPS quality performance category score to assess quality performance for purposes of the Shared Savings Program quality performance standard for ACOs that are in tracks (or payment models within a track) that qualify as Advanced APMs. We also welcome comment on potential alternative approaches for scoring Shared Savings Program quality performance in a way that more closely aligns with MIPS.

In addition, we note that we are also soliciting comment on simplifying MIPS by implementing a core measure set using administrative claims-based measures that can be broadly applied to communities or populations and developing measure set tracks around specialty areas or public health conditions to standardize and provide more cohesive reporting and participation. We refer readers to section III.I.3.a.(3) of this proposed rule for more information on these approaches.

Currently, for ACOs in tracks (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. In section III.I.3.b.(1)(ii) of this proposed rule, we are proposing to add the MIPS All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions (MCC) measure to the MIPS quality performance category. If this measure were to be added to MIPS quality performance category, implementation of the measure would be delayed until the 2021 performance period for MIPS as explained in section III.I.3.B.(1)(ii). If the MCC measure were to be included in the MIPS quality performance category, we would also consider including the MIPS claims-based measures (MCC and MIPS All-Cause Readmission measure) in the MIPS APM scoring standard for ACOs in tracks (or payment models within a track) that are not Advanced APMs and in the MIPS quality performance category equivalent score for ACOs in tracks that are Advanced APMs, in order to fully align the quality scoring methodology under the Shared Savings Program with the MIPS scoring methodology to reduce the burden on ACOs and their eligible clinicians of tracking to multiple quality reporting requirements and quality scoring methodologies. We would then use this score for purposes of assessing quality performance under the Shared Savings Program for all ACOs. These MIPS claims-based measures are similar to those currently used to assess ACO quality under the Shared Savings Program. The proposed MIPS MCC and ACO MCC are similar because they both target patients with multiple chronic conditions but the cohort, outcome, and risk model for the proposed MIPS MCC measure would vary from the ACO MCC measure. The cohort for the ACO MCC includes eight conditions whereas the MIPS MCC measure includes nine conditions, where the additional condition is diabetes. The ACO MCC measure does not adjust for social risk factors whereas the MIPS MCC measure adjusts for two area-level social risk factors: (1) AHRQ socioeconomic status (SES) index; and (2) specialist density. For more detailed information on the MIPS MCC measure please refer to Appendix 1 Table AA (New Quality Measures Proposed for Addition for the 2023 Payment Year and Future Years) of this proposed rule. Both the MIPS and Shared Savings Program versions of the All-Cause Readmission measure were developed to fully align with the original hospital measure of Hospital-Wide Readmission. The MIPS and Shared Savings Program versions of the All Cause Readmission measure are essentially re-specifications of the same hospital measure and are updated annually to maintain that alignment. Because of this, the measures have a very similar, or identical, definition for included patients, outcome definition, and risk adjustment model. The primary

difference among the measures is only the entity that is accountable—either an ACO or a MIPS-eligible clinician—but the specifications are otherwise aligned. We also welcome comment on potentially including all of the MIPS claims-based measures in the MIPS quality performance category score for ACOs (instead of the 3 claims-based measures that are currently included in the Shared Savings Program quality score), and using this score (converted to a percentage of points earned out of the total points available) in place of the current Shared Savings Program quality score to assess quality performance for all ACOs for purposes of the Shared Savings Program. We note that we would also continue to assess ACOs on the CAHPS for ACOs survey but quality performance would be calculated by MIPS based on the methodology used for scoring the CAHPS for MIPS survey and included in the MIPS quality performance category score. The scoring and benchmarking approach for the CAHPS for MIPS is to assign points based on each summary survey measure (SSM) and then average the points for all the scored SSMs to calculate the overall CAHPS score. In contrast, ACOs currently, receive up to 2 points for each of the 10 SSMs for a total of 20 points.

In addition, we are soliciting comment on determining the threshold for minimum attainment in the Shared Savings Program using the MIPS APM quality performance category scoring. As noted previously in this section, ACOs in the first performance year of their first agreement period are considered to have met the quality performance standard and therefore to be eligible to share in savings or minimize shared losses, if applicable, when they completely and accurately report all quality measures. ACOs in all other performance years are required to completely and accurately report and meet the minimum attainment level on at least one measure in each domain, to be determined to have met the quality performance standard and to be eligible to share in savings. For these ACOs, minimum attainment is defined as a score that is at or above 30 percent or the 30th percentile of the performance benchmark. The 30th percentile for the Shared Savings Program is the equivalent of the 4th decile performance benchmark under MIPS APM quality performance category scoring. As we look to more closely align with MIPS quality performance category scoring in future years, we are considering how to determine whether ACOs have met the minimum attainment level. For example, minimum attainment could continue to be defined as complete and accurate reporting for ACOs in their first performance year of their first agreement period, while a MIPS quality performance category score that is at or above the 4th decile across all MIPS quality performance category scores would be required for ACOs in all other performance years under the Shared Savings Program. ACOs with quality scores under the 4th decile of all MIPS quality performance category scores would not meet the quality performance standard for the Shared Savings Program and thus would not be eligible to share in savings or would owe the maximum shared losses, if applicable. In addition, ACOs with quality scores under the 4th decile of all MIPS quality performance category scores would be subject to compliance actions and possible termination. We recognize that a requirement that ACOs achieve an overall MIPS quality performance category score (or equivalent score) that meets or exceeds the 4th decile across all MIPS quality performance category scores is a higher standard than the current requirement that ACOs meet the 30th percentile on one measure per Shared Savings Program quality domain; however, section 1899(b)(3)(C) of the Act not only gives us discretion to establish quality performance standards for the Shared Savings Program, but also indicates that we should seek to improve the quality of care furnished by ACOs over time by specifying higher standards. We believe that increasing the minimum attainment level would incentivize improvement in the quality of care provided to the beneficiaries assigned to an ACO. Furthermore, consistent with section 1899(b)(3)(C) of the Act, it is appropriate to require a higher standard of care in order for ACOs to continue to share in any savings they achieve. Given the maturity of the Shared Savings Program, we are also considering setting a higher threshold, such as the median or mean quality performance category score across all MIPS quality category scores, for determining eligibility to share in savings under the Shared Savings Program for all ACOs, other than those ACOs in their first performance year of their first agreement period. We welcome comment on these potential approaches or other approaches for determining Shared Savings Program quality minimum attainment using MIPS data.

We are also seeking comment on how to potentially utilize the MIPS quality performance category score to adjust shared savings and shared losses under the Shared Savings Program, as applicable. Currently, for all Shared Savings Program ACOs and Track 1+ Model ACOs, the ACO's quality score is multiplied with the maximum sharing rate of the track to determine the final sharing rate and therefore the amount of shared savings, if applicable. For some ACOs under two-sided models, specifically ACOs in Track 2 and the ENHANCED track, the ACO's quality score is also used in determining the amount of shared losses owed, if applicable. Under Track 2 and the ENHANCED track, the loss sharing rate is determined as 1 minus the ACO's final sharing rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively. Under the Track 1+ Model and two-sided models of the BASIC track (Levels C, D and E), the amount of shared losses is determined based on a fixed 30 percent loss sharing rate, regardless of the ACO's quality score. Thus, a higher quality score results in the ACO receiving a higher proportion of shared savings in all Shared Savings Program tracks and the Track 1+ Model, or greater mitigation of shared losses in Track 2 and the ENHANCED track. We could apply the MIPS quality performance category score to determine ACOs' shared savings and shared losses, if applicable, in the same manner. For instance, as an alternative to the current approach to determining shared savings payments for Shared Savings Program ACOs, we could establish a minimum attainment threshold, such as a score at or above the 4th decile of all MIPS quality performance category scores or the median or mean quality performance category score, that if met would allow ACOs to share in savings based on the full sharing rate of their track. We welcome comment on these or other potential approaches for utilizing the MIPS quality performance category score or an alternative score in determining shared savings or shared losses under the Shared Savings Program.

In addition, we are considering an option under which we would determine the MIPS quality performance category score for all Shared Savings Program ACOs as it is currently calculated for non-ACO group reporters using the CMS Web Interface. That is, ACOs would receive a score for each of the measures they report and zero points for those measures they do not report. This would be a change from the current methodology under which ACOs must report all Web Interface measures to complete quality reporting. We note that currently, for ACOs in the first year of their first agreement period,

minimum attainment is set at the level of complete and accurate reporting of all measures. If we were to adopt the MIPS quality performance category score as the Shared Savings Program quality score, we would consider no longer imposing a different quality standard for ACOs in the first year of their first participation agreement versus ACOs in later performance years. Given that the Shared Savings Program is evolving and many Medicare quality programs including MIPS are incentivizing performance rather than reporting, we are considering no longer transitioning from pay-for-reporting to pay-for-performance during an ACO's first agreement period in the Shared Savings Program. We believe that requiring all ACOs regardless of time in the program to be assessed on quality performance would be an appropriate policy since nearly 100 percent of ACOs consistently satisfactorily report all quality measures. We welcome comment on this alternative for determining the MIPS quality performance category score.

Lastly, we are seeking comment on using the MIPS quality improvement scoring methodology rather than the Shared Savings Program Quality Improvement Reward to reward ACOs for quality improvement. Under the Shared Savings Program, we currently allow ACOs not in their first performance year in the program to earn a Quality Improvement Reward in each of the four quality domains. In contrast, under MIPS improvement points are generally awarded as part of the MIPS quality performance category score if a MIPS eligible clinician (1) has a quality performance category achievement percent score for the previous performance period and the current performance period; (2) fully participates in the quality performance category for the current performance period; and (3) submits data under the same identifier for the 2 consecutive performance periods. If we were to adopt the MIPS quality performance category score for the Shared Savings Program quality score, quality improvement points earned under MIPS would be included in that score, and we would not have a need to add additional points to it. We welcome public comment on this or other approaches to considering improvement as part of using the MIPS quality performance category or an equivalent score, to determine quality performance under the Shared Savings Program.

We are seeking stakeholder feedback on the approaches discussed in this section of the proposed rule and any other recommendations regarding the potential alignment of the Shared Savings Program quality performance standard with the MIPS quality performance category in the assessment of ACO quality performance in the future for purposes of the Shared Savings Program.

2. Technical Change To Correct Reference in SNF–3 Day Rule Waiver Provision

In the December 2018 final rule, we made a number of amendments to § 425.612 (83 FR 68080). As part of these amendments, we redesignated paragraphs (a)(1)(v)(A) through (C) of § 425.612 as paragraphs (a)(1)(v)(C) through (E). In making these amendments, we inadvertently omitted a necessary update to a cross-reference to one of these provisions. Accordingly, we propose to remove the phase ''paragraph (a)(1)(v)(B)'' from § 425.612(a)(1)(v)(E), and in its place add the phrase ''paragraph (a)(1)(v)(D).''

F. Open Payments

1. Background

a. Open Payments Policies

The Open Payments program is a statutorily-mandated program that promotes transparency by providing information about the financial relationships between the pharmaceutical and medical device industry and certain types of health care providers and makes the information available to the public. Section 1128G of the Act requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as ''applicable manufacturers'') to annually submit information for the preceding calendar year about certain payments or other transfers of value made to ''covered recipients,'' currently defined as physicians and teaching hospitals.

Payments or other transfers of value that must be reported include such things as research, honoraria, gifts, travel expenses, meals, grants, and other compensation. The type of information required to be reported includes, but is not limited to, the date and amount of the payment or other transfer of value, identifying information about the covered recipient, and details about products associated with the transaction. When a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological or medical supply, the name of that covered drug, device, biological or medical supply also must be reported under section 1128G of the Act. The estimated burden of these reporting requirements, as outlined under OMB control number 0938–1237, is just over 1 million hours over the course of 1 year.

Section 1128G of the Act establishes certain minimum dollar thresholds for required reporting, with two bases for reporting, individual and aggregate payments or transfers of value. To determine if small individual payments or other transfers of value made to a covered recipient exceed the aggregate threshold and must be reported, applicable manufacturers and applicable GPOs must aggregate all individual payments made across all payment categories within a given reporting year. The statutory threshold established in 2013 was $10 for individual payments, and $100 for aggregated payments, and this amount has increased with the consumer price index each year. For CY 2019, the annual reporting thresholds for individual payments or other transfers of value is $10.79 and the aggregate amount is $107.91.

The Open Payments program yields transparency that provides information to the general public that may influence their health care decision-making and choice of providers, as well as information that researchers looking into potential correlations between financial relationships and provider behaviors may use. More than 51 million records have been disclosed under the Open Payments program since August 2013, enabling significant transparency into covered exchanges of value. We have been committed to stakeholder engagement in an effort to limit burden in the Open Payments program reporting processes and improve clarity for the public. Additional background about the program and guidance, including FAQs, about how the program works and what type of information is required to be reported is available at *www.cms.gov/OpenPayments*.

In the February 8, 2013 **Federal Register** (78 FR 9458), we issued regulations implementing section 1128G of the Act to create the Open Payments program. Section 1128G of the Act requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as ''applicable manufacturers'') to submit information annually about certain payments or other transfers of value made to ''covered recipients,'' currently defined as physicians and teaching hospitals, during the course of the preceding calendar year. Additionally, section 1128G of the Act defines covered drugs, devices, biologicals, or medical supplies as those covered under Medicare or a State plan under Medicaid or the CHIP

(or a waiver of such a plan); and requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or physician's immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Under section 1128G(e)(10)(A) of the Act, the term ''payment or other transfer of value'' refers to a transfer of anything of value, though some exclusions apply.

In the CY 2015 PFS final rule with comment period (79 FR 67548), we revised the regulations by standardizing reporting in the Open Payments program. Specifically, we: (1) Deleted the definition of ''covered device''; (2) removed the special rules for payments or other transfers of value related to continuing education programs; (3) clarified the marketed name reporting requirements for devices and medical supplies; and (4) required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

In the CY 2017 PFS proposed rule (81 FR 46395), we solicited information from the public on a wide variety of information regarding the Open Payments program. Since the implementation of the program and changes made in the CY 2015 PFS final rule with comment period, various commenters have provided us feedback. Consequently, we identified areas in the rule that might benefit from revision and solicited public comments to inform future rulemaking. We sought comment on whether the nature of payment categories listed at § 403.904(e)(2) are adequately inclusive to facilitate reporting of all payments or transfers of value, and sought ways to streamline or make the reporting process more efficient while facilitating our role in oversight, compliance, and enforcement, along with posing other program-specific questions. A summary of solicited comments was published in the CY 2017 PFS final rule (81 FR 80428–80429).

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–270) was signed into law. Section 6111 of the SUPPORT Act amended the definition of ''covered recipient'' under section 1128G(e)(6) of the Act with respect to information required to be submitted on or after January 1, 2022, to include physician assistants (PA), nurse practitioners (NP), clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA), and certified nurse midwives (CNM), in addition to the previously listed covered recipients of physicians and teaching hospitals. This rule proposes to codify the Open Payments provisions from the SUPPORT Act, proposes to address public comments received from the CY 2017 PFS proposed rule by simplifying the process for reporting data by adjusting the nature of payment categories, and proposes changes to standardize data on reported covered drugs, devices, biologicals, or medical supplies.

b. Legal Authority

Three principal legal authorities from the Social Security Act ground our proposed provisions:

- Sections 1102 and 1871, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1861, which defines providers and suppliers.
- Section 1128G, as amended by section 6111 of the SUPPORT Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a State plan under Medicaid or CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals, and to PAs, NPs, CNSs, CRNAs, and CNMs for information required to be submitted under section 1128G of the Act on or after January 1, 2022.

c. Proposed Changes

In this rule, we propose to revise several Open Payments regulations at 42 CFR part 403. We are proposing that the following provisions be effective for data collected beginning in CY 2021 and reported in CY 2022: (1) Expanding the definition of a covered recipient to include the categories specified in the SUPPORT Act; (2) expanding the nature of payment categories; and (3) standardizing data on reported covered drugs, devices, biologicals, or medical supplies. We are also proposing a correction to the national drug codes (NDCs) reporting requirements for drugs and biologicals that, should the rule be finalized as proposed, would be effective 60 days following the publication of the final rule. We believe this would give all stakeholders sufficient time to prepare for these requirements.

(1) Expanding the Definition of a Covered Recipient

Section 1128G of the Act requires applicable manufacturers and applicable GPOs to report annually information about certain payments or other transfers of value made to covered recipients, as well as ownership or investment interests held by physicians or their immediate family members in such entities, though at section 1128G(e)(7) of the Act it excepts physicians who are employed by the reporting manufacturer, such that manufacturers do not report payments to their own employees. As we noted previously, section 6111 of the SUPPORT Act expanded the definition of covered recipients from physicians and teaching hospitals to include PAs, NPs, CNSs, CRNAs, and CNMs; it likewise expanded to these individuals the same exception for manufacturer-employment. The SUPPORT Act requires these changes to be in effect for information required to be submitted on or after January 1, 2022. In short, applicable manufacturers will be required to report transfers of value pertaining to these additional provider types in the same way they have been required to report transfers of value to physicians and teaching hospitals. Since the information is reported to CMS in the calendar year following the year in which it was collected, this means that the data would be collected by the industry during CY 2021.

We are proposing to revise § 403.902 to align with the statutory requirements in sections 1128G(e)(6)(A) and (B) of the Act. Specifically, we are proposing to revise the definition of ''covered recipient'' in § 403.902 to include PAs, NPs, CNSs, CRNAs, and CNMs. In addition, we are proposing at § 403.902 to reference the definitions of these additional provider types as defined in sections 1861(aa)(5)(A), 1861(aa)(5)(B), 1861(bb)(2), and 1861(gg)(2) of the Act.

We are also proposing to update certain provisions in part 403, subpart I to include provider and supplier types other than physicians as specified in sections 1128G(e)(6)(A) and (B) of the Act. Specifically, we propose the following revisions:

- In § 403.902, to add the definitions of ''certified nurse midwife,'' ''certified registered nurse anesthetist,'' ''clinical nurse specialist,'' ''non-teaching hospital covered recipient,'' ''nurse practitioner,'' and ''physician assistant.''
- In § 403.902, to revise the definition of ''covered recipient'' by adding physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife'' after the phrase ''Any physician.''
- In § 403.904(c)(1), (f)(1)(i)(A), and (h)(7), to replace the term ''physician''

with the phrase ''non-teaching hospital.''

• In § 403.904(c)(3), to replace the term ''physician'' in the title with the phrase ''non-teaching hospital,'' add the phrase ''non-teaching hospital'' after ''In the case of a,'' and remove the phrase ''who is a physician'' from the text.

• In § 403.904(c)(3)(ii) and (iii), (f)(1)(i)(A)(*1*), (f)(1)(i)(A)(*3*) and (*5*), and (f)(1)(v), to change the term ''physician'' to the phrase ''non-teaching hospital covered recipient.''

• In § 403.904(h)(13), to remove the phrase ''who is a physician'' and add the phrase ''non-teaching hospital'' after ''In the case of.''

• In § 403.904(f)(1), to remove the phrase ''(either physicians or teaching hospitals).''

• In § 403.908(g)(2)(ii), to change the words ''physicians and teaching hospitals'' to the term ''Covered recipients.''

(2) Nature of Payment Categories

Applicable manufacturers and applicable GPOs must characterize the nature of payments made to covered recipients by selecting the ''Nature of Payment'' category that most closely describes the reported payment. Some of the ''Nature of Payment'' categories, as specified at § 403.904(e)(2), are specifically required by section 1128G(a)(1)(A)(vi) of the Act, while the statute also allows the Secretary to define any other nature of payment or other transfer of value.

Based upon information we obtained from the public comments solicited in the CY 2017 PFS proposed rule (81 FR 46395), stakeholders have identified debt forgiveness, long term medical supply or device loan, and acquisitions (among others) as useful categories to add to comply with the general reporting requirement under section 1128G(a)(1)(A) of the Act. Therefore, and so as to add clarity to the types of payments or transfers of value made by applicable manufactures and applicable GPOs to covered recipients, we are proposing to revise the ''Nature of Payment'' categories in § 403.904(e)(2) by consolidating two duplicative categories and by adding the three new categories described below.

First, the categories that we are proposing to consolidate include two separate categories for continuing education programs. Section 1128G(a)(1)(A)(vi)(XIII) of the Act requires manufacturers to report direct compensation for serving as faculty or a speaker for medical education programs. The current § 403.904(e)(2)(xiv) and (xv) distinguish between accredited/certified and unaccredited/non-certified continuing education programs. At proposed revised § 403.904(e)(2)(xv), we are proposing to consolidate these categories and make the regulatory wording match the statutory language ''medical education programs,'' which we believe would streamline the reporting requirements while not detracting from the underlying context of the data. Although we defined separate categories at the inception of the Open Payments program, we no longer believe that the distinction in this category is necessary.

In addition, we are proposing three additional categories that would operate prospectively and would *not* require the updating of previously reported payments or other transfers of value that may fall within these new categories.

The three new categories are as follows:

• *Debt Forgiveness* (proposed § 403.904(e)(2)(xi)): This would be used to categorize transfers of value related to forgiving the debt of a covered recipient, a physician owner, or the immediate family of the physician who holds an ownership or investment interest.

• *Long-Term Medical Supply or Device Loan* (proposed new § 403.904(e)(2)(xiv)): Section 403.904 currently contains an exclusion from reporting for the loan of a covered device, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days, or a quantity of 90 days of average use, respectively. This new category would be used to characterize the loans of covered devices or medical supplies for longer than 90 days. (*Note:* We are proposing to combine current paragraphs on continuing education programs § 403.904(e)(2)(xiv) and (xv) to replace paragraph (e)(2)(xv) as noted in the consolidating continuing education programs above.)

• *Acquisitions* (proposed § 403.904(e)(2)(xviii)): This addition would provide a category for characterizing buyout payments made to covered recipients in relation to the acquisition of a company in which the covered recipient has an ownership interest.

We also are proposing to add the definition of ''long-term medical supply or device loan'' to § 403.902 as ''the loan of supplies or a device for 91 days or longer.'' For consistency within the definitions section, we propose to redesignate § 403.904(h)(5)—which contains the definition of ''short-term medical supply or device loan'' to § 403.902. As a result, we are proposing a new § 403.904(h)(5) to be ''short-term medical supply or device loan.''

(3) Standardizing Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies

When applicable manufacturers or applicable GPOs report payments or transfers of value related to specific drugs and biologicals, we currently require names and NDCs to be reported to the Open Payments program. However, based upon the lack of federally-recognized identifiers when we started the Open Payments program, we have not required analogous reporting for medical devices from the manufacturers. However, the Food and Drug Administration (FDA) established and continues to implement a system for the use of standardized unique device identifiers (UDIs) for medical devices and has issued regulations at 21 CFR part 801, subpart B, and 21 CFR part 830, requiring, among other things, that a UDI be included on the label of most devices distributed in the United States. (See 78 FR 58785, September 24, 2013.) Based upon the FDA's UDI regulatory requirements and the HHS Office of the National Coordinator's requirement that UDIs form part of the Common Clinical Data Set (45 CFR part 170), we believe that the use of UDIs and device identifiers (DIs), a subcomponent of the UDI, have become more standardized. Moreover, the HHS Office of Inspector General (OIG) included a recommendation for Open Payments to require more specific information about devices in an August 2018 report (OEI–03–15–00220).

With the standardization and typical use of UDIs and based upon OIG's recommendation, we propose that the DI component, the mandatory fixed portion of the UDI assigned to a device, if any, should be incorporated into Open Payments reporting that applicable manufacturers or applicable GPOs provide. We do not propose to require a full UDI. We believe such a step would substantially aid in enhancing the quality of the Open Payments data because the identifiers can be used to validate submitted device information. This effort would also enhance the usefulness of Open Payments data to the public by providing more precise information about the medical supplies and devices associated with a transaction. Specifically, we are proposing to revise § 403.904(c)(8) to require applicable manufacturers and applicable GPOs to provide the DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly.

We also seek to further clarify the reporting requirements with regard to drugs and biologicals. Since the outset of the Open Payments program, NDCs have been required for both research and non-research payments. In § 403.904(f)(1)(iv), we require that NDCs be reported for drugs and biologicals used in research. However, in the CY 2015 PFS final rule with comment period (79 FR 67548), the non-research payment NDC requirement was erroneously removed when changes were made to the rule text regarding marketed names. We propose to correct this error in order to reiterate that NDCs are required for both research and non-research payments and to make the change effective 60 days from publishing the final rule.

We propose to revise § 403.904(c)(8) to require DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly. We also propose to reincorporate language that specifically requires reporting of NDCs.

As a result of the proposed changes to § 403.904(c)(8), we are also proposing technical changes to § 403.904(f)(1)(iv) and to add mirrored definitions from 21 CFR 801.3 for ''device identifier'' and ''unique device identifier'' to § 403.902.

G. Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior To Furnishing Home Infusion Therapy

Section 5012 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255; enacted December 13, 2016) created a separate Medicare Part B benefit under section 1861(s)(2)(GG) and section 1861(iii) of the Act to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment in the beneficiary's home, effective for January 1, 2021. Section 5012 of the Cures Act also added section 1834(u) to the Act that establishes the payment and related requirements for home infusion therapy under this benefit.

Specifically, section 1834(u)(6) of the Act requires that prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) of the Act for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

We recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy treatment options. For example, a physician may verbally discuss the treatment options with the patient during the visit and annotate the treatment decision in the medical records before establishing the infusion plan. Some physicians may also provide options in writing to the patient in the hospital discharge papers or office visit summaries, as well as retain a written patient attestation that all options were provided and considered. The frequency of discussing these options could vary based on a routine scheduled visit or according to the individual's clinical needs.

We are soliciting comments regarding the appropriate form, manner and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy under Medicare Part B as required under section 1834(u)(6) of the Act. We also invite comments on any additional interpretations of this notification requirement.

H. Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

1. Enrollment of Opioid Treatment Programs

a. Legislative and Regulatory Background

As previously explained in more detail in this proposed rule, the SUPPORT Act was designed to alleviate the nationwide opioid crisis by: (1) Reducing the abuse and supply of opioids; (2) helping individuals recover from opioid addiction and supporting the families of these persons; and (3) establishing innovative and long-term solutions to the crisis. The SUPPORT Act attempts to fulfill these objectives, in part, by establishing a new Medicare benefit category for opioid treatment programs (OTPs) pursuant to section 2005 thereof. Section 2005(d) of the SUPPORT Act amended section 1866(e) of the Act by adding a new paragraph (3) classifying OTPs as Medicare providers (though only with respect to the furnishing of opioid use disorder treatment services). This will enable OTPs that meet all applicable statutory and regulatory requirements to bill and receive payment under the Medicare program for furnishing such services to Medicare beneficiaries.

b. Definition of and Certain Requirements for OTPs

As already mentioned, an OTP is currently defined in 42 CFR 8.2 as a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1). Section 2005(b) of the SUPPORT Act added a new section 1861(jjj)(2) to the Act defining an OTP as an entity that meets, among other things, the definition of an OTP in § 8.2 (or any successor regulation). Section 1861(jjj)(2) of the Act also outlines certain additional requirements that an OTP must meet to qualify as such. These requirements include the following:

(1) Accreditation

Consistent with new section 1861(jjj)(2)(C) of the Act, as added by section 2005(b) of the SUPPORT Act, and also required under 42 CFR 8.11(a)(2), an OTP must have a current, valid accreditation by an accrediting body or other entity approved by the SAMHSA, the federal agency that oversees OTPs. A core purpose of OTP accreditation is to ensure that an OTP meets: (1) Certain minimum requirements for furnishing medication-assisted treatment (MAT); and (2) the applicable accreditation standards of SAMHSA-approved accrediting bodies, of which there presently are six. The accreditation process includes, but is not limited to, an accreditation survey, which involves an onsite review and evaluation of an OTP to determine compliance with applicable federal standards.

(2) Certification

A second requirement addressed in section 1861(jjj)(2)(B) of the Act, as added by section 2005(b) of the SUPPORT Act, is also in current regulations referenced in 42 CFR 8.11(a). Along with accreditation, an OTP must have a current, valid certification by SAMHSA for such a program. The prerequisites for certification (as well as the certification process itself) are outlined in 42 CFR 8.11 and include, but are not restricted to, the following:

- Current and valid accreditation (as described previously);
- Adherence to the federal opioid treatment standards described in § 8.12;
- Compliance with all pertinent state laws and regulations, as stated in § 8.11(f)(1);
- Per § 8.11(f)(6), compliance with all regulations enforced by the Drug Enforcement Administration (DEA)

under 21 CFR chapter II; this includes registration by the DEA before administering or dispensing opioid agonist treatment medications; and

• As stated in § 8.11(a)(2), compliance with all other conditions for certification established by SAMHSA.

Under § 8.11(a)(3), certification is generally for a maximum 3-year period, though this may be extended by 1 year if an application for accreditation is pending. SAMHSA may revoke or suspend an OTP's certification if any of the applicable grounds identified in § 8.14(a) or (b), respectively, exist. Under § 8.11(e)(1), an OTP that has no current certification from SAMHSA but has applied for accreditation with an accreditation body may obtain a provisional certification for up to 1 year.

At the time of application for certification or any time thereafter, an OTP may request from SAMHSA an exemption from the regulatory requirements of §§ 8.11 and 8.12. Section 8.11(h), which governs the exemption process, cites an example of a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible; he or she may choose to seek an exemption from some of the staffing and service standards.

According to SAMHSA statistics, there are currently about 1,677 active OTPs; of these, approximately 1,585 have full certifications and 92 have provisional certifications.

(3) OTP Enrollment

Most pertinent to the discussion and proposals below, section 2005(b) of the SUPPORT Act, which added a new section 1861(jjj)(2)(A) to the Act, requires that an OTP be enrolled in the Medicare program under section 1866(j) of the Act to qualify as an OTP and to bill and receive payment from Medicare for opioid use disorder treatment services. Per section 1861(jjj)(2)(A) of the Act, the provisions of this proposed rule would establish requirements that OTPs must meet in order to enroll in Medicare.

c. Current Medicare Enrollment Process

(1) Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help ensure that providers and suppliers that seek to bill the Medicare program for services or items furnished to Medicare beneficiaries are qualified to do so under federal and state laws. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. As further explained below, CMS and its Medicare Administrative Contractors (MACs; hereafter occasionally referred to as ''contractors'') carefully and closely screen and review Medicare enrollment applicants to verify that they meet all applicable legal requirements.

CMS has taken various steps via regulation to outline a process for enrolling providers and suppliers in the Medicare program. In the April 21, 2006 **Federal Register** (71 FR 20754), we published the ''Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment'' final rule that set forth certain requirements in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570) that providers and suppliers must meet to obtain and maintain Medicare billing privileges. In the April 21, 2006 final rule, we cited sections 1102 and 1871 of the Act as general authority for our establishment of these requirements, which were designed for the efficient administration of the Medicare program.

Subsequent to the April 21, 2006 final rule, we published additional provider enrollment regulations. These were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) Engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items.

One of the provider enrollment regulations was the ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers'' final rule published in the February 2, 2011 **Federal Register** (76 FR 5862). This final rule implemented various provisions of the Affordable Care Act, including the following:

• Added a new § 424.514 that required submission of application fees by institutional providers (as that term is defined in § 424.502) as part of the Medicare, Medicaid, and Children's Health Insurance Program (CHIP) provider enrollment processes.

• Added a new § 424.518 that established Medicare, Medicaid, and CHIP provider enrollment screening categories and requirements based on the CMS-assessed level of risk of fraud, waste, and abuse posed by a particular category of provider or supplier.

We also published the ''Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment'' final rule in the December 5, 2014 **Federal Register** (79 FR 72499) wherein we addressed several vulnerabilities in the provider enrollment process. As part of the December 2014 final rule—

• We expanded the number of reasons for which we can: (1) deny a prospective provider's or supplier's enrollment in the Medicare program under § 424.530; or (2) revoke the Medicare enrollment of an existing provider or supplier under § 424.535.

• We supplemented the existing denial reason in § 424.530(a)(3) such that we could deny a prospective provider's or supplier's Medicare enrollment if a managing employee (as that term is defined in § 424.502) of the provider or supplier has, within the 10 years preceding enrollment or revalidation of enrollment, been convicted of a federal or state felony offense that we determined to be detrimental to the best interests of the Medicare program and its beneficiaries.

• We expanded the existing revocation reason in § 424.535(a)(8) to allow us to revoke a provider's or supplier's enrollment if we determine that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.

In addition to these final rules, we have also made several other regulatory changes to 42 CFR part 424, subpart P to address various program integrity issues that have arisen.

(2) Form CMS–855—Medicare Enrollment Application

Under § 424.510, a provider or supplier must complete, sign, and submit to its assigned MAC the appropriate Form CMS–855 (OMB Control No. 0938–0685) application in order to enroll in the Medicare program and obtain Medicare billing privileges. The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, Provider Enrollment, Chain, and Ownership System) captures information about the provider or supplier that is needed for CMS or its MACs to determine whether the provider or supplier meets all Medicare

requirements. Data collected on the Form CMS–855 is carefully reviewed and verified by CMS or its MACs and includes, but is not limited to:

- General identifying information (for example, legal business name, tax identification number).
- Licensure and/or certification data.
- Any final adverse actions (as that term is defined in § 424.502) of the provider or supplier, such as felony convictions, exclusions by the HHS Office of Inspector General (OIG), or state license suspensions or revocations.
- Practice locations and other applicable addresses of the provider or supplier.
- Information regarding the provider's or supplier's owning and managing individuals and organizations and any final adverse actions those parties may have.
- As applicable, information about the provider's or supplier's use of a billing agency.

The Form CMS–855 application is used for a number of provider enrollment transactions, such as:

- Initial enrollment: The provider or supplier is enrolling in Medicare for the first time, enrolling in another MAC's jurisdiction, or seeking to enroll in Medicare after having previously been enrolled.
- Change of ownership: The provider or supplier is reporting a change in its ownership.
- Revalidation: The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515.
- Reactivation: The provider or supplier is seeking to reactivate its Medicare billing privileges after being deactivated under § 424.540.
- Change of information: The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving a provider's or supplier's initial enrollment application, reviewing and confirming the information thereon, and determining whether the provider or supplier meets all applicable Medicare requirements, CMS or the MAC will either: (1) Approve the application and grant billing privileges to the provider or supplier (or, depending upon the provider or supplier type involved, simply recommend approval of the application and refer it to the state agency or to the CMS regional office, as applicable); or (2) deny enrollment under § 424.530.

d. Proposed OTP Enrollment Provisions

(1) Legal Basis and Necessity

As mentioned earlier, section 1861(jjj)(2)(A) of the Act requires OTPs to enroll in Medicare to bill and receive payment. In the proposals discussed in this section III.I.3. of this proposed rule, we outline the proposed requirements and procedures with which OTPs must comply to enroll and remain enrolled in Medicare. In doing so, we are relying on the authority granted to us not only under section 1861(jjj)(2)(A) of the Act but also under several other statutory provisions. First, section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Second, sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

We believe, and it has been our longstanding experience, that the provider enrollment process is invaluable in helping to ensure that: (1) All potential providers and suppliers are carefully screened for compliance with all applicable requirements; (2) problematic providers and suppliers are kept out of Medicare; and (3) beneficiaries are protected from unqualified providers and suppliers. Indeed, without this process, the Medicare program and Medicare beneficiaries are endangered, and billions of Trust Fund dollars may be paid to unqualified or fraudulent parties.

Nor, we add, are our general concerns restricted to the mere need and desire to establish provider enrollment requirements for OTPs. Though a very critical one, provider enrollment is only a single component of CMS' much broader program integrity efforts. We emphasize that in establishing and implementing an overall Medicare OTP process per the SUPPORT Act and implementing an overall program integrity strategy, our objectives will extend to matters such as: (1) Monitoring OTP billing patterns; (2) ensuring the proper payment of OTP claims; (3) performing OTP audits as required by law; (4) making certain that OTP beneficiaries receive quality care; and (5) taking action (enrollment-related or otherwise) against non-compliant or abusive OTP providers. In other words, it should not be assumed for purposes of the OTP process that the term ''program integrity'' is limited to the provider enrollment concept, for it actually applies to many other types of payment safeguards as well.

(2) OTP Enrollment Requirements

(a) Addition of 42 CFR 424.67 and General OTP Requirement To Enroll

We propose to establish a new 42 CFR 424.67 that would include most of our proposed OTP provisions. In paragraph (a), we are proposing that in order for a program to receive Medicare payment for the provision of opioid use disorder treatment services, the provider must qualify as an OTP (as that term is defined in § 8.2) and enroll in the Medicare program under the provisions of subpart P of this part and this section. As previously indicated, subpart P outlines the requirements and procedures of the enrollment process. All providers and suppliers that seek to bill Medicare must enroll in Medicare and adhere to all enrollment requirements in subpart P. Proposed § 424.67 would implement the above-mentioned requirement stated in section 1861(jjj)(2)(A) of the Act.

(b) OTPs—Procedures and Compliance

In paragraph (b) of § 424.67, we are proposing several specific enrollment requirements that OTPs must meet that either clarify or supplement those contained in subpart P.

(i) OTPs: Form CMS–855B

In § 424.67(b)(1), we propose that an OTP must complete in full and submit the Form CMS–855B application (''Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers'') (OMB Control No.: 0938–0685) and any applicable supplement or attachment thereto (which would be submitted to OMB under control number 0938–0685) to its applicable Medicare contractor. While we recognize that the Form CMS–855B is typically completed by suppliers rather than providers, we believe that certain unique characteristics of OTPs (for example, OTPs would only bill Medicare Part B) make the Form CMS–855B the most suitable enrollment application for OTPs. The supplement or attachment would capture certain information that is: (1) Unique to OTPs but not obtained via the Form CMS–855B; and (2) necessary to enable CMS to effectively screen their applications and confirm their qualifications.

As part of this general requirement concerning CMS–855 form completion, we propose two subsidiary requirements as part of the aforementioned supplement/attachment.

First, in § 424.67(b)(1)(i), we propose that the OTP must maintain and submit to CMS (via the applicable supplement or attachment) a list of all physicians and other eligible professionals (as the

term ''eligible professional'' is defined in section 1848(k)(3)(B) of the Act) who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. The list must include the physician's or other eligible professional's first and last name and middle initial, Social Security Number, National Provider Identifier, and (4) license number (if applicable). This requirement, in our view, would enable us to: (1) Confirm that these individuals are qualified to perform the activities in question; and (2) screen their prescribing practices, the latter being an especially important consideration in light of the nationwide opioid epidemic.

Second, we propose in § 424.67(b)(1)(ii) that the OTP must certify via the Form CMS–855B and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in § 424.67(b) and (d) (discussed below). This is to help ensure that the OTP fully understands its obligation to maintain constant compliance with the requirements associated with OTP enrollment.

We do not believe that the requirements addressed in proposed § 424.67(b)(1) duplicate any other information collection effort involving OTPs. Indeed, the OTP enrollment process will capture various data elements not collected via other means, such as the SAMHSA certification process. Such data elements include the name, social security number (SSN) and National Provider Identification (NPI) number of all eligible professionals at the OTP who are legally authorized to prescribe, order, or dispense controlled substances. While SAMHSA's approved accreditation bodies do verify that these individuals have appropriate licensure, they do not collect this information on a form, screen against federal databases, or have a database that keeps this information. CMS, however, intends to conduct these activities.

(ii) OTPs: Application Fee

As mentioned previously in our discussion of the February 2, 2011 final rule, under § 424.514, prospective and revalidating institutional providers that are submitting an enrollment application generally must pay the applicable application fee. (For CY 2019, the fee amount is $586.) Section 424.502 defines an institutional provider as any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and non-physician practitioner organizations, which are exempt from the fee requirement if they are enrolling as a physician or non-physician practitioner organization), Form CMS–855S, Form CMS–20134, or an associated internet-based PECOS enrollment application. Since an OTP, as a specialized facility, would be required to complete the Form CMS–855B to enroll in Medicare as an OTP (and would not be enrolling as a physician and non-physician organization), we believe that an OTP would meet the definition of an institutional provider under § 424.502. It would therefore be required to pay an application fee consistent with § 424.514; we are proposing to clarify this requirement to pay the fee in new § 424.67(b)(2).

(c) OTPs: Categorical Risk Designation

We previously referenced § 424.518, which outlines screening categories and requirements based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the level of scrutiny with which CMS will screen and review providers or suppliers within that category.

There are three categories of screening in § 424.518: High, moderate, and limited. Irrespective of which category a provider or supplier type falls within, the MAC performs the following screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location:

- Verifies that a provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.
- Conducts state license verifications.
- Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

However, providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Furthermore, for those in the high categorical risk level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are intended to correspond to the heightened risk involved.

There currently are only three provider or supplier types that fall within the high categorical risk level under § 424.518(c)(1): Newly/initially enrolling home health agencies (HHAs); newly/initially enrolling suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); and newly/initially enrolling Medicare Diabetes Prevention Program (MDPP) suppliers. We are now proposing to assign newly enrolling OTPs to the high categorical risk level.

A principal concern is that, as indicated previously, we have no historical information on OTPs (either from an enrollment, billing, or claims payment perspective) upon which we can fairly estimate the degree of risk they may pose. This is because OTP services are an entirely new Medicare benefit. We expressed similar concerns regarding our inclusion of MDPP suppliers in § 424.518(c)(1). That is, in the CY 2017 PFS proposed rule (81 FR 46162), we proposed to assign MDPP suppliers to the high categorical risk level because the MDPP could bring organization types that are entirely new to Medicare.

Our concerns about OTPs go well beyond the above-referenced lack of historical information, though. The opioid epidemic has, in our view, increased the potential for unscrupulous providers to take advantage of Medicare beneficiaries through fraudulent billing schemes and abusive prescribing practices; recent examples include ''patient brokers'' in Massachusetts, as well as excessive stays in ''sober homes'' in Florida. Furthermore, there is a heightened risk in OTP facilities compared to other types of providers due to: (1) The core service provided at the facilities—the prescribing and dispensing of methadone and other opioids as part of medication-assisted treatment for opioid addiction; and (2) the nature of the patients at the facilities, that is, individuals grappling with opioid addiction. By assigning OTPs to the ''high-risk'' screening level—thereby capturing fingerprints of all 5 percent or greater owners and conducting site visits—we would be taking a preventative approach to stopping fraudulent billing and prescribing practices and keeping Medicare beneficiaries safe.

Given the foregoing, we are proposing four regulatory provisions. First, we are

proposing to state in new § 424.67(b)(3) that newly enrolling OTP providers will be screened at the high categorical risk level in accordance with the requirements of § 424.518(c). Second, we are proposing to add a new paragraph (iv) to § 424.518(c)(1) that would add newly enrolling OTPs to the types of providers and suppliers screened at the high categorical risk level. Third, we are proposing to add a new paragraph (xii) to § 424.518(b)(1) whereby OTPs that are revalidating their current Medicare enrollment (under § 424.515) would be screened at the moderate categorical risk level (which involves a site visit but does not include the fingerprint submission requirement of the high categorical risk level). This would be consistent with our approach towards DMEPOS suppliers, HHAs, and MDPPs, which are screened at the high categorical risk level when newly enrolling and at the moderate level when revalidating. Fourth, and consistent with the addition of new § 424.518(b)(1)(xii), we propose to require that, upon revalidation, the OTP successfully complete the moderate categorical risk level screening required under § 424.518(b) in order to remain enrolled in Medicare. This provision would be designated as new § 424.67(d)(1)(iii); as discussed below, proposed paragraph (d) addresses ongoing obligations and standards with which enrolled OTPs must comply.

(d) OTPs: Certification

We are proposing in new § 424.67(b)(4) that to enroll in Medicare, an OTP must have in effect a current, valid certification by SAMHSA for such a program. This requirement is consistent with both section 1861(jjj)(2)(B) of the Act and § 8.11. We consider SAMHSA certification to be extremely important because it would: (1) Assist us in ensuring that the provider is qualified to furnish OTP services; and (2) help confirm that the provider is in compliance with the relevant provisions of part 8 and other applicable requirements (such as federal opioid treatment standards).

We noted earlier that, under § 8.11(e), OTPs with no current SAMHSA certification that have applied for accreditation with an accreditation body are eligible to receive a provisional certification for up to 1 year. To receive a provisional certification, an OTP must submit to SAMHSA certain information required under § 8.11(e), along with:

- A statement identifying the accreditation body to which the OTP has applied for accreditation;
- The date on which the OTP applied for accreditation;
- The dates of any accreditation surveys that have taken place or are expected to take place; and
- The expected schedule for completing the accreditation process.

Under proposed § 424.67(b)(4)(ii), we state that we would not accept a provisional certification under § 8.11(e) in lieu of the certification described in § 8.11(a). As already mentioned, section 1861(jjj)(2)(B) of the Act states that an OTP must have in effect a certification by SAMHSA, a requirement we interpret to mean full SAMHSA certification rather than provisional certification. Indeed, provisional certification under § 8.11(e) applies to OTPs that do not have a current SAMHSA certification but have applied for accreditation with an accreditation body. Section 1861(jjj)(2)(C) of the Act, however, requires actual accreditation rather than the mere application for accreditation. Thus, we believe that full certification should be required.

(e) OTPs: Managing Employees

Consistent with sections 1124 and 1124A of the Act, an enrolling provider or supplier must disclose all of its managing employees on the Form CMS–855 application. Section 424.502 of our regulations defines a managing employee as a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over (or who directly or indirectly conducts) the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier. We are proposing in new § 424.67(b)(5) that all of the OTP's staff that meet the regulatory definition of managing employee must be reported on the Form CMS–855 application and/or any applicable supplement. Such individuals would include, but not be limited to, the OTP's medical director and program sponsor (both as described in § 8.2).

(f) Standards Specific to OTPs

Given the previously mentioned concerns about the nationwide opioid crisis and the need for drugs to be prescribed and, moreover, dispensed, in a careful, reasonable manner, we believe that OTPs should adhere to certain standards unique to the services they provide. In particular, we wish to ensure that problematic providers and personnel are not prescribing or dispensing drugs on behalf of the OTP. To this end, we propose the following additional requirements with which OTPs must comply in order to enroll in Medicare.

In new § 424.67(b)(6)(i), we propose that an OTP must not employ or contract with a prescribing or ordering physician or other eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted (as that term is defined in 42 CFR 1001.2) of a federal or state felony that we deem detrimental to the best interests of the Medicare program and its beneficiaries, based on the same categories of detrimental felonies, as well as case-by-case detrimental determinations, found at 42 CFR 424.535(a)(3). This provision would apply irrespective of whether the individual in question is: (1) Currently dispensing narcotics at or on behalf of the OTP; or (2) a W–2 employee of the OTP. We note that SAMHSA recognizes the importance of dispensing personnel in an OTP's operations by requiring, as part of the certification process, disclosure of the names and state license numbers of all OTP personnel (other than program physicians) who legally dispense narcotic drugs even if they are not, at present, responsible for administering or dispensing methadone at the program. Such individuals include pharmacists, registered nurses, and licensed practical nurses. (See *https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs.apply*.) We, too, acknowledge the crucial roles of such persons in ensuring the safe dispensing of medicines and believe that those with felonious histories pose a potential risk to the health and safety of Medicare beneficiaries.

This overarching concern regarding possible patient harm also lies behind our proposed standards in new § 424.67(b)(6)(ii) and (iii). In the former paragraph, we propose that the OTP must not employ or contract with any personnel, regardless of whether the individual is a W–2 employee of the OTP, who is revoked from Medicare under § 424.535 or any other applicable section in Title 42, or who is on the preclusion list under §§ 422.222 or 423.120(c)(6). In § 424.67(b)(6)(iii), we propose that the OTP must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who has a current or prior adverse action imposed by a state oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. We would consider the

factors enumerated at § 424.535(a)(22) in each case of patient harm that potentially applies to this provision.

Concerning § 424.67(b)(6)(ii), we believe that OTP personnel who are revoked from Medicare for problematic behavior present a potential threat to the OTP's patients. We hold a similar view regarding persons on the preclusion list (as that term is defined in §§ 422.2 and 423.100). Indeed, such individuals are precluded from receiving payment for Medicare Advantage (MA) items and services or Part D drugs furnished or prescribed to Medicare beneficiaries under, respectively, §§ 422.222 or 423.120(c)(6), due to, in general, a prior felony conviction, a current revocation, or behavior that would warrant a revocation if the person were enrolled in Medicare. As for § 424.67(b)(6)(iii), we discuss in detail our proposed new revocation reason at § 424.535(a)(22) in section III.H.2. of this proposed rule. This proposed new revocation ground pertains to improper conduct that led to patient harm. In light of the aforementioned and critical need to preserve the safety of Medicare beneficiaries, we believe that § 424.67(b)(6)(iii) is an appropriate requirement.

(g) Provider Agreement

(i) General Requirement

As previously mentioned, section 2005(d) of the SUPPORT Act amended section 1866(e) of the Act by adding a new paragraph (3) classifying OTPs as Medicare providers, though only with respect to the furnishing of opioid use disorder treatment services. Under section 1866(a)(1) of the Act, all Medicare providers (as that term is defined in section 1866(e) of the Act) must enter into a provider agreement with the Secretary. Section 1866(a)(1) outlines required terms of the provider agreement, such as allowed charges for furnished services.

Consistent with these requirements, and as previously discussed in more detail in this proposed rule, we are proposing to revise various sections of 42 CFR part 489 to include OTPs within the category of providers that must sign a provider agreement in order to participate in Medicare. To incorporate this requirement into § 424.67 as a prerequisite for enrollment, we propose to state in new § 424.67(b)(7)(i) that an OTP must, in accordance with the provisions of 42 CFR part 489, sign (and adhere to the terms of) a provider agreement with CMS in order to participate and enroll in Medicare.

(ii) Appeals

Under § 489.53, we may terminate a provider agreement if any of the circumstances outlined in that section apply (for example, the provider under § 489.53(a)(1) fails to comply with the provisions of Title XVIII of the Act). The provider may, however, appeal any such termination pursuant to 42 CFR part 498. This process is akin to what occurs with Medicare revocations, whereby: (1) Medicare may revoke a provider's or supplier's Medicare enrollment for any of the reasons identified in § 424.535; and (2) the provider or supplier may appeal said revocation under part 498. There is, though, an additional important result of the revocation process; under § 424.535(b), when a provider's or supplier's billing privileges are revoked, any provider agreement in effect at the time of revocation is terminated effective with the date of revocation.

Given this linkage in § 424.535(b) between a revocation of enrollment and the termination of a provider agreement, we are concerned about the potential for duplicate appeals processes (that is, one for the revocation and the other for the provider agreement termination) involving a revoked OTP. The same concern, of course, would apply in the reverse situation, in which a termination of the provider agreement under § 489.53 led to a revocation under § 424.535 because a provider agreement is a requirement for enrollment pursuant to proposed § 424.67(b)(7)(i). We believe that having dual appeals processes for OTPs would impose unnecessary administrative burdens on OTPs and CMS. A single appeals process would, in our view, be more efficient. To this end, we propose in new § 424.67(b)(7)(ii) that an OTP's appeals under 498 of a Medicare revocation (under § 424.535) and a provider agreement termination (under § 489.53) must be filed jointly and, as applicable, considered jointly by CMS under part 498 of this chapter. We note that there is precedence for such a consolidated approach. Under §§ 422.222(a)(2)(ii)(B) and 423.120(c)(6)(v)(B)(2) (which apply to Medicare Part C and D, respectively), if a provider's or prescriber's inclusion on the preclusion list (*see https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html* for background information on the preclusion list) is based on a contemporaneous Medicare revocation under § 424.535, the appeals of the preclusion list inclusion and the revocation must be filed jointly and considered jointly under part 498.

We would appreciate comment on our proposed consolidated appeals process, including suggestions of alternative processes and the potential operational components thereof.

(h) OTPs: Other Applicable Requirements

To ensure that the OTP meets all other applicable requirements for enrollment, we are proposing at § 424.67(b)(8)) that the OTP must comply with all other applicable requirements for enrollment specified in § 424.67 and in part 424, subpart P.

(i) OTPs: Denial of Enrollment and Appeals Thereof

We are proposing to state in new § 424.67(c)(1)(i) and (ii) that CMS may deny an OTP's enrollment application on either of the following grounds:

- The provider does not have in effect a current, valid certification by SAMHSA as required under § 424.67(b)(4) or fails to meet any other applicable requirement in § 424.67.
- Any of the reasons for denial of a prospective provider's or supplier's enrollment application in § 424.530 applies.

In new § 424.67(c)(2), we are proposing that an OTP may appeal the denial of its enrollment application under part 498.

We believe that § 424.67(c)(1)(i) is necessary so as to comply with the previously mentioned statutory and regulatory requirements that an OTP be SAMHSA-certified. Concerning paragraphs (c)(1)(ii) and (2), we note that because an OTP is a Medicare provider, it must be treated in the same manner as any other provider or supplier for purposes of enrollment and appeal rights; that is, subpart P and the appeals provisions in part 498 apply to OTPs to the same extent they do to all other providers and suppliers. We accordingly believe it is appropriate to include paragraphs (c)(1)(ii) and (2) in this proposed rule.

(j) OTPs: Continued Compliance, Standards, and Reasons for Revocation

For reasons identical to those behind our proposed addition of paragraph (c), we propose several provisions in new § 424.67(d).

In paragraph (d)(1), we are proposing to state that, upon and after enrollment, an OTP:

- Must remain validly certified by SAMHSA as required under § 8.11.
- Remains subject to, and must remain in full compliance with, the provisions of part 424, subpart P and

those in § 424.67. This includes, but is not limited to, the provisions of § 424.67(b)(6), the revalidation provisions in § 424.515, and the deactivation and reactivation provisions in § 424.540.

In paragraph (d)(2), we are proposing that CMS may revoke an OTP's enrollment if:

- The provider does not have a current, valid certification by SAMHSA or fails to meet any other applicable requirement or standard in § 424.67, including, but not limited to, the OTP standards in §§ 424.67(b)(6) and (d)(1).
- Any of the revocation reasons in § 424.535 applies.

Finally, in new paragraph (d)(3), we are proposing that an OTP may appeal the revocation of its enrollment under part 498.

(k) OTPs: Prescribing Individuals

We believe it is important for us to be able to monitor the prescribing and dispensing practices occurring at an OTP. We have an obligation to ensure that beneficiary safety is maintained and the Trust Funds are protected. Accordingly, we propose under new § 424.67(e)(1) (and with respect to payment to OTP providers for furnished drugs) that the prescribing or medication ordering physician's or other eligible professional's National Provider Identifier must be listed on Field 17 (the ordering/referring/other field) of the Form CMS–1500 (Health Insurance Claim Form; 0938–1197) (or the digital equivalent thereof)). We note that our use of the term ''medication ordering'' is merely intended to reiterate that our proposed provision applies to any physician or other eligible professional who prescribes or orders drugs in the OTP arena.

Section 424.67(e)(1), in our view, would help us: (1) Ensure that the physician or other eligible professional in question is qualified to prescribe drugs on behalf of the OTP; and (2) monitor the prescribing individual in relation to each claim. This requirement would have to be met in order for an OTP claim for a prescribed drug to be paid. So as to avoid the impression, however, that this is the only requirement necessary for claim payment, we propose to further clarify in new paragraph (e)(2) that all other applicable requirements in § 424.67, part 424, and part 8 must also be met.

(l) OTPs: Relationship to 42 CFR Part 8

To help ensure that OTPs understand their continuing need to comply with the provisions in part 8 (several of which are referenced above) and to clarify that the provisions in § 424.67 are generally restricted to the enrollment process, we propose to state in new § 424.67(f) that § 424.67 shall not be construed as: (1) Supplanting any of the provisions in part 8; or (2) eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8.

(m) Effective and Retrospective Date of OTP Billing Privileges

Section 424.520 of Title 42 outlines the effective date of billing privileges for provider and supplier types that are eligible to enroll in Medicare. Paragraph (d) thereof sets forth the applicable effective date for physicians, non-physician practitioners, physician and non-physician practitioner organizations, and ambulance suppliers. This effective date is the later of: (1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the supplier first began furnishing services at a new practice location In a similar vein, § 424.521(a) states that physicians, non-physician practitioners, physician and non-physician practitioner organizations, and ambulance suppliers may retrospectively bill for services when the supplier has met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to:

- 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- 90 days prior to their effective date if a Presidentially-declared disaster under the *Robert T. Stafford Disaster Relief and Emergency Assistance Act,* 42 U.S.C. 5121–5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

To clarify the effective date of billing privileges for OTPs and to account for circumstances that could prevent an OTP's enrollment prior to the furnishing of Medicare services, we propose to include newly enrolling OTPs within the scope of both § 424.520(d) and § 424.521(a). We believe that the effective and retrospective billing dates addressed therein achieves a proper balance between the need for the prompt provision of OTP services and the importance of ensuring that each prospective OTP enrollee is carefully and closely screened for compliance with all applicable requirements.

2. Revision(s) and Addition(s) to Denial and Revocation Reasons in §§ 424.530 and 424.535

a. Improper Prescribing

Under § 424.535(a)(14), CMS may revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part D drugs that:

- Is abusive, and/or represents a threat to the health and safety of Medicare beneficiaries; or
- Fails to meet Medicare requirements.

This revocation reason was finalized in the ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' final rule that was published in the May 23, 2014 **Federal Register** (79 FR 29844). It was designed to address situations, which we discussed in that final rule, where prescribers of Part D drugs engaged in prescribing activities that were or could be harmful to Medicare beneficiaries and the Trust Funds or were otherwise inconsistent with Medicare policies. Since the provision's inception, we have revoked the enrollments of practitioners who have engaged in a variety of improper prescribing practices. We believe these administrative actions have helped to shield beneficiaries and the program at large from improper prescribing practices.

The dispensing of drugs in the treatment of opioid use disorder is, as indicated previously, an important component of an OTP's function. Akin to our rationale for the establishment of § 424.535(a)(14) in 2014, we are concerned about potential instances where OTP physicians and other eligible professionals prescribe drugs in an improper fashion. This is an especially important consideration given the nationwide opioid epidemic and the need to reduce opioid abuse. Given this, we believe that § 424.535(a)(14) should no longer be restricted to Part D drugs but must extend to all Medicare drugs, including Part B drugs. Improper prescribing in the Part B context is no less troubling or potentially dangerous than prescribing in the Part D context. Thus, only through such an expansion can we, on a much broader and necessary scale, further deter parties from improper Medicare prescribing practices.

In the introductory text of § 424.535(a)(14), we currently state that CMS determines that the physician or other eligible professional has a pattern or practice of prescribing Part D drugs. Consistent with the above discussion,

we are proposing to revise this paragraph to include Part B drugs so we would specify the prescribing of ''Part B or D drugs.'' We note that this proposal would affect prescriptions of any Part B or D drugs, not merely those prescriptions given to beneficiaries using OTPs.

b. Patient Harm

As referenced previously, and due to the importance of ensuring patient safety in all provider and supplier settings (not merely those involving OTPs), we are also proposing to add § 424.535(a)(22) as a new revocation reason; this would be coupled with a concomitant new denial reason in § 424.530(a)(15). These two paragraphs would permit us to revoke or deny, as applicable, a physician's or other eligible professional's (as that term is defined in 1848(k)(3)(B) of the Act) enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation or denial on this ground is appropriate, CMS would consider the following factors:

- The nature of the patient harm.
- The nature of the physician's or other eligible professional's conduct.
- The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

++ License restriction(s) pertaining to certain procedures or practices,

++ Required compliance appearances before state oversight board members,

++ Required participation in rehabilitation or mental/behavioral health programs,

++ Required abstinence from drugs or alcohol and random drug testing,

++ License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

++ Administrative/monetary penalties; or

++ Formal reprimand(s).

- If applicable, the nature of the IRO determination(s).
- The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.
- Any other information that CMS deems relevant to its determination.

We currently lack the legal basis to take administrative action against a physician or other eligible professional for a matter related to patient harm based solely on an IRO determination or an administrative action (excluding a state medical license suspension or revocation) imposed by a state oversight board, a federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. We believe, however, that our general rulemaking authority under sections 1102, 1866(j)(1)(A), and 1871 of the Act gives us the ability to establish such legal grounds. As alluded to in this proposed rule and in previous rulemaking efforts, we have long been concerned about instances of physician or other eligible professional misconduct, and we believe our authority to take action to stem such behavior should be expanded to include the scenarios identified in proposed § 424.530(a)(15) and § 424.535(a)(22). Indeed, state oversight boards, such as medical boards and other administrative bodies, have found certain physicians and other eligible professionals to have engaged in professional misconduct and/or negligent or abusive behavior involving patient harm. IRO determinations, too, have offered valuable, independent analyses and findings of provider misconduct that we should have the opportunity to use to promote the best interests of Medicare beneficiaries. We believe that our proposed revocation and denial authorities would improve overall patient care by preventing certain problematic physicians and other eligible professionals from treating Medicare patients.

We recognize that situations could arise where a state oversight board has chosen to impose a relatively minor sanction on physician or other eligible professional for conduct that we deem more serious. We note, however, that we, rather than state boards, is ultimately responsible for the administration of the Medicare program and the protection of its beneficiaries. State oversight of licensed physicians or practitioners is, in short, a function entirely different from federal oversight of Medicare. We accordingly believe that we should have the discretion to review such cases to determine whether, in the agency's view, the physician's or other eligible professional's conduct warrants revocation or denial. Yet it should in no way be assumed, on the other hand, that a very modest sanction would automatically result in revocation or denial action. We emphasize that we would only take such a measure after the most careful consideration of all of the factors outlined above.

A number of these factors, we add, are not altogether dissimilar from those which we presently use for determining whether a revocation under § 424.535(a)(14) is appropriate (for example, general frequency and degree of the behavior in question, number of prior sanctions). We have found them to be useful in our § 424.535(a)(14) determinations and, for this reason, believe they will prove likewise with respect to § 424.530(a)(15) and § 424.535(a)(22). Certain of our other proposed criteria are designed to pertain to the unique facts addressed in these two provisions (for example, the extent of patient harm) and, in our view, would help ensure a thorough review of the case at hand.

Sections 424.530(a)(15) and 424.535(a)(22) would apply to physicians and other eligible professionals in OTP and non-OTP settings. Revocation or denial action could be taken against physicians and other eligible professionals in solo practice or who are part of a group or any other provider or supplier type.

To clarify the scope of the term ''state oversight board'' in the context of §§ 424.530(a)(15) and 424.535(a)(22), we propose to define this term in § 424.502. Specifically, we would state that, for purposes of §§ 424.530(a)(15) and 424.535(a)(22) only, ''state oversight board'' means ''any state administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the state.''

We welcome comment not only on our proposed definition of ''state oversight board'' but also on our proposed revocation and denial authorities. We are especially interested in securing public feedback on additional means of preventing fraud, waste, and abuse in OTP setting; for instance, we would appreciate suggestions—based on stakeholder experience in the OUD and OTP arenas—from which we could develop further regulatory authority to take action against problematic OTPs.

I. Deferring to State Scope of Practice Requirements

When the Medicare program was signed into law in 1965, most skilled medical professional services in the United States were provided by physicians, with the assistance of nurses. Over the decades, the medical professional field has diversified and allowed for a wider range of certifications and specialties, including the establishment of mid-level practitioners such as nurse practitioners (NPs) and physician assistants (PAs). These practitioners are also known as advanced practice providers (APPs) or non-physician practitioners (NPPs). Medicare policies and regulations have been updated over recent years to make changes to allow NPPs to provide services in Medicare-certified facilities within the extent of their scope of practice as defined by state law. In recognition of the qualifications of these practitioners, we seek to continue this effort.

1. Ambulatory Surgical Centers

a. Background

Ambulatory surgical centers (ASCs), as defined at 42 CFR 416.2, are distinct entities that operate exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following an admission. The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting. Currently, there are approximately 5,767 Medicare certified ASCs in the United States.

Section 1832(a)(2)(F)(i) of the Act specifies that ASCs must meet health, safety, and other requirements specified by the Secretary in order to participate in Medicare. The Secretary is responsible for ensuring that the ASC Conditions for Coverage (CfCs) protect the health and safety of all individuals treated by ASCs, whether they are Medicare beneficiaries or other patients. The ASC regulations were established in the ''Medicare Program; Ambulatory Surgical Services'' final rule published in the August 5, 1982 **Federal Register** (47 FR 34082), and have since been amended several times.

The regulations for Medicare and Medicaid participating ASCs are set forth at 42 CFR part 416. Section 416.42, ''Condition for coverage—Surgical services'', states that surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

Currently, the ASC CfCs have two conditions that include patient assessment requirements for patients having surgery in an ASC, anesthetic risk and pre-surgery evaluation, and pre-discharge evaluation. In the November 18, 2008 final rule, ''Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates final rule (73 FR 68502), which revised some existing standards and created some new requirements. One of the new conditions added in 2008 was § 416.52, ''Conditions for coverage—Patient admission, assessment and discharge''. This condition sets standards pertaining to patient pre-surgical assessment, post-surgical assessment, and discharge requirements that must be met before patients leave the ASC. Specifically, the discharge requirements at § 416.52(b)(1) require that a post-surgical assessment be completed by a physician, or other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable state health and safety laws, standards of practice, and ASC policy. The other discharge condition, at § 416.42(a)(2), also finalized in the November 18, 2008 final rule, allows anesthetists, in addition to physicians, to evaluate each patient for proper anesthesia recovery. The requirement at § 416.42(a)(1) requires a physician to examine the patient immediately before surgery to evaluate the risk of anesthesia and the procedure to be performed.

Through various inquiries from ASCs and communication with CMS by industry associations, we have received many requests to align the anesthetic risk and pre-surgery evaluation standard at § 416.42(a)(1) with the pre-discharge standard at § 416.42(a)(2) by allowing an anesthetist, in addition to a physician, to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure. For those ASCs that utilize non-physician anesthetists, also known as certified registered nurse anesthetists (CRNAs), this revision would allow them to perform the anesthetic risk and evaluation on the patient they are anesthetizing for the procedure to be performed by the physician. CRNAs are advanced practice registered nurses who administer more than 43 million anesthetics to patients each year in the United States. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the PFS amount for services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in most rural hospitals. A study published by Nursing Economic$ in May/June 2010, found that CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measureable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.[101] We believe this alignment provides for continuity of care for the patient and allows the patient's anesthesia professional to have familiarity with the patient's health characteristics and medical history.

b. Proposed Provisions

We are proposing to revise § 416.42(a), Surgical services, to allow either a physician or an anesthetist, as defined at § 410.69(b), to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure to be performed. By amending the CfCs to allow an anesthetist or a physician to examine and evaluate the patient before surgery for anesthesia risk and the planned procedure risk, we would be making ASC patient evaluations more consistent by allowing the option for the same clinician to complete both pre- and post-procedure anesthesia evaluations.

This proposed change is a continuation of our efforts to reduce regulatory burden. This change would increase supplier flexibility and reduce burden, while allowing qualified clinicians to focus on providing high-quality healthcare to their patients. We are also requesting comments and suggestions for other ASC requirements that could be revised to allow greater flexibility in the use of NPPs, and reduce burden while maintaining high quality health care.

2. Hospice

a. Background

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual, and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Medicare regulations define ''palliative care'' as patient and family centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual,

[101] Paul F. Hogan et al., ''Cost Effectiveness Analysis of Anesthesia Providers.'' Nursing Economic$. 2010; 28:159–169.

emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3). The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. The hospice interdisciplinary group works with the patient, family, caregivers, and the patient's attending physician (if any) to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families and caregivers about changes in their condition. The care plan will shift over time to meet the changing needs of the patient, family, and caregiver(s) as the patient approaches the end of life.

The regulations for Medicare and Medicaid participating hospices are set forth at 42 CFR part 418. Section 418.3 defines the term ''attending physician'' as being a doctor of medicine or osteopathy, an NP, or a PA in accordance with the statutory definition of an attending physician at section 1861(dd)(3)(B) of the Act. Section 51006 of the Bipartisan Budget Act of 2018 revised the statute to add PAs to the statutory definition of the hospice attending physician for services furnished on or after January 1, 2019. As a result, PAs were added to the definition of a hospice attending physician as part of the ''Medicare Program; FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements'' final rule which was published in the August 6, 2018 **Federal Register** (83 FR 38622, 38634) (hereinafter referred to as the ''FY 2019 Hospice final rule'').

The role of the patient's attending physician, if the patient has one, is to provide a longitudinal perspective on the patient's course of illness, care preferences, psychosocial dynamics, and generally assist in assuring continuity of care as the patient moves from the traditional curative care model to hospice's palliative care model. The attending physician is not meant to be a person offered by, selected by, or appointed by the hospice when the patient elects to receive hospice care. Section 418.64(a) of the hospice regulations requires the hospice to provide physician services to meet the patient's hospice-related needs and all other care needs to the extent that those needs are not met by the patient's attending physician. Thus, if a patient does not have an attending physician relationship prior to electing hospice care, or if the patient's attending physician chooses to not participate in the patient's care after the patient elects to receive hospice care, then the hospice is already well-suited to provide physician care to meet all of the patient's needs as part of the Medicare hospice benefit. If the patient has an attending physician relationship prior to electing hospice care and that attending physician chooses to continue to be involved in the patient's care during the period of time when hospice care is provided, the role of the attending physician is to consult with the hospice interdisciplinary group (also known as the interdisciplinary team) as described in § 418.56, and to furnish care for conditions determined by the hospice interdisciplinary group to be unrelated to the terminal prognosis. The hospice interdisciplinary group must include the following members of the hospice's staff: A physician; a nurse; a social worker; and a counselor. The interdisciplinary group may also include other members based on the specific services that the patient receives, such as hospice aides and speech language pathologists. The hospice interdisciplinary group, as a whole, in consultation with the patient's attending physician (if any), the patient, and the patient's family and caregivers, are responsible for determining the course of the patient's hospice care and establishing the individualized plan of care for the patient that is used to guide the delivery of holistic hospice services and interventions, both medical and non-medical in nature.

b. Proposed Provisions

In the role of a consultant to the hospice interdisciplinary group, the hospice patient's chosen attending physician may, at times, write orders for services and medications as they relate to treating conditions determined to be unrelated to the patient's terminal prognosis. The law allows for circumstances in which services needed by a hospice beneficiary would be completely unrelated to the terminal prognosis, but we believe that this situation would be the rare exception rather than the norm. Section 418.56(e) requires hospices to coordinate care with other providers who are also furnishing care to the hospice patient, including the patient's attending physician who is providing care for conditions determined by the hospice interdisciplinary group to be unrelated to the patient's terminal prognosis. As part of this coordination of care, it is possible that hospices may receive orders from the attending physician for drugs that are unrelated to the patient's terminal prognosis.

The FY 2019 Hospice final rule amended the regulatory definition of attending physician, as required by the statute, to include physician assistant. Following publication of the FY 2019 Hospice final rule, stakeholders raised concerns regarding the requirements of § 418.106(b). As currently written, hospices may not accept orders for drugs from attending physicians who are PAs because § 418.106(b) specifies that hospices may accept drug orders from physicians and NPs only. This regulatory requirement may impede proper care coordination between hospices and attending physicians who are PAs, and we believe that it should be revised.

Therefore, we propose to revise § 418.106(b)(1) to permit a hospice to accept drug orders from a physician, NP, or PA. We propose that the PA must be an individual acting within his or her state scope of practice requirements and hospice policy. We also propose that the PA must be the patient's attending physician, and that he or she may not have an employment or contractual arrangement with the hospice. The role of physicians and NPs as hospice employees and contractors is clearly defined in the hospice CoPs; however, the CoPs do not address the role of PAs. Therefore, we believe that it is necessary to limit the hospice CoPs to accepting only those orders from PAs that are generated outside of the hospice's operations.

The role of a PA is not defined in the hospice CoPs because the statute does not include PA services as being part of the Medicare hospice benefit. As such, there are no provisions in the hospice CoPs to address specific PA issues such as personnel requirements, descriptions of whether such services would be considered core or non-core, or provisions to address issues of co-signatures. To more fully understand the current and future role of NPPs, including PAs, in hospice care and the hospice CoPs, we request public comment on the following questions:

- What is the role of a NPP in delivering safe and effective hospice care to patients? What duties should they perform? What is their role within the hospice interdisciplinary group and how is it distinct from the role of the physician, nurse, social work, and counseling members of the group?

- Nursing services are a required core service within the Hospice benefit, as provided in section 1861(dd)(B)(i) of the Act, which resulted in the defined role for NPs in the Hospice COPs. Should other NPPs also be considered core services on par with NP services? If not, how should other NPP services be classified?
- In light of diverse existing state supervision requirements, how should NPP services be supervised? Should this responsibility be part of the role of the hospice medical director or other physicians employed by or under contract with the hospice? What constitutes adequate supervision, particularly when the NPP and supervising physician are located in different offices, such as hospice multiple locations?
- What requirements and time frames currently exist at the state level for physician co-signatures of NPP orders? Are these existing requirements appropriate for the hospice clinical record? If not, what requirements are appropriate for the hospice clinical record?
- What are the essential personnel requirements for PAs and other NPPs?

J. Advisory Opinions on the Application of the Physician Self-Referral Law

1. Statutory and Regulatory Background

Section 4314 of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted August 5, 1997), added section 1877(g)(6) to the Act. Section 1877(g)(6) of the Act requires the Secretary to issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. On January 9, 1998, the Secretary issued a final rule with comment period in the **Federal Register** to implement and interpret section 1877(g)(6) of the Act (the 1998 CMS advisory opinions rule). (See Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions (63 FR 1646).) The regulations are codified in §§ 411.370 through 411.389 (the physician self-referral advisory opinion regulations).

Section 1877(g)(6)(A) of the Act states that each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion. Section 1877(g)(6)(B) of the Act requires the Secretary, in issuing advisory opinions regarding the physician self-referral law, to apply the rules in paragraphs (b)(3) and (4) of section 1128D of the Act, to the extent practicable. This paragraph also requires the Secretary to take into account the regulations promulgated under paragraph (b)(5) of section 1128D of the Act.

Section 1128D of the Act was added to the statute by section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, effective August 21, 1996). Among other things, section 1128D of the Act requires the Secretary, in consultation with the Attorney General, to issue written advisory opinions as to specified matters related to the anti-kickback statute in section 1128B(b) of the Act, the safe harbor provisions in § 1001.952, and other provisions of the Act under the authority of the Office of Inspector General (OIG). To implement and interpret section 1128D of the Act, the Office of Inspector General (OIG) issued an interim final rule with comment period in the February 19, 1997 **Federal Register** entitled Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG (62 FR 7350), revised and clarified its regulations in the July 16, 1998 **Federal Register** (68 FR 38311), and updated its regulations in a final rule published in the July 17, 2008 **Federal Register** that solely revised certain procedural requirements for submitting payments for advisory opinion costs (73 FR 40982) (collectively, the OIG advisory opinion rule). The regulations are codified in part 1008 of this title of the Code of Federal Regulations (the OIG advisory opinion regulations).

Section 1128D(b)(3) of the Act prohibits the Secretary from addressing in an advisory opinion whether: (1) Fair market value shall be or was paid or received for any goods, services, or property; or (2) an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986. In the 1998 CMS advisory opinions rule, we incorporated these provisions into the physician self-referral law regulations (63 FR 1646). Section 1128D(b)(4)(A) of the Act states that an advisory opinion related to OIG authorities is binding as to the Secretary and the party or parties requesting the opinion. This section is redundant of the provision in section 1877(g)(6)(A) of the Act, and therefore, not incorporated into the physician self-referral advisory opinion regulations. Section 1128D(b)(4)(B) of the Act provides that the failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B of the Act. We incorporated section 1128D(b)(4)(B) of the Act in the physician self-referral regulations at § 411.388.

As discussed previously, section 1877(g)(6)(B) of the Act requires the Secretary, to the extent practicable, to take into account the regulations issued under the authority of section 1128D(b)(5) of the Act (that is, the OIG advisory opinion regulations). Section 1128D(b)(5)(A) requires that the OIG advisory opinion regulations must provide for: (1) The procedure to be followed by a party applying for an advisory opinion; (2) the procedure to be followed by the Secretary in responding to a request for an advisory opinion; (3) the interval in which the Secretary will respond; (4) the reasonable fee to be charged to the party requesting an advisory opinion; and (5) the manner in which advisory opinions will be made available to the public. We interpret Congress' directive to take into account OIG regulations to mean that we should use the OIG regulations as our model, but that we are not bound to follow them (63 FR 1647). Nonetheless, in the 1998 CMS advisory opinions rule, we largely adopted OIG's approach to issuing advisory opinions, stating that we intend for physician self-referral law advisory opinions to provide the public with meaningful advice regarding whether, based on specific facts, a physician's referral for a designated health service (other than a clinical laboratory service) is prohibited under section 1877 of the Act (63 FR 1648).

2. Proposed Revisions to the CMS Advisory Opinion Process and Regulations

In the June 25, 2018 **Federal Register**, we published a Request for Information Regarding the Physician Self-Referral Law (83 FR 29524) (June 2018 CMS RFI) that sought recommendations from the public on how to address any undue impact and burden of the physician self-referral statute and regulations. Although we did not specifically request comments on the CMS advisory opinion regulations, we received a number of comments urging that CMS reconsider its approach to advisory opinions and transform the process such that the regulated industry may obtain expeditious guidance on whether a physician's referrals to an entity with which he or she has a financial relationship would be prohibited under section 1877 of the Act. These commenters stated their belief that the current advisory opinion process could be improved. Some commenters stated also that the process is too restrictive, noting that CMS has placed what the commenters see as unreasonable limits on the types of questions that qualify for

an advisory opinion (for example, CMS will not issue an advisory opinion where the arrangement at issue is hypothetical and does not issue advisory opinions on general questions of interpretation) and CMS advisory opinions apply only to the specific circumstances of the requestor. These commenters asserted that the OIG's advisory opinion process, upon which the CMS advisory opinion process is modeled, is inappropriate for a payment statute. These commenters noted that OIG opines on matters related to a felony criminal statute, whereas the physician self-referral law, by contrast, is a payment rule. The commenters highlighted the complexity of the physician self-referral regulations, the strict liability nature of the physician self-referral law, and the need for certainty before arrangements are initiated and claims submitted as reasons why an advisory opinion process related to a felony criminal statute is inappropriate for the physician self-referral law. Other commenters asserted that the process is arduous and inefficient. These commenters noted that the advisory opinion process can extend beyond the 90-day timeframe provided for at § 411.380 and asserted that it lags behind the OIG process in terms of efficiency.

In designing its advisory opinion process, OIG carefully balanced stakeholders' desire for an accessible process and meaningful and informed opinions with its need to closely scrutinize arrangements to insure that requesting parties are not inappropriately granted protection from sanctions. (63 FR 38312 through 38313). We appreciate that there are important differences between the physician self-referral law, a strict liability statute designed to prevent payment for services where referrals are affected by inherent financial conflicts of interest, and the anti-kickback statute, which is a criminal law designed to prosecute intentional acts of fraud and abuse.

More than 20 years have passed since the CMS advisory opinion regulations were issued. In those 20 years, we have issued 30 advisory opinions,[102] 15 of which addressed the 18-month moratorium on physician self-referrals to specialty hospitals in which they have an ownership or investment interest. In light of the comments received on the RFI, we have undertaken a fresh review of the CMS advisory opinion process. We agree that it is important to have an accessible process that produces meaningful opinions on the applicability of section 1877 of the Act, especially in light of the perceived complexity of the physician self-referral regulations, including the requirements of the various exceptions and the key terminology applicable to many of the exceptions, and we recognize that our current advisory opinion process has not been utilized by stakeholders or resulted in a significant number of issued opinions to date. Accordingly, we have reviewed our advisory opinion regulations in an effort to identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process.

Failure to satisfy the requirements of an exception to the physician self-referral law carries significant consequences, regardless of a party's intent.[103] The safe harbors under the anti-kickback statute are voluntary, and the failure of an arrangement to fit squarely within a safe harbor does not mean that the arrangement violates the anti-kickback statute. By contrast, the physician self-referral law prohibits a physician's referral if there is a financial relationship that does not satisfy the requirements of one of the enumerated exceptions. In other words, the physician self-referral law is a strict liability law, and parties that act in good faith may nonetheless face significant financial exposure if they misunderstand or misapply the law's exceptions.

Regulated parties' desire for certainty must be balanced with CMS' interest in maintaining the integrity of the advisory opinion process, and ensuring that it is not used to inappropriately shield improper financial arrangements. But we believe that the risk of such misuse is acceptably low with respect to the section 1877 of the Act advisory opinion process because the advisory opinion authority at section 1877(g) of the Act is narrowly tailored. CMS can only issue favorable advisory opinions for arrangements that do not violate section 1877 of the Act—for example, because there is no referral for designated health services, there is no financial relationship, or the arrangement meets an exception. In contrast, OIG has issued favorable advisory opinions for arrangements that do not fit within a safe harbor where it has concluded, based on a totality of the facts and circumstances, that the arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute. CMS cannot similarly extend protection beyond the exceptions, so there is a built-in safeguard against protecting an arrangement that the law would not otherwise protect. Furthermore, a favorable advisory opinion from CMS does not immunize parties from liability under the anti-kickback statute.

a. Matters Subject to Advisory Opinions (§ 411.370)

Section 1877(g)(6) of the Act requires the Secretary to issue advisory opinions concerning ''whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section.'' In accordance with section 1877(g)(6)(B) of the Act, CMS adopted in regulation the rules in paragraphs (b)(3) and (4) of section 1128D of the Act, which prohibit the OIG from opining on whether an arrangement is fair market value and whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code. In addition to these statutory restrictions on matters that are not subject to advisory opinions, our current regulation at § 411.370(b)(1) states that CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties. When explaining this regulation, we stated that we interpret section 1877(g)(6) of the Act to allow for opinions on specific referrals involving physicians in specific situations (63 FR 1649). We also noted our reasons for avoiding opinions on generalized arrangements, stating that it would not be possible for an advisory opinion to reliably identify all the possible hypothetical factors that might lead to different results (*Id.*).

Under our current regulations, CMS accepts requests for advisory opinions that involve existing arrangements, as well as requests that involve arrangements into which the requestor plans to enter. Some commenters on the June 2018 CMS RFI suggested that CMS expand the scope of the requests that it will consider for an advisory opinion to include requests that involve hypothetical fact patterns and general questions of interpretation. It is our position that some requests are not appropriate for an advisory opinion.

[102] These advisory opinions are available on CMS' website, at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory opinions.html.* This number does not include advisory opinion requests that were withdrawn.

[103] The CMS Voluntary Self-Referral Disclosure Protocol (SRDP) allows providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. Under the SRDP, CMS may reduce the amount due and owing for violations of section 1877 of the Act. Information about the SRDP can be found at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol.pdf.*

Further, although we are proposing a number of changes to improve the advisory opinion process for stakeholders, we believe that expanding the process to include questions regarding hypothetical fact patterns or general interpretation could overwhelm the agency. Thus, we are not proposing an expansion of the scope of requests at this time; however, we are soliciting comments on whether we should do so in the future. We are proposing minor clarifications to § 411.370(b) regarding matters that qualify for advisory opinions and the parties that may request them. Specifically, we are proposing to clarify that the request for an advisory opinion must ''relate to'' (rather than ''involve'') an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. Requestors continue to be obligated to disclose all facts relevant to the arrangement for which an advisory opinion is sought. We are also proposing revisions to the regulation text for grammatical purposes.

We note that CMS currently responds to questions pertaining to the physician self-referral law through the CMS Physician Self-Referral Call Center. Although we are unable to provide formal guidance or an opinion regarding whether a specific referral is permissible or whether a financial relationship satisfies the requirements of an exception, we are able to assist parties with identifying relevant guidance. The CMS Physician Self-Referral Call Center is free to the public, and inquiries may be sent to *1877CallCenter@cms.hhs.gov*. For additional information, *see https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Call-Center.html*. CMS also responds to frequently asked questions (FAQs) regarding the physician self-referral law from time to time. FAQs issued to date may be found on our website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/FAQs.html*.

Current § 411.370(e) states that CMS does not accept an advisory opinion request or issue an advisory opinion if: (1) The request is not related to a named individual or entity; (2) CMS is aware that the same or substantially the same course of action is under investigation or is or has been the subject of a proceeding involving HHS or another governmental agency; or (3) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry. We are proposing changes to this regulation. First, we are proposing to add to the reasons that CMS will not accept an advisory opinion request or issue an advisory opinion. Specifically, we are proposing that CMS will reject an advisory opinion request or not issue an advisory opinion with respect to a request that does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information. We believe that this is important to the agency's ability to focus its resources on complete requests.

Second, we are proposing to amend current § 411.370(e)(2), which states that CMS will not issue an advisory opinion if it is aware that the same, or substantially the same, course of action is under investigation or is or has been the subject of a proceeding involving HHS or other government entities. Although CMS consults with other HHS components and governmental agencies, including OIG and DOJ, on pending advisory opinion requests, we believe the current regulation is too restrictive, and unnecessarily limits CMS' flexibility to issue timely guidance to requestors engaged in or considering legitimate business arrangements. Therefore, we are proposing to ease the restriction at § 411.370(e)(2) that prohibits the acceptance of an advisory opinion request or issuance of an advisory opinion if CMS is aware of pending or past investigations or proceedings involving a course of action that is ''substantially the same'' as the arrangement or proposed arrangement between or among the parties requesting an advisory opinion, and instead allow CMS more discretion to determine, in consultation with OIG and DOJ, whether acceptance of the advisory opinion request or issuance of the advisory opinion is appropriate. Specifically, we propose at § 411.370(e)(2) that CMS may elect not to accept an advisory opinion request or issue an advisory opinion if, after consultation with OIG and DOJ, it determines that the course of action described in the request is substantially similar to conduct that is under investigation or is the subject of a proceeding involving HHS or other law enforcement agencies, and issuing an advisory opinion could interfere with the investigation or proceeding. We propose to retain at renumbered § 411.370(e)(1)(iii) the restriction on accepting requests if CMS is aware that the specific course of action (involving the same specific parties) is under investigation or is, or has been the subject of a proceeding involving the Department or another governmental agency. We also propose to clarify that CMS would consult with OIG and DOJ regarding investigations or proceedings involving the same course of conduct described in an advisory opinion request. We seek comments on this approach.

Although we are not proposing changes to § 411.370(f) which describes the effects of an advisory opinion on other government authority, we note that a determination regarding whether a referral is prohibited by section 1877 of the Act is a determination that rests solely and exclusively with the Secretary (and, in this case, the Administrator, to whom the Secretary has delegated this authority). Under section 1877(g)(6) of the Act, an advisory opinion is binding on the Secretary, and if the Secretary determines that a particular fact pattern does not trigger liability under section 1877 of the Act, that determination is binding on the Secretary, as well as any component of HHS that exercised the authority delegated by the Secretary. Such a determination would preclude the imposition of sanctions under section 1877(g) of the Act.[104] A favorable advisory opinion would not, however, insulate parties from liability under the anti-kickback statute or any other laws or regulations outside of section 1877 of the Act. It would also not preclude OIG from exercising its authority under the Inspector General Act of 1978 (Pub. L. 95–452, as amended by Pub. L. 115–254, enacted October 05, 2018). In a physician self-referral law advisory opinion, CMS may opine on whether an arrangement is ''commercially reasonable'' as defined by the physician-self-referral law regulations. Such a determination by CMS may not apply in the context of the anti-kickback statute and should not be interpreted as such. A CMS determination that an arrangement is or is not a ''financial relationship,'' as defined at section 1877(a)(2) of the Act and § 411.354(a), or that an arrangement satisfies a specific requirement of an exception to the physician self-referral law (for example, whether a compensation arrangement is ''commercially reasonable''), would be a separate and distinct inquiry from any determination by law enforcement that the arrangement does or does not violate the anti-kickback statute.

b. Timeline for Issuing an Advisory Opinion (§ 411.380)

Section 1877(g)(6) of the Act does not impose any deadlines by which the

[104] The Secretary has delegated the civil monetary penalty authority under section 1877 of the Act to the OIG.

agency must respond to an advisory opinion request, but section 1128D(b)(5)(B)(i) of the Act provides that the Secretary shall be required to issue an advisory opinion no later than 60 days after the request is received. In the 1998 CMS advisory opinions rule, we adopted a 90-day timeframe for most requests. In addition, for requests that we determine, in our discretion, involve complex legal issues or highly complicated fact patterns, we reserved the right to issue an advisory opinion within a reasonable timeframe. We created this timeframe based upon our estimates on the volume and complexity of expected requests, and based upon our then-current staffing situation.

We are proposing to modify this time period and establish a 60-day timeframe for issuing advisory opinions. The 60-day period would begin on the date that CMS formally accepts a request for an advisory opinion. The 60 days would be tolled during any time periods in which the request is being revised or additional information compiled and presented by the requestor. We are also considering whether CMS should provide requestors with the option to request expedited review. We believe that a more efficient and expeditious process could give stakeholders more certainty and encourage innovative care delivery arrangements. We seek comment on the proposed changes to the timeframe, whether CMS in the final rule should include a provision on expedited review and, if so, the parameters for expedited review.

c. Certification Requirement (§ 411.373)

In the 1998 CMS advisory opinions rule, we adopted a requirement identical to OIG's requirement that a requestor must certify to the truthfulness of its submissions, including its good faith intent to enter into proposed arrangements. CMS finalized regulations that require a requestor to make two certifications as part of its request for an advisory opinion. Under current § 411.373(a), the requestor must certify that, to the best of the requestor's knowledge, all of the information provided as part of the request is true and correct and constitutes a complete description of the facts regarding which an advisory opinion is being sought. If the request relates to a proposed arrangement, current § 411.373(b) states that the request must also include a certification that the requestor intends in good faith to enter into the arrangement described in the request. A requestor may make this certification contingent upon receiving a favorable advisory opinion from CMS or from both CMS and OIG. Under current § 411.372(b)(8), if the requestor is an individual, the individual must sign the certification; if the requestor is a corporation, the certification must be signed by the Chief Executive Officer, or a comparable officer; if the requestor is a partnership, the certification must be signed by a managing partner; and, if the requestor is a limited liability company, the certification must be signed by a managing member. We are proposing to revise § 411.372(b)(8) to clarify that the certification must be signed by an officer that is authorized to act on behalf of the requestor. We are also considering whether it would be appropriate to eliminate the certification requirement in our regulations, given that section 1001 of Title 18 of the United States Code prohibits material false statements in matters within the jurisdiction of a federal agency. We seek comment on whether the existing certification requirement creates undue burden for requestors, and whether the requirement is necessary given Section 1001.

d. Fees for the Cost of Advisory Opinions (§ 411.375)

In the 1998 CMS advisory opinions rule, we established a fee that is charged to requestors to cover the actual costs incurred by CMS in responding to a request for an advisory opinion. Under current § 411.375, there is an initial fee of $250, and parties are responsible for any additional costs incurred that exceed the initial $250 payment. A requestor may designate a triggering dollar amount, and CMS will notify the requestor if CMS estimates that the costs of processing the request have reached or are likely to exceed the designated triggering amount. This fee structure was modeled after OIG regulations that were in effect at that time.

Since CMS issued the 1998 CMS advisory opinions rule, OIG has updated its regulations to eliminate the initial fee, and instead charges requesting parties a consolidated final payment based on costs associated with preparing an opinion (73 FR 15936). We believe it is appropriate to adopt an hourly fee of $220 for preparation of an advisory opinion. We believe this amount reflects the costs incurred by the agency in processing an advisory opinion request. We are also considering adding a provision establishing an expedited pathway for requestors that seek an advisory opinion within 30 days of the request. If we establish such a pathway, we would consider charging $440 an hour to process the request, reflecting the extra resources necessary to produce an advisory opinion within the abbreviated timeframe. We request comments on this approach. To ensure that obtaining an advisory opinion is affordable, and to prevent unfair surprises to requestors at the end of the process, we are considering promulgating a cap on the amount of fees charged for an advisory opinion. We solicit comments on the amount of the cap. We also request comments on whether CMS should eliminate the initial $250 fee.

e. Reliance on an Advisory Opinion (§ 411.387)

As we consider improvements to the advisory opinion process, we are also considering regulatory changes to clarify current CMS policies and practices, and make our advisory opinions more useful compliance tools for stakeholders. Specifically, we are soliciting comment on proposals, described in more detail below, to remove some of the regulatory provisions limiting the universe of individuals and entities that can rely on an advisory opinion, and to add language expressing what we believe are permissible uses of an advisory opinion.

Section 1877(g)(6)(A) of the Act states that an advisory opinion shall be binding on the Secretary and on the party or parties requesting an opinion. Consistent with the policy adopted by OIG, CMS took the view that an advisory opinion may legally be relied upon only by the requestors. While section 1877 of the Act is silent on how third parties may use an advisory opinion, in regulation, CMS has precluded legal reliance on the opinion by non-requestor third parties. At the time, we stated that advisory opinions are capable of being misused by persons not a party to the transaction in question in order to inappropriately escape liability (63 FR 1648). While such a preclusion may be appropriate for purposes of an OIG advisory opinion on the application of a criminal statute, we believe it may be unduly restrictive in the context of a strict liability payment rule that applies regardless of a party's intent.

In practice, CMS does anticipate that parties to an arrangement that is subject to a favorable advisory opinion will rely on the opinion, even if the parties did not join in the request. If, for instance, CMS determines that an arrangement does not constitute a financial relationship because it satisfies all requirements of an applicable exceptions to the physician self-referral law, that determination would necessarily apply equally to any individuals and entities that are parties to the specific arrangement, for example, the referring physician and the entity to which he or she refers patients

for designated health services. Thus, even if the physician party to the arrangement was not a requestor of the advisory opinion, the physician party is entitled to rely on that advisory opinion. We are proposing changes to § 411.387 to reflect this view. Specifically, we are proposing at § 411.387(a) that an advisory opinion would be binding on the Secretary and that a favorable advisory opinion would preclude the imposition of sanctions under section 1877(g) of the Act with respect to the party or parties requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the advisory opinion is issued.

We are proposing at § 411.387(b) that the Secretary will not pursue sanctions under section 1877(g) of the Act against any individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion. Even though a favorable advisory opinion with respect to one arrangement would not legally preclude CMS from pursuing violations against parties to a different arrangement, in practice, the Secretary would not consider using enforcement resources for purposes of imposing sanctions under section 1877(g) of the Act to investigate the actions of parties to an arrangement that CMS believes is materially indistinguishable from an arrangement that has received a favorable advisory opinion. As discussed above, such a determination would not preclude a finding by DOJ or OIG that the arrangement violates the anti-kickback statute or any other law. All facts relied on and influencing a legal conclusion in an issued favorable advisory opinion are material; deviation from that set of facts would result in a party not being able to claim the protection proposed in § 411.387(b). If parties to an arrangement are uncertain as to whether CMS would view it as materially indistinguishable from an arrangement that has received a favorable advisory opinion, then those parties can submit an advisory opinion request to query whether a referral is prohibited under section 1877 of the Act because the arrangement is materially indistinguishable from an arrangement that received a favorable advisory opinion. We seek comment on this approach.

Finally, we are also proposing at § 411.387(c) to recognize that individuals and entities may reasonably rely on an advisory opinion as non-binding guidance that illustrates the application of the self-referral law and regulations to specific facts and circumstances. We believe that stakeholders already look to advisory opinions issued by OIG and CMS to inform their decision-making, and these proposed changes would make clear that CMS acknowledges that such reliance is permissible and reasonable. We request comments on all aspects of these proposals.

f. Rescission (§ 411.382)

Under current § 411.382, CMS may rescind or revoke an advisory opinion after it is issued. To date, CMS has not rescinded an advisory opinion. At the time we finalized this regulation, which is modeled on OIG's rescission authority regulation, we sought comment on whether this approach reasonably balanced the government's need to ensure that advisory opinions are legally correct and the requestor's interest in finality (63 FR 1653). We are again requesting comment on this issue. Specifically, we are soliciting comments on whether CMS should retain a more limited right to rescind an advisory opinion; that is, CMS could rescind an advisory opinion only when there is a material regulatory change that impacts the conclusions reached, or when a party has received a negative advisory opinion and wishes to have the agency reconsider the request in light of new facts or law.

g. Other Modifications to Procedural Requirements

We are proposing minor modifications to § 411.372 to improve readability and clarity. We are also proposing to eliminate the reference to the provision of stock certificates as part of the advisory opinion request submission, as these are typically electronic and may not necessarily list the name of the owner. We are requesting comments on these and other updates to the procedure for submitting an advisory opinion request that will improve the efficiency of the review process.

K. CY 2020 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the proposed rule sets forth changes to the Quality Payment Program starting January 1, 2020, except as otherwise noted for specific provisions. The 2020 performance period of the Quality Payment Program should build upon the foundation that has been established in the first 3 years of the program, which provides a trajectory for clinicians moving to performance-based payments, and will gradually prepare clinicians for the 2022 performance period of the program and the 2024 MIPS payment year. Participation in both tracks of the Quality Payment Program—Advanced Alternative Payment Models (APMs) and Merit-based Incentive Payment System (MIPS)—have increased from 2017 to 2018.[105] The number of QPs—Qualifying APM Participations—nearly doubled from 2017 to 2018, from 99,076 to 183,306 clinicians. In MIPS, 98 percent of eligible clinicians participated in 2018, up from 95 percent in 2017. As the Quality Payment Program continues to mature, CMS recognizes additional long-term improvements will need to occur. Beginning with the 2024 MIPS payment year, the cost performance category will be weighted at 30 percent, which has been gradually increased in the last few years, and the performance threshold will be set at the mean or median of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. Beginning in the 2022 performance period, there will no longer be the same flexibility in establishing the weight of the cost performance category or in establishing the performance threshold. Refer readers to sections III.K.3.c.(2)(a) and III.K.3.e.(2) of this proposed rule for more information about the statutory requirements related to these provisions.

b. Summary of Major Proposals

(1) MIPS Value Pathways Request for Information

CMS is committed to the transformation of MIPS, which will allow for: More streamlined and cohesive reporting; enhanced and timely feedback; and the creation of MIPS Value Pathways (MVPs) of integrated measures and activities that are meaningful to all clinicians from specialists to primary care clinicians and patients. The new MVPs would remove barriers to APM participation and promote value by focusing on quality, interoperability, and cost. Additionally, MVPs would create a cohesive and meaningful participation experience for clinicians by moving away from siloed activities and measures and towards an aligned set of measures that are more relevant to a clinician's scope of practice, while further reducing reporting burden and

[105] Quality Payment Program (QPP) Participation in 2018: Results at a Glance *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/586/2018%20QPP%20Participation%20Results%20Infographic.pdf.*

easing the transition to APMs. MVPs are described in greater detail at section III.K.1.b.(2) and the full Request for Information at section III.K.3.a. of this proposed rule.

(2) Major MIPS Proposals

The major MIPS proposals in this year's proposed rule include a focus on a strategic vision to further transform MIPS by empowering patients and simplifying MIPS to improve value and reduce burden. We envision a future state of the program where patients have the information needed to make informed decisions about their healthcare, clinicians improve health outcomes and quality of care for their patients in alignment with the Meaningful Measures initiative,[106] and the data collection burden is limited in alignment with the Patients over Paperwork initiative.[107] Hence, we are proposing to apply a new MVPs framework to future proposals beginning with the 2021 MIPS Performance Year. MVPs would utilize sets of measures and activities that incorporate a foundation of promoting interoperability and administrative claims-based population health measures and layered with specialty/condition specific clinical quality measures to create both more uniformity and simplicity in measure reporting. The MVP framework will also connect quality, cost, and improvement activities performance categories to drive toward value; integrate the voice of patients; and reduce clinician barriers to movement into Advanced APMs. Further, the MVP framework would reduce the number of performance measures and activities clinicians may select. Ultimately, we believe this would decrease clinician burden and improve performance data quality, while still accounting for different types of specialties and practices. In addition to comments requested on the framework, we are seeking feedback on several implementation elements within section III.K.3.a. of this proposed rule. Within this section, we describe our vision that includes the following:

- Furthering the application of the Meaningful Measures framework.
- Implementing a measure set using additional administrative claims-based quality measures.
- Developing MVPs, using an approach which connects measures and activities from the quality, cost, and improvement activities performance categories; requiring completion of the Promoting Interoperability performance category to maintain alignment with hospitals; and focusing on a specialty or condition to standardize and provide more cohesive reporting and participation.
- Providing timely quality and cost performance data feedback using administrative claims, registry, and electronically submitted data to enhance a clinician self-tracking to facilitate care improvements.
- Enhancing information available to patients to inform decision making, including increasing the patient reported measures in MVPs.

This vision will ultimately help us to better measure and incentivize value, ensure participation is more meaningful to clinicians and their patients, provide information to patients to assist with clinician selection, reduce clinician reporting burden, respond to program concerns, and increase alignment with APMs, and increase alignment with APMs. The RFI solicits comment on the types of information that would be useful to patients (Medicare beneficiaries) and individual clinicians reporting data for purposes of sharing on CMS public websites. We have assessed new opportunities, such as, implementation of a foundational claims-based population health core measure set using administrative claims-based quality measures that can be broadly applied to communities or populations, development of MVP measure tracks to provide uniformity in measure reporting and to unify performance categories, and enhancement of the patient voice, to increase simplicity, reduce burden, and increase the value of MIPS performance data. We strongly encourage feedback on how we can best realize our path to value vision of MIPS Value Pathways.

In addition to this framework, we are making two significant proposals for the 2020 MIPS performance period:

- As discussed in section III.K.3.g.(2) of this proposed rule, we are proposing to strengthen the Qualified Clinical Data Registry (QCDR) measure standards for MIPS to require measure testing, harmonization, and clinician feedback to improve the quality of QCDR measures available for clinician reporting. These policies relate to CY 2020 and CY 2021 for QCDRs.
- As discussed in section III.K.3.c.(2)(b)(iii) of this proposed rule, we are proposing to add new episode-based measures in the cost performance category to more accurately reflect the cost of care that specialists provide. Further, we are proposing to revise the total per capita cost and the Medicare Spending Per Beneficiary (MSPB) measures in response to stakeholders' feedback suggestions.

While we continue efforts to strengthen the Quality Payment Program, we remain interested in clinician participation and engagement in the program. Finally, as the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, enacted February 9, 2018) extended the flexibility and transition years within the Quality Payment Program, we believe these proposed policies for Year 4 and our strategic vision will assist us in working towards a more robust program in the future.

(3) Major APM Proposals

(a) Aligned Other Payer Medical Home Models

We are proposing to add the defined term, Aligned Other Payer Medical Home Model, to § 414.1305. The proposed definition of Aligned Other Payer Medical Home Model includes the same characteristics as the definitions of Medical Home Model and Medicaid Medical Home Model, but it applies to other payer payment arrangements. We believe that structuring this proposed definition in this manner is appropriate because we recognize that other payers could have payment arrangements that may be appropriately considered medical home models under the All-Payer Combination Option.

Neither the current Medical Home Model financial risk and nominal amount standards nor the Medicaid Medical Home Model financial risk and nominal amount standards apply to other payer payment arrangements. Consistent with our proposal to define the term Aligned Other Payer Medical Home Model, we are proposing to amend § 414.1420(d)(2), (d)(4), and (d)(8) of our regulations to also apply the Medicaid Medical Home Model financial risk and nominal amount standards, including the 50 eligible clinician limit, to Aligned Other Payer Medical Home Models.

(b) Marginal Risk for Other Payer Advanced APMs

We are proposing to modify our definition of marginal risk when determining whether a payment arrangement is an Other Payer Advanced APM. We propose that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual

[106] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[107] *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html.*

expenditures would be used for comparison to the marginal risk rate specified in with exceptions for large losses and small losses as described in § 414.1420(d). Average marginal risk would be computed by adding the marginal risk rate at each percentage of level to determine to determine participants' losses, and dividing it by the percentage above the benchmark to get the average marginal risk. When considering average marginal risk in the context of total risk, we believe that certain risk arrangements can create meaningful and significant risk-based incentives for performance and at the same time ensure that the payment arrangement has strong financial risk components.

(c) Estimated APM Incentive Payments and MIPS Payment Adjustments

As we discuss in section VI.E.10.a. of this proposed rule, for the 2022 payment year and based on estimated Advanced APM participation during the 2020 QP Performance Period, we estimate that between 175,000 and 225,000 clinicians will become Qualifying APM Participants (QPs). As a QP for the 2022 payment year, an eligible clinician is excluded from the MIPS reporting requirements and payment adjustment and qualifies for a lump sum APM Incentive Payment equal to 5 percent of their aggregate payment amounts for covered professional services for the year prior to the payment year. We estimate that the total lump sum APM Incentive Payments will be approximately $500–600 million for the 2022 Quality Payment Program payment year.

We estimate that approximately 818,000 clinicians would be MIPS eligible clinicians for the 2020 MIPS performance period in section VI.E.10.b.(1)(b) of this proposed rule. The final number will depend on several factors, including the number of eligible clinicians excluded from MIPS based on their status as QPs or Partial QPs, the number that report as groups, and the number that elect to opt into MIPS. In the 2022 MIPS payment year, MIPS payment adjustments, which only apply to payments for covered professional services furnished by a MIPS eligible clinician, will be applied based on a MIPS eligible clinician's performance on specified measures and activities within four integrated performance categories. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments ($584 million) and positive MIPS payment adjustments ($584 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Up to an additional $500 million is also available for the 2022 MIPS payment year for additional positive MIPS payment adjustments for exceptional performance for MIPS eligible clinicians whose final score meets or exceeds the additional performance threshold of 80 points that we are proposing in section III.K.3.e.(3) of this proposed rule. However, the distribution will change based on the final population of MIPS eligible clinicians for the 2022 MIPS payment year and the distribution of final scores under the program.

2. Definitions

At § 414.1305, we are proposing to define the following terms:

- Aligned Other Payer Medical Home Model.
- Hospital-based MIPS eligible clinician.
- MIPS Value Pathway.

We are additionally proposing to revise at § 414.1305 the following term:

- Rural area.

These terms and definitions are discussed in detail in relevant sections of this proposed rule.

3. MIPS Program Details

a. Transforming MIPS: MIPS Value Pathways Request for Information

(1) Overview

In this proposed rule, we are proposing to apply a new MIPS Value Pathways (MVP) framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year to simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. As discussed in section III.K.3.a.(3)(a) of this proposed rule, the MVP framework would be implemented as early as feasible to produce a MIPS program that more effectively meets the 7 strategic objectives described in the CY 2018 QPP final rule (82 FR 53570) and drives continued progress and improvement. The MVP framework would connect measures and activities across the 4 MIPS performance categories, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients. As discussed in section III.K.3.a.(3)(a) of this proposed rule, we are proposing to apply this MVP framework to future proposals beginning with the 2021 MIPS performance period rather than the 2020 MIPS performance period, so that we can seek necessary feedback on the details of implementing this transformative approach and address additional details of the methodology in next year's rulemaking cycle. We understand that clinicians want timely performance feedback data on quality and cost to track their performance and prepare to take on risk, as required in Advanced APMs, and we intend to provide enhanced feedback and data analysis information to clinicians in the future. We plan to engage with clinician professional organizations and front-line clinicians to develop the MVPs.

(2) MVP Framework

(a) MVP Overview

We believe the MVPs will reduce the complexity of the MIPS program and the burden to participate. We intend to simplify MIPS while continuing to reward high value clinicians and help all clinicians improve care and engage patients. While we emphasized flexibility during the initial years of MIPS, we believe we must balance flexibility with a degree of standardization to hold clinicians accountable for the quality of care, identify and reward high value care, and limit clinician burden. Any solution to improving MIPS performance measurement data must account for the large variation in specialty, size, and composition of clinician practices. MVPs allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to the population they are caring for, a specialty or medical condition.

The MIPS program aims to drive quality and value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. For purposes of this discussion, we define ''value'' as a measurement of quality as related to cost, ''value-based care'' as paying for health care services in a manner that directly links performance on cost, quality, and the patient's experience of care, and ''high value clinicians'' as clinicians that perform well on applicable measures of quality and cost. We believe implementing a ''path to value'' framework will transform the MIPS program by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes, and also by promoting robust and accessible healthcare data, and interoperability.

We are targeting policies that remove APM participation barriers as clinicians

and practices prepare to take on and successfully manage risk as practices build out their quality infrastructures with components that align with the MIPS performance categories. Critical practice infrastructure components that support higher value care and readiness to join APMs include performance measurement tracking, performance improvement processes, interoperability, and data information systems that assist clinicians and practices in monitoring performance and adopting new workflows and care delivery methods. Performance measure reporting for specific populations encourages practices to build an infrastructure with capabilities to compile and analyze population health data, a critical capability in assuming and managing risk. For example, quality measurement can bolster the development of a practice infrastructure that rapidly integrates evidence-based best practices into the structure and execution of care delivery, to leverage a value-based payment, and to produce achievement of better health outcomes. Improvement Activities add a continuous clinical practice improvement component, that can help clinicians use the experiences and perspectives of front-line staff and beneficiaries to constantly assess, reconfigure, and innovate processes and systems of care delivery to better manage revenue and risk expenditure. Sensitivity to cost and experience with cost measures within a practice infrastructure is critical to managing value based payment and APM risk, while awareness of and sensitivity to cost from the beneficiary perspective (out-of-pocket cost, cost of time off from work for the patient and/or caregiver, cost of disruption of normal activities/relationships) can help support shared decision-making. An interoperability infrastructure component supports the development of a practice infrastructure that recognizes the critical role of information exchange in supporting safe, effective, and efficient coordination and transitions of care through a complex health care system, and better management of costs and risk. We believe that experience with MVPs, in which there is measurement of quality (of care and of experience of care) and cost-efficiency, continuous improvement/innovation within the practice, and efficient management and transfers of information, will remove barriers to APM participation.

We believe it is important to transform the MIPS program. We must change the current program to move along the path to value and enter a future state of MIPS, which includes a more cohesive and simplified participation experience for clinicians, increased voice of the patient, increased CMS provided data and feedback to clinicians to reduce reporting burden, and facilitated movement to Alternative Payment Models. Please refer to the on line MVP graphic (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/587/MIPS%20Value%20Pathways%20Diagrams.zip*) that provides an overview of our vision for the MIPS future state.

We have built the MIPS program recognizing the large variation in specialty, size, and composition of clinician practices, providing broad flexibility for clinician choice of measures and activities, data submission types, and individual or group level participation. Although we believe this flexibility contributed to Year 1 participation of 95 percent of MIPS eligible clinicians, including 94 percent of rural practices and 81 percent of small practices,[108] and the increase in Year 2 participation to 98 percent of MIPS eligible clinicians.[109] we also believe there is room to improve upon the program. Specifically, we believe this flexibility has inadvertently resulted in a complex MIPS program that is not producing the level of robust clinician performance information we envision providing to meet patient needs and spur clinician care improvements.

Although we have been reducing the numbers of MIPS quality measures in accordance with the Meaningful Measures initiative (*see* 83 FR 59763 through 59765), we have heard concerns from some stakeholders that MIPS presents clinicians with too much complexity and choice (for example, of several hundred MIPS and QCDR quality measures), causing unnecessary burden. As noted in the CY 2019 PFS final rule (83 FR 59720), we have received feedback that some clinicians find the performance requirements confusing, and that it is difficult for them to choose measures that are meaningful to their practices and have a direct benefit to beneficiaries.

We have also heard concerns from stakeholders that MIPS does not allow for sufficient differentiation of performance across practices due to clinician quality measures selection bias. This detracts from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality. For example, in its June 2017 Report to Congress, MedPAC documented the need for changes to the MIPS program to increase clarity, reduce complexity, and make the burden of data submission worthwhile through higher impact. MedPAC recommended in their March 2018 Report to Congress using a uniform set of population-based measures for clinicians paid by Medicare who are not participating in an advanced APM, and provided an illustrative voluntary value model that used administrative claims and patient experience surveys. The MedPAC model did not include any specific clinical specialty or practice level measures.

We believe a hybrid approach is warranted—where clinicians are measured on a unified set of measures and activities around a clinician condition or specialty, layered on top of a base of population health measures, which would be included in virtually all of the MVPs. Over time, the information clinicians and groups are required to submit will be less burdensome and more meaningful to clinicians and patients. At the same time, we intend to analyze Medicare information to provide to clinicians and patients more information to improve the health of the Medicare beneficiaries. Finally, we anticipate capturing additional information important to patients. We envision applying this framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year as we integrate new MVPs, so that eventually, all MIPS eligible clinicians would have to participate through an MVP or a MIPS APM. We seek feedback on numerous elements related to the MVPs in sections III.K.3.a.(3)(a)(i) through III.K.3.a.(3)(a)(iv) of this proposed rule.

(b) Clinician Data Feedback

Clinicians have expressed an interest in leveraging data, such as timely claims data, to track performance and inform care improvements. We understand that performance data feedback on administrative claims-based quality and cost measures would potentially assist clinicians in understanding their performance and preparing to take on risk as required in Advanced APMs. We see the critical need for data feedback and intend to provide enhanced clinician driven data feedback and analysis information under the future MVP approach. We are interested in

[108] 2017 Quality Payment Program Reporting Experience, March 20, 2019 (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/491/2017%20QPP%20Experience%20Report.pdf*).

[109] Quality Payment Program (QPP) Participation in 2018: Results at a Glance, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/586/2018%20QPP%20Participation%20Results%20Infographic.pdf*.

whether clinicians would like to see outlier analysis or other types of actionable data feedback and are seeking comments on clinician data feedback content and timing needs in section III.K.3.a.(6) of this proposed rule.

(c) Enhancing Information for Patients

The MIPS program aims to drive quality and value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. We believe that our performance measurement should focus more on patient reported measures, including patient experience and satisfaction measures and clinical outcomes measures, as we believe that clinicians can use feedback from the patient perspective to inform care improvement efforts. We believe that MVPs should include patient reported measures when feasible. We believe implementing an MVP framework will transform the MIPS program by better informing and empowering patients to make decisions about their healthcare and helping clinicians achieve better outcomes, and also by promoting robust and accessible healthcare data and interoperability.

We are dedicated to putting patients first and providing the information they need to be engaged and active decision-makers in their care. We believe that whenever feasible the MIPS program should provide meaningful information at the individual clinician level. We believe we need specific specialty information from multispecialty groups and are considering approaches to use the MVPs to require reporting relevant to multiple specialty types within a group to provide more comprehensive information for patients. We seek comment, as discussed in section III.K.3.a.(3)(b) of this proposed rule, on the best ways to identify which MVPs should be reported by multispecialty groups and how we should balance the need for information at the individual clinician level with the burden of reporting.

We are also looking at ways that we can gather and display information that is useful to patients. We are considering approaches, as discussed in section III.K.3.a.(6) of this proposed rule, to developing and reporting on Physician Compare a ''value indicator'' representing each clinician's performance on cost, quality, and the patient's experience of care. We are committed to learning more about the types of information patients use in making decisions and determining what information can be derived from the data reported or gathered as part of MIPS.

(3) Implementing MVPs

(a) MVP Definition, Development, Specification, Assignment, and Examples

We are seeking comments on the development and structure of MVPs, which would connect measures and activities across the quality, cost, and improvement activities performance categories. We believe that interoperability is a foundational element and thus would generally apply to all clinicians, regardless of the specific MVP, for whom the Promoting Interoperability performance category is required. MVPs would support our vision to measure value, reduce burden, simplify the MIPS performance measurement and scoring approaches, and ensure strong alignment of quality and cost measures. The four guiding principles we would use to define MVPs are:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.

2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.

3. MVPs should include measures that encourage performance improvements in high priority areas.

4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

We request public comments on the MVP guiding principles noted above. We also request public comments on how to best develop MVPs to allow for the development of better comparative data, reduce burden, and provide valuable information to patients and clinicians.

MVPs would be organized around clinician specialty or health condition and encompass a set of related measures and activities. We intend to ensure equity in MVPs so that clinicians are not advantaged by reporting one MVP over another (for example, in terms of reporting burden and scoring), but also want to include measures that have opportunities for improvement. Bundling quality and cost measures and improvement activities that are highly correlated in addition to the measures from the Promoting Interoperability performance category will strengthen clinical improvement and streamline reporting. As an initial step, we are proposing to require that beginning with the 2020 Call for measures process, MIPS quality measure stewards must link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. We refer readers to section III.K.3.c.(1)(d)(i) of this proposed rule for further discussion of our proposal.

We believe that MVPs can be created with significant input from clinicians and specialty societies, to ensure that measures and activities within MVPs are relevant and important to clinician practices. The most significant change with MVPs is that eventually all MIPS eligible clinicians would no longer be able to select quality measures or improvement activities from a single inventory. Instead, measures and activities in an MVP would be connected around a clinician specialty or condition (*see* examples of potential MVPs in section III.K.3.a.(3)(a) of this proposed rule). We also intend that a population health measure/administrative claims-based measures would be layered into measuring the quality performance category, applied whenever there is a sufficient case minimum. Cost measures would be specific to the MVP and applied only when a clinician or group meets the case minimum. MVPs could potentially also allow for the use of multi-category measures, should they be developed, as clinician feedback has indicated there is an interest in the development of these performance measures that simultaneously address two or three of the MIPS performance categories (83 FR 35932).

As outlined in our goals for the Promoting Interoperability performance category in section III.K.3.c.(4)(b), we look to continue MIPS alignment with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, where appropriate. We envision Promoting Interoperability performance category measures, which focus on the meaningful use of certified EHR technology to support care coordination and electronic health information exchange, to be a key structural part of any MVP. Initially, there would be a uniform set of Promoting Interoperability measures in each MVP, though in future years we may consider customizing the Promoting Interoperability measures in each MVP. At this time, we are not considering making modifications to the Promoting Interoperability performance category as it becomes incorporated into the MVP framework. We believe that interoperability is a foundational element and thus would apply to all

clinicians, regardless of MVP, for whom the Promoting Interoperability performance category is required. However, we are seeking comment on how the Promoting Interoperability performance category could evolve in the future to meet our goal of greater cohesion between the MIPS performance categories. We believe that eligible clinicians could benefit from more targeted approaches to assessing the meaningful use of health IT which aligns with clinically relevant MVPs cutting across the MIPS performance categories. One approach we could consider is exploring which measures for the Promoting Interoperability performance category would be directly aligned with measures in other MIPS performance categories. For instance, many improvement activities are enabled by, or could be enabled by, the use of certified health IT including care coordination and patient engagement through health information exchange. We could develop Promoting Interoperability measures which measure the use of health IT in conducting these improvement activities, while relevant quality measures for a given MVP could assess quality outcomes associated with these activities. We invite comment on these concepts, as well as other suggestions for how the Promoting Interoperability performance category can be better integrated into MVPs.

We also believe that improvement activities can be closely linked to the quality and cost measures, to encourage improvement on performance of those measures. As clinicians report on a stable set of measures, there is an inherent incentive to change practice patterns to increase performance on required quality and cost measures. We are seeking feedback in section III.K.3.a.(3)(a)(ii) of this proposed rule on how many improvement activities should be included in an MVP and how much flexibility there should be in selecting improvement activities. We also seek feedback on the extent to which improvement activities in MVPs should be specialty-specific, condition-focused improvement activities, versus other areas relevant to the practice such as patient experience and engagement, team-based care, and care coordination. More generally, we would like to understand how improvement activities are used to improve quality measure performance within clinical practices.

Our goal in using MVPs is to standardize which measures and activities are reported, both to reduce clinician burden and better measure performance among comparable clinicians while appropriately recognizing the variability of clinician practices and potentially reducing barriers to moving into APMs, which generally measure quality for their respective participants using the same quality measures. We can also look to APMs for methods of linking quality and value measurement as APMs are designed around value, and address quality, cost, and care redesign for a specific population.

We realize that there are numerous issues on which we need stakeholder feedback to fully implement MVPs, but we believe the basic approach could start in the 2021 MIPS performance period/2023 MIPS payment year. We are requesting public comments on the following issues:

- How to construct MVPs, including approach, definition, development, specification, and examples referenced at III.K.3.a.(3)(a)(i) of this proposed rule;
- How to select measures and activities for MVPs, referenced at III.K.3.a.(3)(a)(ii) of this proposed rule;
- How to determine MVP assignment, referenced at III.K.3.a.(3)(a)(iii) of this proposed rule; and
- How to transition to MVPs, referenced at III.K.3.a.(3)(a)(iv) of this proposed rule.

To begin implementing MVPs, we are proposing to define a MIPS Value Pathway at § 414.1305 as a subset of measures and activities specified by CMS. We anticipate that MVPs may include, but would not be limited to, administrative claims-based population health, care coordination, patient-reported (which may include patient reported outcomes, or patient experience and satisfaction measures), and/or specialty/condition specific measures. MVPs would include a population health quality measure set, and measures and activities such that all 4 MIPS performance categories are addressed, and each performance category would be scored according to its current methodology. Under MVPs, the current MIPS performance measure collection types would continue to be used to the extent possible, but these details need to be worked out and would be addressed in next year's rulemaking cycle. We request comment on performance measure collection types for MVPs in section III.K.3.a.(3)(a)(ii) of this proposed rule.

We provide 4 illustrative examples of MVPs in Table 34. The examples demonstrate how MVPs could be constructed and show the types of measures and activities that might be assigned to each MVP. We present 2 example MVPs for primary care and general medicine, which includes preventive health and diabetes prevention and treatment, as well as two example MVPs for procedural specialties, which include major surgery and general ophthalmology. Within our sample MVPs, we present no more than 4 quality or cost measures or improvement activities for each performance category. However, the exact number of measures and activities could vary across MVPs. We envision that we would no longer require the same number of measures or activities for all clinicians but focus on what is needed to best assess the quality and value of care within a particular specialty or condition. To assign quality measures in these examples, we prioritized outcome and patient reported measures, non-topped out measures, and eCQMs. To assign cost measures, we reviewed existing measures and selected those that fit into the MVP topic. We also included population health measures, which are described in section III.K.3.a.(4) of this proposed rule. We reviewed and selected relevant improvement activities that align with the quality and cost measures in the MVPs. We are interested in feedback on whether improvement activities should focus on improving the quality and cost measures within an MVP or be much broader including any improvement activities that are relevant to the practice. We are interested in exploring approaches to leverage participation in specialty accreditation programs, such as the American College of Surgeons' Commission on Cancer accreditation program. Since specialty accreditation programs may promote the evaluation and improvement of clinical processes and care, we believe it may be appropriate to incorporate attestation to participation in such programs as an approach to satisfy the requirements of the improvement activities performance category, for example, by proposing to specify such participation as an improvement activity for all MVPs or specific MVPs in future rulemaking. To align with the statutory requirement that a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice be given the highest potential score for the improvement activities performance category, we have also included an illustrative example under the Preventive Health MVP to depict how patient-centered medical homes or comparable specialty practices would receive credit under the improvement activities performance category. We anticipate that all measures in the Promoting Interoperability performance category would initially be applicable to

each MVP unless an exclusion applies; thus, we assigned all Promoting Interoperability measures to all MVPs. We welcome comments on the examples of possible MVPs and on options for encouraging interoperability to promote improvements in care and performance measurement results.

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TABLE 34: Examples of Possible MIPS Value Pathways

MVP Example	Quality Measures	Cost Measures	Improvement Activities**	Promoting Interoperability
Preventive Health	• Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID: 226) • Osteoarthritis: Function and Pain Assessment (Quality ID: 109) Adult Immunization Status, proposed (Quality ID: TBD) • Controlling High Blood Pressure (Quality ID: 236) • PLUS: population health administrative claims quality measures (e.g., all-cause hospital readmission)	• Total Per Capita Cost (TPCC_1) • Medicare Spending Per Beneficiary (MSPB_1)	• Chronic Care and Preventive Care for Empaneled Patients (IA_PM_13) • Engage patients and families to guide improvement in the system of care (IA_BE_14) • Collection and use of patient experience and satisfaction data on access (IA_EPA_3)	• All measures in Promoting Interoperability***
Diabetes Prevention and Treatment	• Hemoglobin A1c (HbA1c) Poor Care Control (>9%) (Quality ID: 001) • Diabetes: Medical Attention for Nephropathy (Quality ID: 119) • Evaluation Controlling High Blood Pressure (Quality ID: 236) • PLUS: population health administrative claims quality measures	• Total Per Capita Cost (TPCC_1) • Medicare Spending Per Beneficiary (MSPB_1)	• Glycemic Management Services (IA_PM_4) • Chronic Care and Preventative Care Management for Empaneled Patients (IA_PM_13)	• All measures in Promoting Interoperability ***
Major Surgery	• Unplanned Reoperation within the 30-Day Postoperative Period (Quality ID: 355) • Surgical Site Infection (SSI) (Quality ID: 357) • Patient-Centered Surgical Risk Assessment and Communication (Quality ID: 358) • PLUS: population health administrative claims quality measures	• Medicare Spending Per Beneficiary (MSPB_1) • Revascularization for Lower Extremity Chronic Critical Limb Ischemia (COST_CCLI_1) • Knee arthroplasty (COST_KA_1)	• Use of patient safety tools (IA_PSPA_8) • Implementing the use of specialist reports back to referring clinician or group to close referral loop (IA_CC_1) OR • Completion of an Accredited Safety or Quality Improvement Program (IA_PSPA_28)	• All measures in Promoting Interoperability ***
General Ophthalmology	• Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation (Quality ID: 012) • Diabetic Retinopathy: Communication with Physician Managing Ongoing Diabetes Care (Quality ID: 019)	• Medicare Spending Per Beneficiary (MSPB_1) • Routine Cataract Removal with Intraocular Lens Implantation (COST_IOL_1)	• Implementation of improvements that contribute to more timely communication of test results (IA_CC_2) • Comprehensive eye exam (IA_AHE_7)	• All measures in Promoting Interoperability ***

	• Cataracts: 20/40 or Better Visual Acuity within 90 days Following Cataract Surgery (Quality ID: 191) • PLUS: population health administrative claims quality measures			

*Measures and activities selected for illustrative purposes and are subject to change.

**Recognized or certified patient-centered medical homes or comparable specialty practices could participate in an MVP and still receive credit for the improvement activity performance category.

***See Table 41 in section III.K.3.c.(4)(d)(ii)(B) for the Promoting Interoperability measures.

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The examples in Table 34 are illustrative only, but we envision that we would start building MVPs by reviewing the existing specialty measure sets for the quality performance category. However, some specialty measure sets contain multiple conditions or concepts, so we do not envision a one-to-one correlation between the specialty measure sets and MVPs.

We anticipate that eventually many clinicians would have at least one relevant MVP, while other clinicians may have several. In particular, we believe that multispecialty groups will have more than one relevant MVP. If technically feasible, we would like to establish a methodology that allows us to identify and assign in advance the relevant MVP(s) for MIPS eligible clinicians or groups and require the clinician or groups to report on those MVPs. In addition, we would consider folding MIPS APM measures and activities into MVPs and develop an assignment process as described in the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), applying a hierarchy which applies APM entity final scores over any other final score.

We are interested in feedback on the level of choice that should be provided to clinicians for MVP selection or selection of measures and activities within an MVP. We have heard from some clinicians that they would prefer a clear list of what specific measures and activities they have to perform versus various options of measures and activities to report. We believe a methodology in which clinicians are informed of the potential MVP(s) that are available for a clinician or group to report on would be simpler to communicate and allow for both clinicians and CMS to better understand what measures and activities should be submitted. We are considering assigning MVPs to clinicians and groups, if technically feasible, starting with the 2021 MIPS performance period as MVPs become available and would propose the MVP assignment process in next year's rulemaking cycle. We are considering the feasibility of potential data sources or methods to use to assign clinicians to an MVP, such as the specialty reported on Part B claims or use of Medicare Provider Enrollment, Chain, and Ownership System (PECOS) data. We seek comment on circumstances when we should allow clinicians and groups to select an alternative MVP, rather than the one or more MVP(s) assigned. Those clinicians and groups who would not have an applicable MVP for the 2021 MIPS performance period would continue the current process of reporting MIPS measures and activities for the 4 performance categories. As an alternate option, we could consider self-assignment of MVPs for the 2021 MIPS performance year period with the intention of assigning MVPs to clinicians starting in the 2022 MIPS performance period. Clinicians have had flexibility in choosing MIPS quality measures to date, and we expect retaining a degree of choice will be welcome by some clinicians as we transition to MVPs. We anticipate that the number of available MVPs would increase in the 2022 MIPS performance period and subsequent years, which would allow for MVP assignment for all clinicians and groups. We are requesting public comments on whether clinicians and groups should be able to self-select an MVP or if an MVP should be assigned. If assigned, we are requesting comments on the best way to assign an MVP—should it be based on place of service codes, specialty designation on Part B claims, or in the case of groups, should the assigned MVP(s) be based on the specialty designation of the majority of clinicians in the group, specific services, or other factors?

We are considering approaches to assigning MVPs to multispecialty groups to be inclusive of the different specialties providing care to patients. Alternatively, we are also considering approaches that would allow for self-assignment of MVPs where multispecialty groups would select one or more MVPs that are most relevant to the specialty mix within the group.

We believe the approach to MVPs must find the right balance between having a sufficient number of MVPs to allow clinicians to report on measures and activities relevant to their practices, without developing so many MVPs that reporting is diluted and developing benchmarks is hampered. For example, we would not want to have several MVPs for the same specialty or condition because then only a portion of the MIPS eligible clinicians are reporting on the quality measures, which limits the ability to develop benchmarks and to make meaningful comparisons of clinicians.

In addition, due to differences in collection types for many quality measures, we can have multiple benchmarks for each measure, which further complicates the ability to make meaningful comparisons. The diversity of MVPs and collection types of quality measures may hamper MIPS in meeting its vision of effectively measuring and comparing performance, providing meaningful feedback, incentivizing quality, and providing patients with enhanced information for making clinician selection choices.

We believe Electronic Clinical Quality Measures (eCQMs) have the potential to decrease reporting burden within MVPs. Stakeholders have previously supported eCQMs and the associated reduction in information collection burden under a variety of CMS programs and have made recommendations for improving eCQMs (83 FR 41593). While we support the reporting of eCQMs through the MIPS program, we have identified certain eCQMs for removal. We may propose to remove measures that are extremely topped out, duplicative of a new measure, or are low-adopted measures that have been in the program for 2 or more years. We refer readers to Table Group C of Appendix 1 for the list of previously finalized quality measures proposed for removal in the 2022

payment year. Through our Call for Measures process, and related measure development resources, such as the CMS BluePrint at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* and the CMS Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2018-MDP-annual-report.PDF*, we encourage stakeholders to submit electronically specified measures for CMS consideration. We recognize that there are challenges related to development of new eCQMs and technical aspects, however, we are interested in eCQMs and their potential use in MVPs to reduce reporting burden. For further discussion of strategies for reducing burden associated with reporting eCQMs, refer to the Office of the National Coordinator for Health Information Technology draft report, *Strategy of Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* (*https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf*).

We are interested in feedback on our timeframe for transitioning into MVPs. We anticipate that we will have a number of MVPs proposed for the 2021 MIPS performance period. However, we understand that there are many operational considerations that should be taken into account. We request comment on approaches to accelerate the development and implementation of MVPs, as well as any comments on the optimal timeline for transition.

Over the next year, we may consider convening public forum listening sessions, webinars, and office hours, or use additional opportunities such as the pre-rulemaking measures process to understand what is important to clinicians, patients, and stakeholders, as we develop MVPs.

(i) Request for Feedback on MVP Approach, Definition, Development, Specification, Assignment, and Examples

We are requesting public comments on how MVPs are developed.

- We have stated MVP guiding principles regarding reducing burden, providing comparative performance data to patients and caregivers, encouraging improvements in high priority areas, and reducing barriers to APM participation. Should we consider other guiding principles as we define and develop MVPs?
- In addition to gathering feedback from this proposed rule, how do we best engage stakeholders in the development of MVPs?

++ How would stakeholders like to be engaged in MVP development? What type of outreach would be the most effective in gathering the voice of the patient in the MVP concept and the selection of measures?

++ For quality measures, should we initiate a ''Call for MVPs'' that aligns with policies developed for the Call for Measures and Measure Selection Process, described in section III.K.3.c.(1)(d)(i) of this proposed rule, or should we use an approach similar to the process used to solicit recommendations for new specialty measure sets and revisions to existing specialty measure sets, as described in section III.K.3.c.(1)(d)(i) of this proposed rule?

- How should MVPs be organized, for example, around specialties and areas of practice? Alternatively, should MVPs be organized to address a small number of public health priorities, for example, HIV care or healthcare-associated infections? Please refer to Table 34 for examples of specialty MVPs.
- How can we ensure the right number of MVPs that result in comparable and comprehensive information that is meaningful for the clinicians, patients, and the Medicare program? How should we limit the number of MVPs? Should each specialty have a single MVP?
- How should we build on Promoting Interoperability, a foundational component of MVPs, as we link the 4 categories within MVPs? How could we best promote the use of health information technology and interoperability in practices not yet using electronic health records?
- How can MVPs effectively reduce barriers to clinician movement into APMs, such as practice inexperience with cost measurement and lack of readiness to take on financial risk?

(ii) Request for Feedback on Selection of Measures and Activities for MVPs

We are requesting public comments on the selection of measures and activities in MVPs.

- Please provide feedback on the Example MVPs in Table 34 that might help us in our development of additional MVPs. In the example, there is a list of required quality measures and improvement activities. Should MVPs include only required measures and activities, or a small list of quality measures and activities from which clinicians could choose what to report?
- What criteria should be used for determining which measures and activities should be included in an MVP, such as prioritizing outcome, high priority and patient-reported measures; limiting the number of quality measures to 4, including only cost measures that align with quality measures, etc.? How should performance categories and associated measures and activities be linked (*e.g.,* quality measures aligned with cost measures)?
- For the quality measures, should clinicians and groups be required to use a certain collection type (eCQMs, MIPS Clinical Quality Measures [MIPS CQMs], CMS Web Interface, or QCDR measures) in order to have a comparable data set in the MVPs? What will clinicians' administrative burden be for changing to a new, specific collection type for a measure, for example, changing from MIPS CQM to an eCQM?
- Currently we have similar measures addressing the same clinical topic, with different collection types (for example, eCQMs, MIPS CQMs, QCDR measures, etc.) that have different specifications and separate benchmarks. What methodology could be used to develop a single benchmark when multiple collection types are used? Another solution we may consider to ensure comparable measure data and request feedback on is to require a single collection type. Please also refer to section III.K.3.a.(3)(c) of this proposed rule for more about QCDR measures in MVP.
- Should improvement activities in MVPs be restricted to activities directly related to the clinical outcomes of the quality and cost measures in the MVP, for example, IA_PM_4 ''Glycemic Management Services'' for a Diabetes MVP, or should the selection of improvement activities include cross-cutting activities, for example, IA_EPA_1 Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record? Should attestation to participation in a specialty accreditation program satisfy the improvement activities performance category requirements for an MVP? Should this option be available for all MVPs or limited to specific MVPs, such as particular specialties for which accreditation programs are available? What criteria should we use to identify such programs?

(iii) Request for Feedback on MVP Assignment

We are requesting public comments on how we determine the most relevant MVP for clinicians and groups.

• How should we identify which MVP(s) are most appropriate for a clinician? Would it be based on the clinician specialty as identified in PECOS or the specialty reported on claims? If we assign an MVP, how would we be able to verify the applicability of the assigned MVP?

• Should we provide clinicians and groups more than one applicable MVP and allow clinicians to select their MVP(s) from those identified? What tools would be helpful for clinicians to understand what MVP(s) might be applicable, for example NPI lookup, measure shopping cart, etc.?

(iv) Request for Feedback on Transition to MVPs

We are requesting public comments on how we transition to MVPs beginning with the 2021 MIPS performance period/2023 MIPS payment year.

• What practice level operational considerations do we need to account for in the timeline for implementing MVPs?

(b) Adjusting MVPs for Different Practice Characteristics

(i) Small and Rural Practices Participation in MVPs

We realize that reporting burden associated with MIPS can vary by the size of the practice. Under current quality performance category submission requirements, the same number of measures and activities are reported regardless of group size, which may impose a high burden on small practices, given their very limited resources to address program requirements. Another challenge for small and rural group practices is the lack of a sufficient case mix to report measures that can be reliably scored, which makes the use of a set of administrative claims-based quality and cost measures especially challenging. Policies for submission of measures and scoring for MVPs may need to account for these challenges. As we move towards MVPs, we will be evaluating other policies (such as eligibility requirements, including the low-volume threshold (§ 414.1305), submission requirements (§ 414.1325), scoring (§ 414.1380), etc.) for further modification.

We also want to adopt policies that reduce barriers for small practices transitioning into APMs where available. We have seen that there are innovative small groups including over 83,000 clinicians (in small practices with less than 4 clinicians) that joined the Transforming Clinical Practice Initiative (TCPI) Practice Transformation Networks (PTNs), who followed tailored, targeted and disciplined practices, and transitioned into advanced practices, for example, practices that met APM readiness milestones in their practice assessments and considers itself ready for migrating into an alternative based payment arrangement. Presently, there are a total of 60,311 clinicians that have transitioned to APMs. Within TCPI, these APMs, in alignment with the CMS Healthcare Payment Learning and Action Network APM Framework, are Category 3 (APMs Built on Fee For-Service Architecture) and Category 4 (Population-Based Payment) payment arrangements.[110] We understand that there are certain factors that enable clinicians to make the transition into APMs, including the readiness to take on additional risk, the ability to use timely feedback to make practice changes, willingness to engage in peer-to-peer learning and community of practices, accessing technical assistance, and an ability to invest in infrastructure to enable care improvement and efficiencies. Developing MVPs in alignment with APM measures may assist small practices by providing experience with some APM requirements, and enhanced CMS feedback data on quality and cost performance can help clinicians make practice improvements and increase readiness to participate in Advanced APMs.

(A) Request for Feedback on Small and Rural Practices Participation in MVPs

We are requesting public comments on policies to support small practices.

• How should we structure the MVPs to provide flexibility for small and rural practices and reduce participation burden? What MVP related policies could best assist small and/or rural groups when submitting measures and activities? Should we have alternate measures and activities submission requirements for small and/or rural practices? For example, should small and/or rural practices be allowed to report fewer measures and activities within an MVP?

• How can we mitigate challenges small and/or rural practices have in reporting? What types of technical assistance would be most helpful to help small and/or rural practices to have successful participation in MVPs?

• How can we reduce barriers to small and/or rural groups to transitioning into APMs, such as lack of information on performance on quality and cost measures and limited resources? What approaches could help small practices transition to MVPs?

(ii) Multispecialty Practices Participation in MVPs

At § 414.1305, a group is defined as a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN. Section 1848(q)(1)(D)(ii) of the Act requires that the MIPS process, for assessing group practices, must to the extent practicable reflect the range of items and services furnished by the MIPS eligible clinicians in the group practice involved. Multispecialty groups, especially those groups with a large number of clinicians, often provide an array of services that may not be captured in a single set of measures or in a single MVP. We have also heard similar concerns from stakeholders. In the CY 2019 PFS proposed rule (83 FR 35891), we acknowledged one of the overarching themes we have heard from stakeholders is that we make an option available to groups that would allow a portion of a group to report as a separate sub-group on measures and activities that are more applicable to the sub-group and be assessed and scored accordingly based on the performance of the sub-group. We solicited comment on specific options and questions for implementation of sub-group level reporting in future years in response to some stakeholders who requested the ability to report quality data for a portion of a TIN so that they can report measures and activities more relevant to their practice. However, as we noted in the CY 2019 PFS final rule (83 FR 59742), because there are numerous operational challenges with implementing such a sub-group option, we did not propose any such changes to our established reporting policies regarding the use of a sub-group identifier. In the CY 2018 Quality Payment Program final rule (82 FR 53593), we stated that in future rulemaking we intend to explore the feasibility of establishing group-related policies that would permit participation in MIPS at a sub-group level and create such functionality through a new identifier.

As we consider this transition to MVPs, we are seeking public comment on whether we can use the MVP approach as an alternative to sub-group reporting to more comprehensively capture the range of the items and services furnished by the group practice. This approach could address

[110] *http://hcp-lan.org/workproducts/apm-framework-onepager.pdf.*

stakeholder concerns about reporting on meaningful measures which are related to their practice without adding undue operational and data collection burden associated with creating and maintaining identifiers for sub-groups. Under this approach, multispecialty groups would report on multiple assigned or selected MVPs, where assignment or selection of MVPs would be proposed in future rulemaking, at the group level. Depending on how the MVPs are then combined and scored at the group level, this may eliminate the need for groups to create sub-TIN identifiers and apply eligibility criteria at the sub-TIN level.

We are interested in developing criteria to identify which MVPs are applicable to multispecialty groups and whether or not we should require the reporting of multiple MVPs. Such an approach would provide patients with better information about care and services provided by multispecialty groups. If we require reporting on more than one MVP, we may consider putting a cap on the number of MVPs, measures, and activities to ensure there is no undue burden for multispecialty practices. We are interested in how to improve both large and small multispecialty group reporting of MIPS performance measures and activities.

(A) Request for Feedback on Multispecialty Practices Participation in MVPs

We are requesting public comments on MVP policies for multispecialty practices.

- We are considering a requirement in future years that multiple specialty types within a group report relevant MVPs to provide more comprehensive information for patients. We are seeking comment on whether we can use the MVP approach as an alternative to sub-group reporting to more comprehensively capture the range of the items and services furnished by the group practice. For example, would it better for multispecialty groups to report and be scored on multiple MVPs to offer patients a more comprehensive picture of group practice performance or for multispecialty groups to create sub-groups which would break the overall group into smaller units which would independently report MVPs? How should we balance the need for information for patients on clinicians within the multispecialty practice with the clinician burden of reporting?
- What criteria should be used to identify which MVPs are applicable to multispecialty groups? For example, should it be based on the number or percentage of clinicians from the same specialty in the group? Should a group be able to identify which clinicians will report which MVP?
- Should there be a limit on the number of MVPs that could be reported by a multispecialty group?
- What mechanisms should be used to assess a group's specialty composition to determine which MVPs are applicable? For example, would groups need to submit identifying information to assure that measure MVPs aligned with the number or percent of clinicians of different specialties within a group? Is there information (such as specialty as identified in PECOS or the specialty reported on claims) we could leverage to ensure the appropriateness of MVPs for groups?
- In section III.E.1.c. of this proposed rule, we seek public comment on whether to align Shared Savings Program quality reporting requirements and quality scoring methodology with MIPS. As MIPS transitions to MVPs and addresses multispecialty practices, What MVP policies should be applied to MIPS APM participants?

(c) Incorporating QCDR Measures Into MVPs

As part of our path to value focus, we want participation in MIPS to become more meaningful to patients and clinicians. QCDR measures are not included in our proposals for annual rulemaking and are separate from MIPS measures, which are finalized through the rulemaking process. We refer readers to section III.K.3.g.(2)(c) of this rule for discussion of proposals to strengthen QCDR measures.

Both QCDR and MIPS measures are currently available for clinicians to choose from to fulfill the requirements under the quality performance category. We have been encouraged by clinician adoption of QCDRs and their measures in the time since the Quality Payment Program became operational. Clinicians are interested and dedicated to quality improvement and have worked with QCDRs to foster an innovative and flexible approach to quality measurement and improvement. We continue to believe that participation in these QCDR quality improvement programs is a strong sign of a commitment to quality and improvement.

While this environment has encouraged a flexible approach to quality improvement, we believe it has also contributed to confusion and lack of consistency in measurement as our list of MIPS measures is greatly outpaced by the number of QCDR measures.

As noted in section III.K.3.a.(3)(a) of this rule, we are considering a major change in the submission requirements for MIPS eligible clinicians beginning with the 2021 MIPS performance period. We believe that a smaller and more focused set of quality measures assembled into an MVP, integrated with cost measures and improvement activities, will better serve the program by reducing the complexity of identifying how to participate in the program for clinicians, improving our ability to compare clinicians, and improving beneficiaries' ability to identify high quality practices. A proliferation of measures that are different for every modest variation in practice is contrary to such a goal. Therefore, we need to consider the role of QCDR measures in such an environment.

(i) Request for Feedback on Incorporating QCDR Measures Into MVPs

We are requesting public comments on policies for how QCDR measures would be used in MVPs:

- Should QCDR measures be integrated into MVPs along with MIPS measures, or should they be limited to specific MVPs consisting of only QCDR measures? How do we continue to encourage clinicians to use QCDRs under MVPs?

(d) Scoring MVP Performance

As we are proposing to apply the MVP framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year, we may propose scoring changes in future rulemaking. We anticipate that our basic approach to scoring measures and activities would remain stable with MVPs. In particular, we believe that both quality and cost performance category measures within MVPs would be scored using a scale of 0 to 10 and performance assessed by comparing to a benchmark, using the current approach to calculate benchmarks. We refer readers to sections III.K.3.c.(1)(b) and III.K.3.c.(2)(a) of this proposed rule for further discussion on how the quality and cost performance categories respectively contribute to the final score. For quality measures, we anticipate, when possible, that MVPs would use a single benchmark for each measure and that all clinicians and groups in the MVP would be compared against the same standard. In addition, we would no longer need special scoring policies and bonuses to incent selection of certain measures because clinicians would be required to report

all measures and activities in the MVP. Finally, we could align improvement scoring for quality and cost performance measures, because clinicians would use a stable set of measures, allowing for comparison year-to-year at the measure level. We believe the standardized sets of measures in MVPs would enable us to smoothly integrate new measures and collect data to develop robust benchmarks before scoring these measures on performance. We believe that scoring under the MVPs will potentially reduce barriers to clinicians' movement into APMs, which generally score their respective participants using the same quality measures and strongly align quality and cost measures.

We believe that small practices will continue to face challenges with meeting case minimums that allow reliable scoring of quality measures. Our scoring policies will need to take into account that not all measures reported by small practices can be scored based on the case mix available for reporting.

We anticipate that the underlying scoring framework for scoring improvement activities referenced in III.K.3.d.(1)(d) of this proposed rule would not change for clinicians; however, there could be the potential to better link cost and quality measures and the associated improvement activities. We do not anticipate that the underlying framework for scoring Promoting Interoperability measures referenced in III.K.3.d.(1)(e) of this proposed rule would change because of the introduction of the MVP framework. Promoting Interoperability is a foundational component of MVPs. Scoring policies may be developed as more details of the implementation of MVPs are developed.

We would also consider proposing scoring policies to evaluate MVPs holistically, making sure that scoring across MVPs is equitable and that clinicians are not unfairly advantaged by reporting a specific MVP. We seek feedback on scoring policies that will help us create level comparability across MVPs.

Additionally, if we propose in the future to allow or require multispecialty groups to submit more than a single MVP of measures and activities, we would need to develop scoring policies to fairly score such groups.

(i) Request for Feedback on Scoring MVP Performance

We are requesting comments on the following:

- What scoring policies can be simplified or eliminated with the introduction of MVPs? For example, we may consider eliminating scoring available for 2021 MIPS performance period providing a 3-point floor for each submitted measure that can be reliably scored (83 FR 59842). Additionally, we may consider eliminating the scoring bonuses available for the 2021 MIPS performance period for submitting high-priority measures and use of CEHRT to support quality performance category submissions (83 FR 59850 to 59852). Are there other scoring policies that could be simplified or eliminated?
- We seek feedback on scoring policies that will help us create level comparability across MVPs. Are there approaches we should take to create equity across MVPs and across clinician types, for example, that regardless of the number of measures and activity, no single MVP would ''outperform'' others? For example, should there be an MVP adjustment added to the performance category scores?
- How should we score multispecialty groups reporting multiple MVPs? Should scores be consolidated for a single group score or scored separately (and with separate MIPS payment adjustments) for specialists within the group? Alternatively, should we have an aggregate score for the multispecialty group?

(4) MVP Population Health Quality Measure Set

Section 1848(q)(2)(C)(iii) of the Act provides that the Secretary may use global measures, such as global outcome measures, and population-based measures, for purposes of the MIPS quality performance category. Currently, the MIPS program has one administrative claims-based quality measure, the all-cause readmission measure, which is calculated and scored for groups with 16 or more clinicians that meet a 200-patient case minimum (81 FR 77300). In the CY 2019 PFS proposed rule (83 FR 59719), we discussed our intent to use the Meaningful Measures Initiative within the Quality Payment Program to help address clinician reporting burden and improve patient outcomes through MIPS performance measurement. The Meaningful Measures Initiative represents an approach to quality measures that fosters operational efficiencies, reduces costs associated with collection and reporting burden, and produces quality measurement focused on meaningful outcomes. As we apply the Meaningful Measures framework within MIPS to reduce reporting burden and strengthen the use of measures that matter to patients and clinicians, we are considering how to implement a population health administrative claims-based quality measure set.

Global or population quality measures calculated from administrative claims-based quality data can be used as a foundational measure set to help improve patient outcomes, reduce data reporting burden and costs, better align clinician quality improvement efforts, and increase alignment with APMs and other payer performance measurement. The April 2019 Health Care Payment Learning & Action Network's *Roadmap for Driving High Performance in Alternative Payment Models* (*https://hcp-lan.org/workproducts/roadmap-final.pdf*), intended as a tool to begin identifying promising practices for implementing successful APMs, points out that:

- Payers use HEDIS® quality measures along with administrative claims-based quality measures, such as preventable admissions and readmissions, in designing ACOs and primary care model APMs
- Providers are more likely to participate in APMs if the required measures align with measures they already track (*see* Roadmap page 19), and
- There is room for improvement in the area of quality measurement to meaningfully assess health and quality-of-life outcomes (*see* Roadmap page 60).

We believe an administrative claims-based quality measure set consisting of a small number of quality measures focused on outcomes and intermediate outcomes can move MIPS towards population health measurement.

We have heard from some stakeholders that we should drive quality measurement towards a set of population-based outcome measures. We believe increasing the number of population health measures that utilize administrative claims data in the MIPS program while reducing the number of required condition and specialty specific measures would reduce the burden associated with quality reporting. However, we recognize that the use of an administrative claims-based quality measure set would entail certain tradeoffs. These measures historically have been applicable to primary care clinicians, with less relevance for some specialists. They have also been limited to Medicare fee for service patients, excluding other payer patients, and therefore, have not provided a picture of a clinician's entire practice and patient base. In addition, administrative claims-based quality measures require a large sample to produce reliable results, which presents challenges in a clinician program that allows for participation by individuals

and groups with relatively few patients in a specific measure denominator. However, given the opportunity to reduce burden (because clinicians do not need to report the administrative claims-based quality measures themselves), apply measures across different clinician types, focus on important public health priorities, and reduce barriers to APM participation, we want to find ways to effectively use administrative claims-based population health quality measures in MIPS.

We are working on multiple fronts to find the best and most appropriate measures for the MIPS program. For example, we are working with measure stewards on technical specifications to ensure the measures are reliable and broadly applicable to MIPS eligible clinicians. We intend to have the measures reviewed by a consensus-based entity, for example, the National Quality Forum (NQF) Measure Applications Partnership (MAP). We have looked at the use of administrative claims-based quality measures in the Shared Savings Program and the Comprehensive Primary Care Plus (CPC+) model to identify examples of measures that could be included as MIPS measures. As one example, in addition to an all-cause readmission measure (similar to the one currently used in MIPS), the Shared Savings Program has a measure (ACO—38), the All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions, that we are in the process of adapting and testing for the MIPS program. In section III.K.3.c.(1)(d)(ii) of this proposed rule, we are proposing to add All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure to MIPS for the 2021 MIPS performance period. The Shared Savings Program also has a risk adjusted measure, (ACO—43), the Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91), which assesses the risk adjusted rate of hospital discharges for acute PQI conditions with a principal diagnosis of dehydration, bacterial pneumonia, or urinary tract infection among ACO assigned Medicare fee-for-service (FFS) beneficiaries 18 years and older. In section III.E.1.b., we recognize that the measure steward, AHRQ, has made ''substantive'' change to the measure and propose to redesignate ACO—43 to a pay-for-reporting measure for the 2020 and 2021 performance years, while seeking comment on other approaches including developing historic benchmarks.

As we work to improve and develop a foundational population health quality measure set, we are reviewing measures that we could propose in future rulemaking. We are reviewing whether it would be appropriate to add a measure similar to the ACO—43 Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) to MIPS. We are also reviewing two risk adjusted utilization measures that are included in the CPC+ Model Quality and Utilization Measure Set for the 2019 Performance Period for potential inclusion in the MIPS program: The HEDIS® Acute Hospital Utilization (AHU) (this is the inpatient hospital utilization measure in CPC+ Model that was updated by NCQA in 2018); and the HEDIS® Emergency Department Utilization (EDU).[111] These measures assess the risk-adjusted ratio of observed-to-expected acute inpatient and observation stay discharges during the measurement year reported by surgery, medicine and total among members 18 years of age and older. These measures are currently specified for health plans, but we intend to work with the measure steward, NCQA, for appropriateness for the MIPS program.

Clinicians raised concerns in response to previously proposed administrative claims-based quality measures. These concerns included measure reliability and applicability case size, attribution, risk adjustment, application at the clinician or group level, and degree of actionable feedback for improvements (81 FR 77130 through 77136). We finalized use of the all-cause readmission measure but limited its applicability to groups of 16 or more clinicians with a minimum of 200 cases to mitigate some of the concerns. We did not finalize the proposed AHRQ Acute Conditions Composite and Chronic Conditions Composite measures (81 FR 28192 and 28447). Our intention is to address the technical challenges as we test the Ambulatory Sensitive Condition Acute Composite measure and present to a consensus-based entity (for example NQF) to ensure the measure is reliable. We seek feedback on additional steps to ensure the measure addresses the concerns noted above.

Clinician feedback also called for the examination of potential sociodemographic status risk adjustment for administrative claims-based quality measures. Please refer to section III.K.3.d.(2)(a) of this proposed rule for information on our approach to accounting for risk factors in MIPS, including the complex patient bonus which was finalized for the 2020 MIPS payment year (82 FR 53771 through 53776), as well as plans to take into consideration a second report by ASPE expected in October 2019 on accounting for risk factors in quality, resource use and other measures in Medicare. We are proposing to continue the complex patient bonus in MIPS and would continue to assess the need for and effectiveness of such a scoring adjustment to ensure fair performance comparisons between clinicians.

In summary, we plan to increase the use of global and population based administrative claims-based quality measures as we develop a population health quality measure set and are outlining our proposal to add at least one additional administrative claims-based quality measure starting in the 2021 MIPS performance period in section III.K.3.c.(1)(d)(ii) of this proposed rule.

(a) Request for Feedback on Population Health Quality Measure Set

We are requesting public comments on the use of a population health quality measure set.

- In addition to the quality measures described above, are there specific administrative claims-based quality measures we should consider, including, but not limited to, any that assess specialty care that are specified and/or tested at the clinician/group practice level?
- We would like to balance the desire for quality measures specific to a clinical practice with a reduction in administrative burden for submission. Should administrative claims-based quality measures be used to replace some of the reporting requirements in the quality performance category? For example, if two additional administrative claims-based quality measures were added to MVPs should we reduce the required quality measures by 1 measure for each of the MVPs?
- In addition to testing, what other information or methods should be used to mitigate concerns about administrative claims-based quality measure reliability, applicability, and degree of actionable feedback for clinician performance improvement? What concerns should be prioritized?

(5) Clinician Data Feedback

Clinicians have expressed an interest in leveraging data to track performance and inform care improvements. We see the critical need for data feedback and

[111] The Acute Hospital Utilization and Emergency Department Utilization measures and specifications were developed by the National Committee for Quality Assurance (''NCQA'') under the Performance Measurements contract (HHSM–500–2006–00060C) with CMS and are included in HEDIS® with permission of CMS. HEDIS is a registered trademark of NCQA.

intend to provide enhanced clinician driven data feedback and analysis information under the future MVP approach. We understand that performance data feedback on administrative claims-based quality and cost measures would potentially assist clinicians in understanding their performance and preparing to take on risk as required in Advanced APMs. We are interested in whether clinicians would benefit from receiving feedback on administrative data that is available to us, such as information on the services that their patients receive or information on the clinician's volume of services in comparison to their peers to determine if the clinician is an outlier. Clinicians may also benefit from timely actionable clinical data feedback from registries, and we have proposed to enhance data feedback requirements for QCDRs and registries in sections III.K.3.g.(2)(a)(iii) and III.K.3.g.(3)(a)(ii) respectively of this proposed rule. We also understand the need for timely data feedback and are seeking comments on clinician data feedback content and timing needs.

(a) Request for Feedback on Clinician Data Feedback

We are requesting public comments on the Clinician Feedback.

- We would like to provide meaningful clinician feedback on administrative claims-based quality and cost measures. As clinicians and groups move towards joining APMs, is there particular data from quality and cost measures that would be helpful?
- Would it be useful to clinicians to have feedback based on an analysis of administrative claims data that includes outlier analysis or other types of actionable data feedback? What type of information about practice variation, such as the number of procedures performed compared to other clinicians within the same specialty or clinicians treating the same type of patients, would be most useful? What level of granularity (for example, individual clinician or group performance) would be appropriate?

(6) Enhanced Information for Patients

(a) Patient Reported Measures

We intend to incorporate more patient reported outcomes and care experience measures into MVPs. We want to learn how patient reported information is being effectively used in the field to improve care to assist patients with clinician selection and to incentivize high value care. We believe that feedback from the patient perspective can inform care improvement efforts as clinicians assess patient reported feedback to identify ways to elevate quality of care.

MIPS currently includes patient reported measures, including optimal asthma control and measures for functional status assessment following hip and knee replacements, and other patient reported measures are being added. We recognize current limitations with the availability of patient reported measures. Patient reported measures are often specific to a clinical condition or procedure, and we do not have measures that are available or applicable to the majority of clinicians in the MIPS program. The Consumer Assessments of Healthcare Providers and Systems (CAHPS) for MIPS survey, a patient experience survey, is offered to group practices as an optional quality measure and is a high-weighted improvement activity. Section III.K.3.c.(1)(c)(i) of this proposed rule discusses initiatives to expand the information collected in the CAHPS for MIPS survey.

We have assessed additional approaches to gathering information on experience and satisfaction from work both within and outside of the health care environment. The Robert Wood Johnson Foundation working with Patients Like Me, a health information sharing website for patients, has provided guidance on what should be measured through a publication entitled ''Development of a Conceptual Framework of ''Good Healthcare'' from The Patient's Perspective'' [112] We understand that some organizations such as Patients Like Me are working with patients throughout the measure development process to enhance their ability to capture information that is useful to patients. Outside of healthcare, many industries are approaching the measurement of satisfaction as a business priority. Service industries have pioneered single question ''surveys'' asked at each encounter to learn if they are meeting customer expectations and satisfying their customers, that could include a question about the service provided or whether the assistance provided addressed their problems. We are interested in how information from single question or brief surveys to measure the quality of patient experience and satisfaction with health care delivery could be better incorporated into MVPs.

[112] *https://patientslikeme_posters.s3.amazonaws.com/2017_Development%20of%20a%20Conceptual%20Framework%20of%20%E2%80%9CGood%20Healthcare%E2%80%9D%20from%20The%20Patient%E2%80%99s%20Perspective.pdf.*

(i) Request for Feedback on Patient Reported Measures

We are requesting public comments on enhancing the patient voice in MVPs. Specifically, we seek comment on:

- What patient experience/satisfaction measurement tools or approaches to capturing information would be appropriate for inclusion in MVPs? How could current commercial approaches for measuring the customer experience outside of the health care sector (for example, single measures of satisfaction or experience) be developed and incorporated into MVPs to capture patient experience and satisfaction information?
- What approaches should we take to get reliable performance information for patients using patient reported data, in particular at the individual clinician level? Given the current TIN reporting structure, are there recommendations for ensuring clinician level specific information in MVPs? Should clinicians be incentivized to report patient experience measures at the individual clinician level to facilitate patients making informed decisions when selecting a clinician, and, if so, how?
- How should patient-reported measures be included in MVPs? How can the patient voice be better incorporated into public reporting under the MVP framework, in particular at the individual clinician level?

(b) Publicly Reporting MVP Performance Information

We believe implementing a path to value will transform our healthcare system by empowering well-informed patients to make decisions about their healthcare and helping clinicians achieve better outcomes. As we consider publicly reporting MVP performance information, we want to ensure that patients have information that is important and useful, which we believe includes information on clinician performance on cost, quality, patient experience, and satisfaction with care.

Currently, all MIPS quality measure information is displayed on Physician Compare clinician and group profile pages at the individual quality measure level. User testing with patients and caregivers has shown that performance on certain individual quality measures is particularly useful for selecting clinicians for their healthcare needs. However, testing has also shown that patients and caregivers are interested in a single overall rating called a ''value indicator'' for a clinician or group when making comparisons across groups or clinicians. To date, a ''value indicator'' to compare the performance of a

clinician or group has not been possible due to the current approach in which clinicians can select from an inventory of measures across a variety of collection types and activities. Since clinicians are not all reporting on the same quality measures, we have been unable to develop direct overall comparisons under our public reporting standards. However, we believe that MVPs, in which clinicians of a particular specialty are held accountable for a uniform set of quality and cost measures, would better allow for such comparisons.

Related to the MVP approach, we seek comment on the types of clinician performance information we should include in the display for a single ''value indicator''. As we think about value and information that is important to patients, we want to incorporate measurement of cost, quality, and patient experience and satisfaction in a way that is meaningful to patients. We have heard that Medicare patients and caregivers greatly desire information such as a value indicator, to help make decisions about their healthcare. We seek comment on whether displaying an overall indicator for the MVP for a clinician or group would be useful for patients' making healthcare decisions. We refer readers to the Public Reporting on Physician Compare at section III.K.3.h.(4) of this proposed rule for additional considerations for publicly reporting these types of information such as a value indicator, patient narratives, and patient reported outcome measures.

(i) Request for Feedback on Publicly Reporting MVP Performance Information

We seek feedback on approaches to publicly reporting MVP performance information:

- What considerations should be taken into account if we publicly report a value indicator, as well as corresponding measures and activities included in the MVPs?
- If we develop a value indicator, what data elements should be included? For example, should all reported measures and activities be aggregated into the value indicator?
- How would a value indicator, based on information from MVPs, be useful for patients making health care decisions?
- What methods of displaying MVP performance information should we consider other than our current approach to using star ratings for quality measure information on clinician profile pages?
- What factors should be considered to ensure publicly reported MVP information is comparable across relevant clinicians and groups?

b. Group Reporting

For previous discussions of the policies for group reporting, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77070 through 77073) and the CY 2018 Quality Payment Program final rule (82 FR 53592 through 53593). In addition, for previous discussions of the policies for group reporting related to the Promoting Interoperability performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77214 through 77216) and the CY 2018 Quality Payment Program final rule (82 FR 53687).

It has come to our attention that the regulation text regarding group reporting at § 414.1310(e)(3) through (5) contains duplicative language. Specifically, it is duplicative of the regulation text at § 414.1310(e)(2)(ii) through (iv). To avoid redundancy and potential confusion, we are proposing to remove § 414.1310(e)(3) through (5). In addition, we have noticed that previously established policies for group reporting with regard to the Promoting Interoperability performance category (81 FR 77214 through 77216, 82 FR 53687) are not reflected in the regulation text for group reporting at §§ 414.1310(e)(2)(ii) and for virtual groups at § 414.1315(d)(2). In the CY 2017 Quality Payment Program final rule (81 FR 77215), we stated that to report as a group for the Promoting Interoperability performance category, the group will need to aggregate data for all of the individual MIPS eligible clinicians within the group for whom they have data in CEHRT. In an effort to more clearly and concisely capture our existing policy for the Promoting Interoperability performance category, we are proposing to revise §§ 414.1310(e)(2)(ii) and 414.1315(d)(2. Specifically, we are proposing to revise § 414.1310(e)(2)(ii) to state that individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.

Similarly, we are proposing to revise § 414.1315(d)(2) to state that solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

We request comments on these proposals.

c. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

We refer readers to § 414.1330 through § 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

In the CY 2020 PFS proposed rule, we seek to:

- Propose to weigh the quality performance category at 40 percent for the 2022 MIPS payment year, 35 percent for the 2023 MIPS payment year, 30 percent for the 2024 MIPS payment year as described in § 414.1330(b)(4), (5), and (6); The associated increases to the weight of the cost performance category are discussed in section III.K.3.c.(2) of this proposed rule;
- Seek comment on adding narratives to the CAHPS for MIPS survey and on whether the survey should collect data at the individual eligible clinician level;
- Propose to increase the data completeness criteria to 70 percent for the 2022 MIPS payment year as described in § 414.1340(b)(3);
- Propose to require MIPS quality measure stewards to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible;
- Seek comment as to whether we should consider realigning the MIPS quality measure update cycle with that of the eCQM annual update process;
- Propose changes to the MIPS quality measure set as described in Appendix 1 of this proposed rule, including: Substantive changes to existing measures, addition of new measures, removal of existing measures, and updates to specialty sets.
- Seek comment on whether we should increase the data completeness threshold for extremely topped out quality measures that are retained in the program due to limited availability of measures for a specific specialty and potential alternative solutions in addressing extremely topped out measures;
- Propose to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in

the program for 2 consecutive CY performance periods;

- Propose to remove quality measures from the program in instances where the measure steward or owner refuses to enter into a user agreement with CMS; and
- Request information on a Potential Opioid Overuse Measure.

(b) Contribution to Final Score

Under § 414.1330(b)(2), we state that performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year, and under § 414.1330(b)(3), we state that performance in the quality performance category will comprise 45 percent of a MIPS eligible clinician's final score for MIPS payment year 2021. Section 1848(q)(5)(E)(i)(I) of the Act, as amended by section 51003(a)(1)(C)(i) of the Bipartisan Budget Act of 2018, provides that 30 percent of the final score shall be based on performance for the quality performance category, but that for each of the 1st through 5th years for which MIPS applies to payments, the quality performance category performance percentage shall be increased so that the total percentage points of the increase equals the total number of percentage points that is based on the cost performance category performance is less than 30 percent for the respective year. As discussed in section III.K.3.c.(2) of this proposed rule, we propose to weight the cost performance category at 20 percent for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. Accordingly, we are proposing to add § 414.1330(b)(4) to provide that performance in the quality performance category will comprise 40 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year. In addition, we are proposing at § 414.1330(b)(5) to state that the quality performance category comprises 35 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year. Lastly, we are proposing to add § 414.1330(b)(6) to state that the quality performance category comprises 30 percent of a MIPS eligible clinician's final score for the 2024 MIPS payment year and future years. We believe that being transparent in how both the quality and cost performance category weights will be modified over the next few years of the program will allow stakeholders to better plan and anticipate how eligible clinicians and group scores will be calculated in future years as we incrementally make changes to the final score weights. We seek comment on our proposals to incrementally reduce the weight of the quality performance category as we gradually increase the weight of the cost performance category. Specifically, the quality performance category will comprise 40 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year, 35 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year and future years.

(c) Quality Data Submission Criteria

(i) Submission Criteria for Groups Electing To Report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

We are not proposing any changes to the established submission criteria for the CAHPS for MIPS Survey. We refer readers to the CY 2019 PFS final rule (83 FR 59756) for previously finalized policies regarding the CAHPS for MIPS survey.

Although we are not making any proposals in regard to the CAHPS for MIPS survey this year, we are interested in feedback to add to the survey, in future years, specific to a solicitation of comments we previously requested to expand the survey to add narratives in the CY 2018 Quality Payment Program final rule (82 FR 53630). Currently, the CAHPS for MIPS survey is available for only groups to report under the MIPS. The patient experience survey data that is available on Physician Compare is highly valued by patients and their caregivers as they evaluate their health care options. However, in user testing with patients and caregivers over the last several years, the users regularly request more information from patients like them in their own words, and to publicly report narrative reviews of individual clinicians and groups. User testing further indicates that patients want patient-generated information when selecting a clinician. Since the CAHPS for MIPS survey is only at the group level, we are also interested in feedback related to collection of data on patient experiences from individual clinicians, which would be new data for CMS and consequently new data to publicly report to patients and caregivers. Including data at the individual level is of interest to CMS as we have heard this is valuable to patients and caregivers in making decisions related to their health care. See section III.K.3.h. of this proposed rule where we are seeking comment on public reporting considerations on the Physician Compare website for adding patient narratives in future rulemaking.

Through efforts such as the Patients Over Paperwork initiative and MyHealthEData initiative (*https://www.cms.gov/newsroom/press-releases/trump-administration-announces-myhealthedata-initiative-put-patients-center-us-healthcare-system*), we are dedicated to putting patients first and empowering patients to have the information they need to be engaged and active decision-makers in their care. We are also mindful that a patient is a health care consumer for whom aspects of the health care delivery experience, such as wait times or how a clinician interacts with patients, may factor into a patient's decision to select a clinician. We believe that measuring patient experience can help inform patient decision-making and considered previous government efforts to measure experience, such as the President's Management Agenda—OMB Circular No. A–11 section 280—Managing Customer Experience and Improving Service Delivery (*https://www.whitehouse.gov/wp-content/uploads/2018/06/s280.pdf*). Specifically, the OMB Circular No. A–11 section 280.7 references how should customer experience be measured in the federal government. At a minimum, the federal government customer experience should be measured in seven domains: [113]

- *Overall:* (1) Satisfaction; (2) Confidence/Trust.
- *Service:* (3) Quality.
- *Process:* (4) Ease/Simplicity; (5) Efficiency/Speed; (6) Equity/Transparency.
- *People:* (7) Employee Helpfulness.

While the CAHPS for MIPS survey is an assessment of clinicians within a group, we are looking at ways to enhance that feedback to ensure the customer (patient) experience is being measured in such a way that data from the CAHPS for MIPS survey can be used in healthcare decision making. We are seeking comments on the above referenced seven domains and if additional elements, questions, or context should be added to the current CAHPS for MIPS survey (available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/459/2019%20CAHPS%20for%20MIPS%20Survey_Sample%20Copy.pdf*), or if these domains should be used to measure individual clinicians if a new instrument was developed to gather that data and share the feedback with

[113] President's Management Agenda (2018)—OMB Circular No. A–11 section 280—Managing Customer Experience and Improving Service Delivery (*https://www.whitehouse.gov/wp-content/uploads/2018/06/s280.pdf*).

patients to make decisions about their healthcare.

For considerations as we prepare for future policies and rulemaking, we are also seeking comment on:

• Measures that would expand the information collected in the CAHPS for MIPS survey, including a question regarding the patients' overall experience and satisfaction rating with a recent health care encounter. Patients value the ''voice'' of other patients and want information that helps to choose their clinicians, and whether they would recommend the clinician, group, office or facility to their family and friends, as detailed in section III.K.3.a. of this rule. Several versions of the CAHPS survey, including the CAHPS Clinician & Group Survey 3.0, do have a question regarding the patients' rating of a clinician. We refer readers to the Agency for Healthcare Research and Quality's website on CAHPS Clinician and Group Survey for additional information at *https://www.ahrq.gov/cahps/surveys-guidance/cg/index.html*. We currently do not collect and display information from a single question about the patients' satisfaction or experience. Patient experience measures provide a more objective assessment of health care quality, since satisfaction may change frequently based on subjective expectations. The CAHPS for MIPS survey has traditionally focused on measures of patient experience.

• Method for collecting this type of information from patients and caregivers and if a web, paper, phone, or email based survey would be preferred? Currently the CAHPS for MIPS survey is only administered through paper and phone based methods.

• Should a tool be developed to collect information about individual clinicians? Or should this information be kept at the group level only? Currently patient experience data is only available through the CAHPS for MIPS survey, and this survey does not collect information on individual clinicians.

• Should this data be collected at a pilot level first, provided that such an approach is consistent with our statutory authority, so that we learn from this data before fully implementing broader across the program? If so, we seek comments regarding the framework and implementation criteria of a pilot.

In addition, we are seeking comment on the value of using narrative questions, inviting patients to respond to a series of questions in free text responding to open ended questions and describing their experience with care. Patients can write a response in their own words. We would build from work done by AHRQ to develop a Narrative Elicitation Protocol (*https://www.ahrq.gov/cahps/surveys-guidance/item-sets/elicitation/index.html*), which is a set of open-ended questions that prompt patients to tell a clear and comprehensive story about their experience with a clinician. Narratives from patients about their health care experiences can provide a valuable complement to standardized survey scores, both to help clinicians understand what they can do to improve their care and to engage and inform patients about differences among clinicians. Five questions underwent initial item development for the Clinician & Group CAHPS Survey, focusing on the patient's relationship with the clinician, patient expectations, how the expectations were met, what went well, and what could have been better. We believe patients will be interested in this information to make informed decisions about their healthcare. In section III.K.3.c.(1), we seek comment on how the free text questions might be scored as part of the Quality Payment Program. We seek comment on the value of collecting and displaying information from narrative questions, and whether stakeholders have concerns with the potential burden involved with drafting narrative responses. We also are interested in understanding whether clinicians would find this information useful in improving the care they provide to beneficiaries

As we continue learning about what patient experience data and format is most usable to patients, caregivers, and clinicians we plan to conduct additional item development and testing of implementation processes at CMS. Information gathered from these activities, along with comments received from this rule will be taken into consideration as we consider future policies for future rulemaking, using a human-centered design approach where applicable.

(ii) Data Completeness Criteria

We refer readers to the CY 2019 PFS final rule (83 FR 59756 through 59758) where we discuss and codified at § 414.1340 finalized data completeness criteria.

As described in the CY 2018 Quality Payment Program final rule (82 FR 53632 through 53634), we anticipated on proposing increases to the data completeness thresholds for data submitted on quality measures (QCDR measures, MIPS CQMs, eCQMs, and Medicare Part B Claims measures) in future years of the program. For MIPS payment years 2019 and 2020, the data completeness threshold was finalized and retained at 50 percent. We provided an additional year for individual MIPS eligible clinicians and groups to gain experience with MIPS before increasing the data completeness threshold for MIPS payment year 2021, for which the data completeness threshold was finalized at 60 percent.

We continue to believe it is important to incorporate higher data completeness thresholds over time to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures. We previously noted concerns raised about the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinicians' ability to participate and perform well under MIPS. We want to ensure that an appropriate yet achievable data completeness is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the 2017 performance period of MIPS, as described in Table 35, we believe that it is feasible for eligible clinicians and groups to achieve a higher data completeness threshold.

TABLE 35—CY 2017 DATA COMPLETENESS RATES FOR MIPS INDIVIDUAL ELIGIBLE CLINICIANS, GROUPS, AND SMALL PRACTICES

Average data completeness rate—individual eligible clinician	Average data completeness rate—groups	Average data completeness rate—small practices
76.14	85.27	74.76

With the support of the data in Table 35, we propose to amend § 414.1340 to add paragraph (a)(3) to adopt a higher data completeness threshold for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMS must submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2020 MIPS performance period. As we observe increased use of electronic methods of reporting, such as EHRs and QCDRs, we believe it is important to continue to increase the data completeness threshold, and are interested in stakeholder feedback on an appropriate incremental approach, and on how this incremental increase should be implemented. In crafting our proposal, we also considered other thresholds, such as a higher threshold of 80 percent, but have concerns that requiring every clinician or group to adhere to an increased data completeness threshold that is increased by such a large amount may be considered burdensome to clinicians. We are requesting comments on other considerations or possible thresholds we should consider, such as whether we should increase the data completeness threshold to 80 percent to provide for more accurate assessments of quality.

We have received inquiries regarding perceived opportunities to selectively submit MIPS data that are unrepresentative of a clinician or group's performance, suggesting that certain parties may have misunderstood the intent of our incremental approach to the data completeness thresholds, and may not fully appreciate their current regulatory obligations. As stated in §§ 414.1390(b) and 414.1400(a)(5), all MIPS data submitted by or on behalf of a MIPS eligible clinician, group, or virtual group must be certified as true, accurate and complete. MIPS data that are inaccurate, incomplete, unusable, or otherwise compromised can result in improper payment. Using data selection criteria to misrepresent a clinician or group's performance for a performance period, commonly referred to as ''cherry-picking,'' results in data that are not true, accurate, or complete. Accordingly, we propose to further amend § 414.1340 to add a new subsection (d) to clarify that if quality data are submitted selectively such that the data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5). We believe this clarification will emphasize to all parties that the data submitted on each measure is expected to be representative of the clinician's or group's performance.

We continue to strongly urge all MIPS eligible clinicians to report on quality measures where they have performed the quality actions with respect to all applicable patients.

We would like to note that we are not proposing any changes to § 414.1340(c), which states that groups submitting quality measures data using the CMS Web Interface or a CMS-approved survey vendor to submit the CAHPS for MIPS survey must submit data on the sample of the Medicare Part B patients CMS provides, as applicable. We refer readers to the CY 2019 PFS final rule (83 FR 59756 through 59758) for additional discussion of this requirement. Table 36 describes the data completeness requirements by collection type.

TABLE 36—SUMMARY OF DATA COMPLETENESS REQUIREMENTS AND PERFORMANCE PERIOD BY COLLECTION TYPE FOR THE 2020 MIPS PERFORMANCE PERIOD

Collection type	Performance period	Data completeness
Medicare Part B claims measures	Jan 1–Dec 31	70 percent sample of individual MIPS eligible clinician's, or group's Medicare Part B patients for the performance period.
QCDR measures, MIPS CQMs, and eCQMs.	Jan 1–Dec 31	70 percent sample of individual MIPS eligible clinician's, or group's patients across all payers for the performance period.
CMS Web Interface measures	Jan 1–Dec 31	Sampling requirements for the group's Medicare Part B patients: populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries.
CAHPS for MIPS survey measure	Jan 1–Dec 31	Sampling requirements for the group's Medicare Part B patients.

(d) Selection of MIPS Quality Measures

(i) Call for Measures and Measure Selection Process

In the CY 2019 PFS final rule (83 FR 59758 through 59761), we discuss the importance of classifying measures by meaningful measure areas, and updates to the definition of a high priority measure. We refer readers to the CY 2019 PFS final rule for additional details.

Furthermore, in the CY 2018 Quality Payment Program final rule (82 FR 53635 through 53637), we state that quality measure submissions submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual Call for Measures, which is further described through the CMS Pre-Rulemaking website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.html*. The annual Call for Measures process allows for eligible clinician organizations and other relevant stakeholder organizations to identify and submit quality measures for consideration. Presumably, stakeholders would not submit measures for consideration unless they believe the measures are applicable to clinicians and can be reliably and validly measured. Through the annual convention of the consensus-based entity, stakeholders are given the opportunity provide input on whether or not they believe measures are applicable to clinicians, feasible, scientifically acceptable, reliable, and valid at the clinician level. We intend to continue to submit future MIPS quality measures to the consensus-based entity, as appropriate, and consider the recommendations provided as part of the comprehensive assessment of each measure considered for inclusion in MIPS. In addition, we must go through notice and comment rulemaking to consider stakeholder feedback prior to

finalizing the annual list of quality measures. Furthermore, as required by statute, new measures must be submitted to an applicable specialty-appropriate, peer-reviewed journal. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53636) for additional details on the peer-reviewed journal requirement.

In the CY 2018 Quality Payment Program final rule (82 FR 53636), we requested stakeholders apply the following set of considerations when submitting quality measures for possible inclusion in MIPS:

- Measures that are not duplicative of an existing or proposed measure.
- Measures that are beyond the measure concept phase of development, with a strong preference for measures that have completed reliability, feasibility, and validity testing.
- Measures that are outcomes-based rather than process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnoses and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address of patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.
- Measures that address significant variation in performance and are not considered topped out.
- Measures that are specified as a collection type other than Medicare Part B Claims. We strongly encourage measure stewards to keep this in mind as they develop and submit measures for consideration.

We also encourage stakeholders to consider electronically specifying their quality measures, as eCQMs, in order to encourage clinicians and groups to move towards the utilization of electronic reporting, as we believe electronic reporting will increase timeliness and efficiency of reporting by replacing manual data entry. In addition to the aforementioned considerations, when considering quality measures for possible inclusion in MIPS, we are proposing that beginning with the 2020 Call for Measures process, MIPS quality measure stewards would be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards will be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities as a part of the Call for Measures process. We recognize there are instances where costs measures are not available for all clinician specialties or that improvement activities may not be associated with a given quality measure. However, we believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities. We seek comments on this proposal.

Furthermore, previously finalized MIPS quality measures can be found in the CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). The new MIPS quality measures proposed for inclusion in MIPS for the 2020 performance period and future years are found in Table Group A of Appendix 1 of this proposed rule.

In addition to the individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with choosing quality measures that are most relevant to their scope of practice. The following specialty measure sets have been excluded from this proposed rule because we did not propose any changes to these specialty measure sets: Pathology, Electro-Physiology Cardiac Specialist, and Interventional Radiology. Therefore, for the finalized Pathology specialty measure set, we refer readers to the CY 2019 PFS final rule corrections notice (84 FR 566). In addition, we refer readers to the CY 2018 Quality Payment Program final rule for the finalized Electro-Physiology Cardiac Specialist specialty measure set (82 FR 53990) and the finalized Interventional Radiology specialty measure set (82 FR 54098 through 54099). Our proposals for modifications to existing specialty sets and new specialty sets can be found in Table Group B of Appendix 1 of this proposed rule. Specialty sets may include: New measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Please note that the proposed specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 18, 2019,[114] we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for Year 4 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2019 PFS final rule, the 2019 Measures Under Consideration list, and provides recommendations to add or remove the current MIPS quality measures from existing specialty sets, or provides recommendations for the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and those recommendations that we agree with are being proposed within this proposed rule.

In addition, MIPS quality measures with proposed substantive changes can be found in Table Groups D and DD of Appendix 1 of this proposed rule. As discussed in Table DD of this proposed rule, we have determined based on extensive stakeholder feedback that the 2018 CMS Web Interface measure numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention measure is inconsistent with the intent of the CMS Web Interface version of this measure as modified in the CY 2018 Quality Payment Program final rule (82 FR 54164) and is unduly burdensome on clinicians. Moreover, due to the current guidance, we are unable to rely on historical data to benchmark the measure. Therefore, for the 2018 MIPS performance period and 2020 MIPS payment year, we are excluding the Web Interface version of this measure from MIPS eligible clinicians' quality scores in accordance with § 414.1380(b)(1)(i)(A)(2). Beginning with reporting for the 2019 MIPS performance period and 2021 MIPS payment adjustment, we are proposing in Table DD of this proposed rule to update the CMS Web Interface measure numerator guidance. To the extent that this proposed change constitutes a change to the MIPS scoring or payment methodology for the 2021 MIPS payment adjustment after the start of the 2019 MIPS performance period, we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to modify the measure as proposed in Table DD of this proposed rule because the current guidance is inconsistent with the intent of the CMS Web Interface version of this measure, as modified in the CY 2018 QPP final rule, and unduly burdensome on clinicians. If this modification is finalized as proposed, we expect that we would be

[114] Listserv messaging was distributed through the Quality Payment Program listserv on January 18th, 2019, titled: ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets for the Quality Performance Category and/or Revisions to the Existing Specialty Measure Sets for the Quality Performance Category for the 2020 Program Year of Merit-based Incentive Payment System (MIPS).''

able to benchmark and score the CMS Web Interface version of this measure for the 2019 MIPS performance period and 2021 MIPS payment adjustment.

As discussed in section III.E.1.b of this proposed rule, changes to the CMS Web Interface measures for MIPS that are proposed and finalized through rulemaking would also be applicable to ACO quality reporting under the Medicare Shared Savings Program. As discussed in Table Group A of Appendix 1 of this proposed rule, we propose to add 1 new measure to the CMS Web Interface in MIPS. Furthermore, as discussed in Table Group C of Appendix 1 of this proposed rule, we are proposing to remove 1 measure from the CMS Web Interface in MIPS. If finalized, groups reporting CMS Web Interface measures for MIPS would be responsible for reporting the finalized measure set, inclusive of any finalized measure removals and/or additions. We refer readers to the Appendix 1 of this proposed rule for additional details on the proposals related to changes in CMS Web Interface measures.

On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive as described above. We note that the current cycle of measure updates to MIPS quality measures is separate from the eCQM annual update process. An overarching timeline of milestones related to eCQMs available at *https://ecqi.healthit.gov/ecqm-annual-timeline*. We seek stakeholder comment as to whether we should consider realigning the measure update cycle with that of the eCQM annual update process. We note if the update cycles were to align, quality measure specifications updates would be gathered earlier in the year, which may pose an issue when considerations need to be given, but not limited to: Updates to clinical guidelines and changes in NQF endorsement status.

In addition, we refer readers to the CY 2019 PFS final rule (83 FR 59759) for additional details on reporting requirements of eCQM measures. Furthermore, in section III.D. of this proposed rule, we propose to generally align the CY 2020 eCQM reporting requirements for the eligible professionals participating in the Medicaid Promoting Interoperability Program with the MIPS eCQM reporting requirements. We refer readers to section III.D. of this proposed rule for additional details and criteria on the Medicaid Promoting Interoperability Program proposals.

(ii) Global and Population-Based Measures

Section 1848(q)(2)(C)(iii) of the Act provides that the Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the quality performance category. We believe the purpose of global and population-based measures is to encourage systemic health care improvement for the populations being served by MIPS eligible clinicians. In addition, as described in the CY 2017 Quality Payment Program final rule (81 FR 77130 through 77136), we believe that all MIPS eligible clinicians, including specialists and subspecialists, have a meaningful responsibility to their communities, which is why we chose to focus on population health and prevention measures for all MIPS eligible clinicians. It is important to note that an individual's health relates directly to population and community health, which is an important consideration for quality measurement in MIPS and in general. Furthermore, we have heard from stakeholders that we should drive quality measurement towards a set of population-based outcome measures to publicly report on quality of care.

In addition, we believe including additional administrative claims based measures in the program will reduce the burden associated with quality reporting. Quality measures that are specified through the administrative claims collection type do not require separate data submission to CMS. Administrative claims measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims. For these reasons, in Table Group AA of Appendix 1 of this proposed rule, we are proposing the inclusion of a population health based quality measure (The All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure) beginning with the 2021 MIPS performance period. We are proposing this measure with a delayed implementation until the 2021 performance period of MIPS, to allow for time to work through operational factors of implementing the measure. Factors include allowing for time for the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure to go through the Measures Under Consideration and Measures Application Partnership (MAP) process that is typically applied for all MIPS quality measures. We refer readers to section III.K.3.a.(4) of this proposed rule for additional information on our interest to include other global and population-based measures in future years of MIPS, which we envision would include the modification of the submission requirements under the quality performance category.

(iii) Topped Out Measures

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53637 through 53640), where we finalized the 4-year timeline to identify topped out measures, after which we may propose to remove the measures through future rulemaking. We also refer readers to the 2019 MIPS Quality Benchmarks' file that is located on the Quality Payment Program resource library (*https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html*) to determine which measure benchmarks are topped out for 2019 and would be subject to the scoring cap if they are also identified as topped out in the 2020 MIPS Quality Benchmarks' file. We note that the final determination of which measure benchmarks are subject to the topped out cap would not be available until the 2020 MIPS Quality Benchmarks' file is released in late 2019.

In the CY 2019 PFS final rule (83 FR 59761 through 59763), we finalized that once a measure has reached extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle. However, we would also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to the Agency).

As an example, four of the five quality measures within the pathology specialty set have been identified as extremely topped out in the 2019 benchmarking file. However, we believe that it is important to retain these pathology specific measures in the MIPS quality measure set to ensure that pathologists have a sufficient number of quality measures to report. Quality measures identified as extremely topped out are considered to have high, unvarying performance where no meaningful room for improvement can be identified, and are only identified as such through data received during the submission period. We have heard from stakeholders that

some measures tend to appear topped out or extremely topped out due to clinicians' ability to select measures they expect to perform well on, and because of this, the data we receive is not actually representative of how clinicians perform across the country on these metrics. For this reason, we seek comment on whether we should increase the data completeness threshold for quality measures that are identified as extremely topped out, but are retained in the program due to the limited availability of quality measures for a specific specialty. In addition, we seek comment on potential alternative solutions in addressing extremely topped out measures.

We encourage stakeholders to continue their measure development efforts in creating new pathology specific quality measures that can demonstrate a meaningful performance gap, thereby offering opportunities for quality improvement. We also encourage pathologists to consider reporting on pathology specific QCDR measures through a CMS-approved QCDR available for the 2020 performance period. A list of CMS-approved QCDRs for the 2020 performance period will be made available on or prior to January 1, 2020, and will be posted on the Quality Payment Program resource library at *https://qpp.cms.gov/about/resource-library*.

In addition, in the CY 2019 PFS final rule (83 FR 59761 through 59763), we also finalized our policy to exclude QCDR measures from the topped out measure timeline. When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.

(iv) Removal of Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we discussed removal criteria for quality measures, including that a quality measure may be considered for removal if the Secretary determines that the measure is no longer meaningful, such as measures that are topped out. Furthermore, if a measure steward is no longer able to maintain the quality measure, it would also be considered for removal. In addition, in the CY 2019 PFS final rule (83 FR 59763 through 59765), we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set, we believe incrementally removing non-high priority process measures through notice and comment rulemaking is appropriate. We refer readers to the CY 2019 PFS final rule (83 FR 59763 through 59765) for details on the previously established criteria to remove measures.

In addition to previously established measure removal criteria, we have observed instances where MIPS quality measures have had low reporting rates year over year, and have made it difficult for some MIPS quality measures to achieve a benchmark. As a result, these measures have resulted in clinicians receiving no more than 3 points for each measure that is unable to meet benchmarking criteria. For these reasons, we are proposing to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. We believe that a time period of 2 consecutive CY performance periods is appropriate, as we anticipate that any newly finalized measure would need more than 1 CY performance period in order to observe measure reporting trends, and believe that 2 consecutive CY performance periods allows for sufficient time to monitor reporting volumes. We will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome) prior to determining whether to remove the measure. Removing measures with this methodology ensures that the MIPS quality measures available in the program are truly meaningful and measureable areas, where quality improvement is sought and that measures that are low reported for 2 consecutive CY performance periods are removed from the program. We believe low reported measures can point to that the measure concept does not provide meaningful measurement to most clinicians. If the measure has too few reporting clinicians and does not meet the case minimum and reporting volumes, but other considerations favor retaining the measure, we may consider keeping the MIPS quality measure, with the caveat that the measure steward should have a plan in place (prior to approval of the measure) to encourage reporting of the measure, such as education and communication or potentially measure specification changes. We seek comments on this proposal. In addition, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of quality measures and rationales for removal. We have continuously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. We believe our proposal to remove the quality measures outlined in Table Group C will lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to remove measures should occur through an iterative process that will include an annual review of the quality measures to determine whether they meet our removal criteria.

We have heard from stakeholders concerns on removing measures and the need for more notice before a measure is removed. Therefore, we are interested in what factors should be considered in delaying the removal of measures. For example, we have not heard concerns from stakeholders that selection bias may be impacting low reporting rates, we are interested if this is something we should consider, and how we could determine when low-reporting is due to selection bias versus instances where the measure is not a meaningful metric to the majority of clinicians who would have reported on the measure otherwise. We seek comment on whether we should delay the removal of a specific quality measure by a year, for any of the MIPS quality measures identified for removal. We also request feedback on which quality measure's removal should be delayed for a year, and why.

Furthermore, when we finalize measures to be a part of the MIPS quality measure inventory for a given MIPS payment year, we generally intend that the measures will be available for reporting by or on behalf of all MIPS eligible clinicians since MIPS is a government quality reporting program. It has come to our attention that certain MIPS measure stewards have limited or prohibited the use of their measures by third party intermediaries such as QCDRs and qualified registries. To the extent that MIPS measure stewards limit the availability of previously finalized measures for MIPS quality reporting, including reporting by third party intermediaries on behalf of MIPS eligible clinicians, these limitations may lead to inadvertent increases in burden both for the MIPS eligible clinicians who rely on third party intermediaries and for third party intermediaries themselves. In addition, these limitations may adversely affect our ability to benchmark the measure or the robustness of the benchmark. For these reasons, we propose to adopt an additional removal criterion, specifically, that we may consider a MIPS quality measure for removal if we determine it is not available for MIPS quality reporting by or on behalf of all

MIPS eligible clinicians. We seek comments on this proposal.

(v) Request for Information on Potential Opioid Overuse Measure

To address concerns associated with long-term, high-dose opioids, we developed an electronic clinical quality measure (eCQM) titled: Potential Opioid Overuse. The Potential Opioid Overuse measure captures the proportion of patients aged 18 years or older who receive opioid therapy for 90 days or more with no more than a 7-day gap between prescriptions with a daily dosage of 90 morphine milligram equivalents (MME) or higher. It is intended to report the extent of long-term, high-dose opioid prescribing with the goal of improving patient safety by reducing the potential for opioid-related harms and encouraging the use of alternative pain management. The measure was field tested in 2017. The testing population included 3 test sites, consisting of 19 practices representing 87 clinicians, for CY 2016. Initial results from measure testing indicated that this measure is important, feasible, reliable, valid, and usable. Stakeholders supported the measure concept's importance in addressing a quality improvement opportunity in a priority population.

Through interviews primarily with EHR vendors, we have identified potential challenges for implementing the Potential Opioid Overuse measure. The human readable CQL-based specification is more than 200 pages long in order to accommodate a library providing more information on opioid medications than is currently available to export for the Value Set Authority Center (VSAC). Vendors expressed concerns about the feasibility of accurately capturing some of the medication-specific data elements within the measure, such as medication start and end dates and times, because these are not consistently captured during typical workflows.

We seek to mitigate the usability and feasibility issues for the measure by gathering information from a wider audience of technical implementers to strengthen the potential for measure adoption. We invite public comment on the Potential Opioid Overuse CQL-based specifications in this section. Specifically, we seek comment on the following questions:

- Would you select this measure to support your quality measure initiatives? Why?
- Would you implement this measure in its current state? Why?
- How can we improve the usability of this measure?
- This measure performs medication calculations, to calculate MME, which helps compare different opioids and opioid dosages. Are there any workflow, mapping, or other implementation factors to consider related to the required medication related data elements needed to perform the MME calculations in this measure? Specifically related to: Use of the opioid data library, which clearly lists the required medication information directly in the measure specification; Use of medication end dates, to calculate medication durations; Use of coded medication frequencies, such as ''3 times daily'' or ''every 6 hours,'' required to calculate daily medication dosages.
- Are there any other foreseeable challenges to implementing this measure?

(2) Cost Performance Category

For a description of the statutory basis and our existing policies for the cost performance category, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 PFS final rule (81 FR 77162 through 77177, 82 FR 53641 through 53648, and 83 FR 59765 through 59776, respectively).

In this year's rule, we are proposing to:

- Weight the cost performance category at 20 percent for MIPS payment year 2022, 25 percent for MIPS payment year 2023, and 30 percent for MIPS payment year 2024 and all subsequent MIPS payment years;
- Change our approach to proposing attribution methodologies for cost measures by including the methodology in the measure specifications;
- Add 10 episode-based measures;
- Modify the total per capita cost and Medicare Spending Per Beneficiary (MSPB) measures; and
- Seek comments on the future inclusion of an additional episode-based measure.

These proposals are discussed in more detail in the following sections of this proposed rule.

(a) Weight in the Final Score

In the CY 2019 PFS final rule, we established at § 414.1350(d)(3) that the weight of the cost performance category is 15 percent of the final score for the 2021 MIPS payment year (83 FR 59765 through 59766). Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA of 2018) amended section 1848(q)(5)(E)(i)(II)(bb) of the Act such that for each of the second, third, fourth, and fifth years for which the MIPS applies to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category score. Additionally, section 1848(q)(5)(E)(i)(II)(bb) of the Act as amended states that it shall not be construed as preventing the Secretary from adopting a 30 percent weight if the Secretary determines, based on information posted under section 1848(r)(2)(I) of the Act, that sufficient cost measures are ready for adoption for use under the cost performance category for the relevant performance period.

In the CY 2019 PFS proposed rule, we solicited comments on how we should weight the cost performance category for the 2022 and 2023 MIPS payment years given the changes within the BBA of 2018 (83 FR 35901). Several commenters noted that the increased flexibility provided by the BBA of 2018 should be used to maintain the weight at 10 percent for MIPS payment year 2021 and in future years. A few commenters were concerned about increasing the weight of the cost performance category because of the challenges with the existing attribution and risk-adjustment methodologies. Some commenters recommended that the cost performance category weight should be increased to 30 percent as soon as possible. We considered these comments when we developed our proposals for setting the weight of the cost performance category in this proposed rule.

We are proposing a steady increase in the weight of the cost performance category from the existing weight of 15 percent for the 2021 MIPS payment year to 30 percent beginning with the 2024 MIPS payment year as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act. We believe this gradual and predictable increase would allow clinicians to adequately prepare for the 30 percent weight while gaining experience with the new cost measures. We recognize that cost measures are still being developed and that clinicians may not have the same level of familiarity or understanding of cost measures that they do of comparable quality measures. We also recognize that there may be greater understanding of the measures in the cost performance category as clinicians gain more experience with them.

We are proposing at § 414.1350(d)(4) that the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year. We plan to increase the weight of the cost performance category at standard increments of 5 percent each year until

MIPS payment year 2024. Therefore, we propose at § 414.1350(d)(5) to weight the cost performance category at 25 percent for the 2023 MIPS payment year and propose at § 414.1350(d)(6) to weight the cost performance category at 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. This would allow us to meet the 30 percent cost performance category weight when required by the statute and give clinicians adequate time to gain experience with the cost measures while they represent a smaller portion of the final score. We also believe that a predictable increase in the weight of the cost performance category each year would allow clinicians to better prepare for each year going forward. We considered maintaining the weight of the cost performance category at 15 percent for the 2022 and 2023 MIPS payment years as we recognize that we are still introducing new measures for the cost performance category and clinicians are still gaining familiarity and experience with these new measures. However, recognizing that we are required by the statute to weight the cost performance category at 30 percent beginning with the 2024 MIPS payment year, we are concerned about having to increase the cost performance category's weight significantly for the 2024 MIPS payment year. We invite comments on whether we should consider an alternative weight for the 2022 and/or 2023 MIPS payment years.

In accordance with section 1848(q)(5)(E)(i)(II)(bb) of the Act, we will continue to evaluate whether sufficient cost measures are included under the cost performance category as we move towards the required 30 percent weight in the final score. As described in section III.K.3.c.(2)(b)(iii) of this proposed rule, we are proposing to add 10 episode-based measures to the cost performance category beginning with the 2020 MIPS performance period. We are continuing our efforts to develop more robust and clinician-focused cost measures. We will also be continuing to work on developing additional episode-based measures that we may consider proposing for the cost performance category in future years to address additional clinical conditions. Introducing more measures over time would allow more clinicians to be measured in this performance category, with an increasing focus on costs associated with services provided by clinicians for specific episodes of care. In section III.K.3.c.(2)(b)(v) of this proposed rule, in efforts to ensure that our existing cost measures hold clinicians appropriately accountable, we propose modifications to both the total per capita cost and MSPB measures.

(b) Cost Criteria

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. We will continue to evaluate cost measures that are included in MIPS on an ongoing basis and anticipate that measures could be added, modified, or removed through rulemaking as measure development continues. Any substantive changes to a measure would be proposed for adoption in future years through notice and comment rulemaking, following review by the Measure Applications Partnership (MAP). We would take all comments and feedback from both the public comment period and the MAP review process into consideration as part of the ongoing measure evaluation process. For the CY 2020 performance period and future performance periods, we propose to add 10 newly developed episode-based measures to the cost performance category in section III.K.3.c.(2)(b)(iii) of the proposed rule and propose modifications to both the total per capita cost and MSPB measures in section III.K.3.c.(2)(b)(v) of this proposed rule. In section III.K.3.c.(2)(b)(viii) of this proposed rule, we summarize all new and existing measures that would be included in the cost performance category starting with the CY 2020 performance period. Some modifications to measures used in the cost performance category may incorporate changes that would not substantively change the measure. Examples of such non-substantive changes may include updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. However, as described in section 3 of the Blueprint for the CMS Measures Management System Version 14.1 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), if substantive changes to these measures that are owned and developed by CMS become necessary, we expect to follow the pre-rulemaking process for new measures, including resubmission to the Measures Under Consideration (MUC) list and consideration by the MAP. The MAP provides an additional opportunity for an interdisciplinary group of stakeholders to provide feedback on whether they believe the measures under consideration are applicable to clinicians and complement program-specific statutory and regulatory requirements. Through its Measure Selection Criteria, the MAP focuses on selecting high-quality measures that address the NQF's three aims of better care, healthy people/communities, and affordable care, as well as fill critical measure gaps and increase alignment among programs.

In section III.K.3.c.(2)(b)(v)(A) of this proposed rule, we have summarized the timeline for measure development, including stakeholder engagement activities that are undertaken by the measure development contractor, which include a technical expert panel (TEP), clinical subcommittees, field testing, and education and outreach activities.

(ii) Attribution

In this section of the proposed rule, we discuss our approach to the attribution methodology for cost measures along with revisions to our existing cost measures. In the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169), we adopted an attribution methodology for the total per capita cost measure under which beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries used in the Shared Savings Program. We codified this policy under § 414.1350(b)(2) in the CY 2019 PFS final rule (83 FR 59774). In the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77176), we also adopted an attribution methodology for the MSPB measure under which an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period. We codified this policy under § 414.1350(b)(3) in the CY 2019 PFS final rule (83 FR 59775).

In the CY 2019 PFS final rule (83 FR 59775), we established at § 414.1350(b)(6) that for acute inpatient medical condition episode-based measures, an episode is attributed to each MIPS eligible clinician who bills inpatient E/M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E/M claim lines in that

hospitalization, and at § 414.1350(b)(7) that for procedural episode-based measures, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

As discussed in section III.K.3.c.(2)(b)(v) of this proposed rule, we have reevaluated the total per capita cost and MSPB measures. In the process of evaluating these measures, the TEP identified areas for potential refinement within the attribution methodology, and the revised measures that we propose include substantial changes to the attribution methodology. As we explain in section III.K.3.c.(2)(b)(v), we believe these new attribution methodologies better establish the relationship between the clinician and the patients. In general, for the cost performance category, we believe that attribution is a fundamental element of the measures, and we do not believe that a cost measure can be separated from its attribution methodology. Although in prior rulemaking, we have discussed the attribution methodologies for the cost performance category measures in the preamble and included those methodologies in the regulation text, we intend to take a different approach going forward and address attribution as part of the measure logic and specifications. For this proposed rule and in future rulemaking, we will include the attribution methodology for each cost performance category measure in the measure specifications, which are available for review and public comment at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html* during the public comment period for the proposed rule, and will be available in final form at *https://qpp.cms.gov/about/resource-library* after the final rule is published. We believe this approach is preferable because it would reduce complexity for MIPS eligible clinicians and other stakeholders by presenting the attribution methodology with the rest of the cost measure specifications, ensure non-substantive changes could be implemented without undertaking rulemaking, and align with the approach taken for measures in the quality performance category. Therefore, we propose to revise § 414.1350(b)(2), (3), (6), and (7) to reflect that these previously finalized attribution methods apply for the 2017 through 2019 performance periods. We also propose to establish at § 414.1350(b)(8) that beginning with the 2020 performance period, each cost measure would be attributed according to the measure specifications for the applicable performance period.

In the CY 2017 Quality Payment Program final rule, we established a final policy to attribute cost measures at the TIN/NPI level, regardless of whether a clinician's performance for purposes of MIPS is assessed as an individual (the TIN/NPI level) or as part of a group (the TIN level) (81 FR 77175 through 77176). We codified this policy under § 414.1350(b)(1) in the CY 2019 PFS final rule (83 FR 59774 through 59775). Similar to the attribution methodology for cost measures, we also believe that the level of attribution (TIN/NPI or TIN) is best addressed as part of the measure specifications, allowing for different considerations for group and individual attribution based on the underlying measure specification. For this proposed rule and in future rulemaking, we will include the level of attribution for each cost performance category measure in the measure specifications, which will be publicly available as described in the preceding paragraph. The measure specification documents will provide the methodology for assigning attribution to an individual clinician or a group, which will align with whether the participant is reporting data as an individual clinician or a group under the MIPS program. Therefore, we propose to revise § 414.1350(b)(1) to reflect that the current policy of attributing cost measures at the TIN/NPI level, regardless of whether a clinician's performance for purposes of MIPS is assessed as an individual or a group, applies for the 2017 through 2019 performance periods. We intend for the new regulation text proposed at § 414.1350(b)(8) also to include the level of attribution (individual clinician or group), so we are not proposing additional regulation text. We note that in section III.K.3.c.(2)(b)(vi)(B) of this proposed rule, we propose to limit the assessment of certain cost measures to MIPS eligible clinicians who report as a group based on our assessment of the reliability of the measure at the group and individual level. Although this is not directly related to attribution, it does limit the assessment of certain measures for MIPS eligible clinicians who report as individuals.

(iii) Episode-Based Measures for the 2020 and Future Performance Periods

In this section of the proposed rule, we discuss our proposal to add 10 newly developed episode-based measures to the cost performance category beginning with the 2020 performance period. We developed episode-based measures to represent the cost to Medicare and beneficiaries for the items and services furnished during an episode of care (''episode''). Episode-based measures are developed to compare clinicians on the basis of the cost of the care clinically related to their initial treatment of a patient and provided during the episode's timeframe. Specifically, we define cost based on the allowed amounts on Medicare claims, which include both Medicare payments and beneficiary deductible and coinsurance amounts. We refer our readers to the CY 2019 PFS final rule for more detail on episode-based measures and how they are established (83 FR 59767).

Prior to presenting our cost measures to the MAP for consideration, the measure development contractor has continued to seek extensive stakeholder feedback on the development of episode-based measures, building on the processes outlined in the CY 2018 PFS final rule (82 FR 53644). These processes included convening a TEP and clinical subcommittees to solicit expert and clinical input for measure development, conducting national field testing on the episode-based measures developed, and seeking input from clinicians and stakeholders through engagement activities.

To gather input on the 10 episode-based measures that we are proposing, the measure development contractor convened 10 clinical subcommittees composed of more than 260 clinicians affiliated with 120 specialty societies through an open call for nominations between February 6, 2018 and March 20, 2018. Applicants who submitted materials after the March 20, 2018 deadline were added to a standing pool of nominees and considered for membership in the measure-specific workgroups. The clinical subcommittees met during an in-person meeting in April 2018 to select episode group(s) for development and provide input on the composition of measure-specific workgroups. The smaller measure-specific workgroups were introduced as a refinement to the measure development process based on feedback from members of the first set of clinical subcommittees. The small group size was intended to facilitate more focused discussions. The workgroups—one for each measure—met through in-person meetings and webinars between June and December 2018 to provide detailed clinical input on each component of the episode-based measures. These components include episode triggers and windows (to limit the timing of services included in the episode), item and service assignment, exclusions,

attribution, and risk adjustment variables.

In addition, the 10 episode-based measures we are proposing were developed with input from the Person and Family Committee, a body of patients and their family members and caregivers who provide input iteratively during the measure development process. Discussions regarding patient and caregiver perspectives on the types of episodes that should be prioritized informed the clinical subcommittees' considerations for episode selection. Throughout measure development, the workgroups engaged in bidirectional conversations with the Person and Family Committee to inform measure specifications. For example, patient perspectives on services perceived as aiding recovery or helping to avoid unnecessary costs and complications helped the workgroup provide recommendations for service assignment, and in turn, the workgroup provided questions to the Person and Family Committee, which helped guide their in-depth interviews. After considering each round of input, clinicians had multiple opportunities to solicit additional information and feedback from Person and Family Committee members. In total, the measure developer conducted 84 interviews with 65–70 Person and Family Committee members via one-on-one interviews during development of the 10 episode-based measures.

Finally, as with the measures finalized in the CY 2019 PFS final rule (83 FR 59767), the 10 episode-based measures we are proposing underwent a measure development process based on high level guidance provided to the measure development contractor by a standing TEP. This TEP provided oversight and cross-cutting guidance to the measure development contractor for development of episode-based measures through four meetings between August 2016 and August 2017.

Further detail can be found in the Measure Development Process document at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-measure-development-process.pdf*, which includes a discussion of the detailed clinical input obtained at each step, and details about the components of episode-based measures.

We provided an initial opportunity for clinicians to review their performance under the new episode-based measures via national field testing conducted in fall of 2018. During field testing, we sought feedback from stakeholders on the draft measure specifications, feedback report format, and supplemental documentation through an online form, and we received 67 responses, including 25 comment letters. The measure development contractor shared the feedback on the draft measure specifications with the measure-specific workgroups, who considered it in providing input on further refinements after the end of field testing. A field testing feedback summary report, which details post-field testing refinements added based on the input from the measure-workgroups, is publicly available on the MACRA feedback page (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*).

Similar to previous years, we continued to engage clinicians and stakeholders, conducting extensive outreach activities. These activities included general informational email blasts, targeted email outreach to specialty societies, hosting office hours to gather input on additional opportunities for participation and outreach, and hosting the MACRA Cost Measures Field Testing Webinar to provide information about the measure development process and field test reports and a forum for stakeholder questions to ask questions.

Following the successful field testing and review through the MAP process, we propose to add the 10 episode-based measures listed in Table 37 as cost measures for the 2020 performance period and future performance periods.

The detailed specifications for these 10 episode-based measures are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip*. These specifications documents consist of (i) methodology for constructing each measure, and (ii) measure codes list file with medical codes and clinical logic. First, the methodology document provides an overview of the measure, including a description of the measure numerator and denominator, the patient cohort, and the care settings in which the measure is assessed. In addition, the document includes two one-page, high-level overviews of (i) methodology and (ii) clinical logic and service codes, which were added in response to stakeholder feedback regarding provision of documentation with varying levels of detail to ensure the information is accessible to all stakeholders. The methodology document provides detailed descriptions of each logic step involved in constructing the episode groups and calculating the cost measure. Second, the measure codes list file contains the service codes and clinical logic used in the methodology, including the episode triggers, exclusions, episode sub-groups, assigned items and services, and risk adjustors. More information about the attribution methodology for each measure is available in section A.2 of the methodology documentation. In addition, measure justification forms containing testing results for these measures are available at the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*.

TABLE 37—EPISODE-BASED MEASURES PROPOSED FOR THE 2020 PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS

Measure topic	Episode measure type
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural
Elective Primary Hip Arthroplasty	Procedural.
Femoral or Inguinal Hernia Repair	Procedural.
Hemodialysis Access Creation	Procedural.
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition.
Lower Gastrointestinal Hemorrhage *	Acute inpatient medical condition.
Lumbar Spine Fusion for Degenerative Disease, 1–3 Levels	Procedural.
Lumpectomy Partial Mastectomy, Simple Mastectomy	Procedural.
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural.

TABLE 37—EPISODE-BASED MEASURES PROPOSED FOR THE 2020 PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS—Continued

Measure topic	Episode measure type
Renal or Ureteral Stone Surgical Treatment	Procedural.

*This measure is being proposed only for groups. Please reference section III.K.3.c.(2)(b)(vi)(B) of the proposed rule.

(iv) Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve the physician, practitioner, and other stakeholder communities in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from stakeholders, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other stakeholders.

In December 2016, we published the Episode-Based Measure Development for the Quality Payment Program (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Draft-list-of-episode-groups-and-trigger-codes-December-2016.zip*) and requested input on a draft list of care episode and patient condition groups and codes as required by sections 1848(r)(2)(E) and (F) of the Act. We additionally requested feedback on our overall approach to cost measure development, including several pages of specific questions on the proposed approach for clinicians and stakeholders to provide feedback. We used this feedback to modify our cost measure development and ensure that our approach is continually informed by stakeholder feedback. As required by section 1848(r)(2)(G) of the Act, in January 2018, we posted an operational list of 8 care episode groups and patient condition groups that we refined with extensive stakeholder input, along with the codes and logic used to define these episode groups. This operational list is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-Operational-List-of-Care-Episode-and-Patient-Condition-Codes.zip*.

Under section 1848(r)(5)(A)(iii) of the Act, to evaluate the resources used to treat patients with respect to care episode and patient condition groups, the Secretary shall, as the Secretary determines appropriate, conduct an analysis of resources use with respect to care episode and patient condition groups. In accordance with this section, we used the 8 care episode groups and patient condition groups included in the operational list as the basis for the eight episode-based measures that we developed in 2017 through early 2018 and finalized for use in MIPS in the CY 2019 PFS final rule (83 FR 59767–59773). We did not revise this operational list through rulemaking in 2018 as we did not receive stakeholder feedback requesting updates to how these episode groups are defined and there were no new developments requiring revisions. Under section 1848(r)(2)(H) of the Act,we propose to revise the operational list beginning with CY 2020 to include 10 new care episode and patient condition groups, based on input from clinician specialty societies and other stakeholders. The 10 care episode and patient condition groups were included in the draft list that we posted in December 2016 and refined based on extensive stakeholder input as described in section III.K.3.c.(2)(b)(v)(A) of this proposed rule. Our proposed revisions to the operational list beginning with CY 2020 are available on our MACRA feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*. These care episode and patient condition groups serve as the basis for the 10 new episode-based measures that we are proposing in section III.K.3.c.(2)(b)(iii) of this proposed rule for the cost performance category.

(v) Revised Cost Measures

(A) Re-Evaluation Process for the Total per Capita Cost and Medicare Spending per Beneficiary Clinician Measures

For the purpose of assessing performance of MIPS eligible clinicians in the cost performance category, we finalized both the total per capita cost and MSPB measures to be included in the MIPS program in CY 2017 Quality Payment Program final rule (81 FR 77166). We are proposing to modify both of these measures based on stakeholder input from prior public comment periods and recommendations from the TEP. We also propose to modify the measure title from Medicare Spending Per Beneficiary (MSPB) to Medicare Spending Per Beneficiary clinician (MSPB clinician) to distinguish it from measures with similar names in use in other CMS programs and to improve clarity. We propose to change the name from MSPB to MSPB clinician at §§ 414.1350(b)(3) and 414.1350(c)(2).

The measure development contractor convened the TEP for two in-person meetings in August 2017 and May 2018 to provide input on potential refinements to both measures and for a webinar in November 2018 to determine additional refinements to the measures based on feedback received from field testing. The TEP's discussion from the May 2018 meeting can be found in the TEP Summary Report at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panels.html#a0913*. In addition, the measure development contractor convened the MSPB Service Refinement Workgroup, an expert workgroup that the TEP recommended to provide detailed clinical input on service assignment rules for the revised MSPB clinician measure. The MSPB Service Refinement Workgroup convened twice during summer 2018 to develop the service exclusion list. The service exclusion list contains the service codes and logic for services that are

considered clinically unrelated to the index admission of the revised MSPB clinician episodes and are removed from the episodes and measure calculation. The revised measures underwent field testing in fall of October 2018 during which we sought feedback on the refined measure specifications and supplemental documentation through an online form. At the end of field testing, the measure development contractor shared feedback with the standing TEP, which considered the feedback in determining further measure refinements for the total per capita cost measure. The TEP also discussed the MSPB clinician measure after field testing and had the opportunity to provide input on further refinements to this measure. A field-testing feedback summary report is publicly available on the MACRA feedback page (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*).

(B) Total per Capita Cost Measure

We finalized the total per capita cost measure for use in MIPS as an important measurement of clinician cost performance. Having been used in the Physician Value Modifier program, it had been tested and was reliable for Medicare populations and was familiar to the clinician community. When we finalized this measure for use in MIPS, we noted that as with all the cost measures, we would maintain this measure and update its specifications as appropriate (82 FR 53643). We continue to believe that the existing measure is appropriate to use in MIPS and continue to be committed to maintaining the cost measures with consideration of stakeholder input and testing. However, as a part of our routine measure maintenance, we re-evaluated the total per capita cost measure. The re-evaluation was informed by feedback received on this measure through prior public comment periods, as described in the CY 2017 (81 FR 77017 through 77018) and CY 2018 (82 FR 53577 through 53578) Quality Payment Program final rules, as well as feedback that arose in the measure development contractor's discussions with the TEP during the process of re-evaluation. This feedback is summarized below:

- The total per capita cost measure's attribution methodology assigned costs to clinicians over which the clinician has no influence, such as costs occurring before the start of the clinician-patient relationship.
- The attribution methodology did not effectively identify primary care relationships between a patient and a clinician and could potentially attribute beneficiaries to a clinician not responsible for the beneficiaries' primary care.
- The measure did not account for the shared accountability of clinicians and that attributing costs to a single clinician or clinician group could cause fragmentation of care.
- The beneficiary risk factors were determined one year prior to the start of the performance period, which would preclude the risk adjustment methodology from reflecting the more expensive treatment resulting from comorbidities and/or complications that might arise during the performance period.
- The feedback summarized above informed the four modifications that we are proposing for the total per capita cost measure.

First, we are proposing to change the attribution methodology to more accurately identify a beneficiary's primary care relationships. This is done by identifying a combination of services that occur within a short period of time and indicate the beginning of a relationship. More specifically, a primary care relationship is identified by a candidate event, defined as the occurrence of an E/M service such as an established patient assisted living visit or an outpatient visit (that is, the E/M primary care service), paired with one or more additional services indicative of general primary care (for example, routine chest X-ray, electrocardiogram, or a second E/M service provided at a later date). The candidate event initiates a year-long risk window from the E/M primary care service. The risk window is the period during which a clinician or clinician group could reasonably be held responsible for the beneficiary's treatment costs, and the initiation of the risk window at the onset of the candidate event ensures that costs are attributed only after the start of the clinician-patient relationship. Only the portion of the risk window that overlaps with the performance period, which is divided into 13 four-week blocks called beneficiary-months, is attributable to a clinician for a given performance period. For example, if the risk window were initiated during one MIPS performance period and ends in the following MIPS performance period, only the beneficiary-months that occur during the earlier MIPS performance period would be attributed to the clinician/clinician group to calculate the measure for that particular MIPS performance period. Dividing the performance period into beneficiary-months allows costs to be assigned to clinicians and clinician groups during the parts of the year they are primarily responsible for the patient's care management.

With this methodology, it is possible for multiple candidate events to occur between a clinician and beneficiary over time, and an additional candidate event occurring during an existing risk window reaffirms and extends the period of the clinician's responsibility. For example, if 2 candidate events for the same clinician and the same beneficiary occur 6 months apart, a separate 12-month risk window initiates from the start of each of these candidate events, and the clinician may be attributed beneficiary-months spanning 18 months and 2 different performance periods. As we described above, for risk windows that span multiple performance periods, only the beneficiary-months contained within a given performance period are used to calculate the measure for that performance period. Beneficiary-months that overlap between the 2 risk windows are collapsed to ensure that costs are only accounted for once. Furthermore, if different clinician groups initiated these 2 risk windows for the same beneficiary, the risk windows would occur concurrently and would be attributed to their respective TINs. Within an attributed TIN, only the clinician with the TIN/NPI combination performing the highest number of candidate events is attributed the beneficiary-months, since this TIN/NPI combination is deemed to have the most substantive relationship with the beneficiary. Finally, multiple TINs and TIN/NPIs billing under different TINs may be attributed beneficiary-months for the same beneficiary during the performance period. This attribution method allows multiple clinicians to be considered for the provision of ongoing primary care for a patient, which accounts for changes in primary care relationships (for example, for beneficiaries who move during the year) and reflects shared clinical responsibility for a patient's care.

To illustrate how candidate events identify primary care relationships, we are providing an example of a clinical scenario in which physicians in the primary care medical practice see a beneficiary as part of the beneficiary's routine health maintenance. A beneficiary is feeling unwell and goes to a medical practice. At the practice, the beneficiary sees a family practice clinician who provides an E/M service (one that has been identified as related to primary care) for routine health maintenance. The clinician prescribes a course of medication as part of the care

plan. The beneficiary returns to the same practice 2 months later when she notices new symptoms. At this visit, she sees a different family practice clinician who examines her, adjusts her care plan, and asks her to return in 3 months for a follow-up in case diagnostic testing or a change in medication is required. These two E/M services that occur within proximity (that is, the initial E/M service and the paired event 2 months later—a second E/M service) constitute the candidate event and indicate that a primary care relationship has begun from the time of the first visit to the medical practice. The first E/M service (identified as related to primary care) opens a one-year period (or risk window) from the date of the service. This is illustrated graphically in section 2.0 of the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-TPCC-measure-specs.zip*. During the risk window, the attributed clinician/clinician group can be held responsible for the overall costs of care for that beneficiary. The TIN for the medical practice would be attributed the beneficiary and the TIN/NPI within this practice that provides the most primary care E/M services that initiate candidate events would be attributed the beneficiary. Under the current total per capita cost measure, the TIN and TIN/NPI would have been attributed this beneficiary from the beginning of the calendar year and held accountable for services the beneficiary might have received before her first visit to the medical practice.

Second, we are proposing to change the attribution methodology to more accurately identify clinicians who provide primary care services, by the addition of service category exclusions and specialty exclusions. Specifically, candidate events are excluded if they are performed by clinicians who (i) frequently perform non-primary care services (for example, global surgery, chemotherapy, anesthesia, radiation therapy) or (ii) are in specialties unlikely to be responsible for providing primary care to a beneficiary (for example, podiatry, dermatology, optometry, ophthalmology). As a result of these exclusions, clinician specialties considered for attribution are only those primarily responsible for providing primary care, such as primary care specialties and internal medicine subspecialties that frequently manage patients with chronic conditions that are in their area(s) of expertise. We do not propose to change the adjustment for specialty; as such, the measure would continue to adjust for specialty to account for variation in cost across clinician specialties and in clinician groups with diverse specialty compositions.

Third, we are proposing to change the risk adjustment methodology to determine a beneficiary's risk score for each beneficiary-month using diagnostic data from the year prior to that month rather than calculating one risk score for the entire performance period using diagnostic data from the previous year. This methodology would better account for any changes in the health status of the beneficiary for the duration of a primary care relationship and during the performance period. In addition, we are proposing to add an institutional risk model to improve risk adjustment for clinicians treating institutionalized beneficiaries.

Fourth, we are proposing to change the measure to evaluate beneficiaries' costs on a monthly basis rather than an annual basis. Specifically, the performance period during which costs are assessed is divided into 13 beneficiary-months, mentioned earlier, allowing for the measure and the risk adjustment model to reflect changes in patient health characteristics at any point throughout the performance period. In addition, this refinement would avoid measuring annualized costs for beneficiaries whose death date occurs during the performance period, which could potentially disincentivize care for older and sicker patients.

Further detail about these proposed changes to the measure, as well as a comparison to the total per capita cost measure as currently specified, is available in the measure specifications documents available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-TPCC-measure-specs.zip*.

The revised total per capita cost measure underwent MAP review during the 2018–2019 cycle. In December 2018, the MAP Clinician Workgroup gave the preliminary recommendation of 'conditional support for rulemaking,' with the condition of NQF endorsement. In January 2019, the MAP Coordinating Committee reversed the Clinician Workgroup's preliminary recommendation and provided a final recommendation of ''do not support for rulemaking with potential for mitigation''. More detail on the mitigating factors is available in the MAP's final report at *http://www.qualityforum.org/Publications/2019/03/MAP_Clinicians_2019_Considerations_for_Implementing_Measures_Final_Report.aspx*. We believe that the revised measure provides a more appropriate and valid attribution approach. We considered the option of proposing to remove the current version of the measure from the program and not proposing to replace it with a revised version. However, because we have developed and implemented only a handful of episode-based measures at this time, a substantial proportion of clinicians would be left with only MSPB clinician measure for the cost performance category. Because fewer than half of all clinicians in MIPS meet the case minimum for the MSPB clinician measure, and no other measure addresses the costs of primary care, we believe it is appropriate to use the best version of the total per capita cost measure available to us. While we recognize and value the MAP's expressed concerns regarding the revised measure specifications, we believe we have adequately addressed the mitigating factors through the information we have made publicly available (including testing results in the measure justification forms available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*), as well as our discussions with stakeholders at the MAP and through further education and outreach activities. Thus, we are proposing to include the total per capita cost measure with these revised specifications in the cost performance category beginning with the CY 2020 performance period.

(C) Medicare Spending per Beneficiary Clinician Measure

Similar to the total per capita cost measure, we finalized the MSPB clinician measure for use in MIPS as an important measurement of clinician cost performance. Having been used in the Physician Value Modifier program, it had been tested and was reliable for Medicare populations and was familiar to the clinician community. However, when we finalized this measure for use in MIPS, we noted that as with all the cost measures, we would maintain this measure and update its specifications as appropriate (82 FR 53643). We continue to believe that the existing measure is appropriate to use in MIPS and continue to be committed to maintaining this cost measure with consideration of stakeholder input and testing. Hence, we re-evaluated the MSPB clinician measure as part of our routine measure maintenance. The re-evaluation was

informed by feedback received on this measure through prior public comment periods, as described in the CY 2017 Quality Payment Program final rule (81 FR 77017 through 77018) and the CY 2018 Quality Payment Program final rule (82 FR 53577 through 53578), as well as feedback that arose in the measure development contractor's discussions with the standing TEP during the process of re-evaluation. This feedback is summarized below:

- The attribution methodology did not recognize the team-based nature of inpatient care;
- The attribution based on the plurality of Part B service costs during index admission could potentially attribute episodes to specialties providing expensive services as opposed to those providing the overall care management for the patient; and
- The measure captured costs for services that are unlikely to be influenced by the clinician's care decisions.

The feedback summarized above informed the two modifications that we are proposing as part of the re-evaluation of this measure.

First, we are proposing to change the attribution methodology to distinguish between medical episodes (where the index admission has a medical MS–DRG) and surgical episodes (where the index admission has a surgical MS–DRG). A medical episode is first attributed to the TIN billing at least 30 percent of the inpatient E/M services on Part B physician/supplier claims during the inpatient stay. The episode is then attributed to any clinician in the TIN who billed at least one inpatient E/M service that was used to determine the episode's attribution to the TIN. A surgical episode is attributed to the surgeon(s) who performed any related surgical procedure during the inpatient stay, as determined by clinical input, as well as to the TIN under which the surgeon(s) billed for the procedure. The list of related surgical procedures MS–DRGs may be found in the measure codes list for the revised measure at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/mspb-clinician-zip-file.zip*. This revised attribution methodology accounts for the team-based nature of care provided when managing medical conditions during an inpatient stay and allows for attribution to multiple clinicians to ensure that all clinicians involved in a beneficiary's care are appropriately attributed.

Second, to account for the more limited influence clinicians' performance has on costs when compared with hospitals, we are proposing to add service exclusions to the measure to remove costs that are unlikely to be influenced by the clinician's care decisions. Specifically, we are proposing to exclude unrelated services specific to groups of MS–DRGs aggregated by major diagnostic categories (MDCs). Some examples of unrelated services include orthopedic procedures for episodes triggered by MS–DRGs under Disorders of Gastrointestinal System (MDC 06 and MDC 07) or valvular procedures for episodes triggered by MS–DRGs under Disorders of the Pulmonary System (MDC 04).

Further detail about these proposed changes to the measure is included in the measure specifications documents, which are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/mspb-clinician-zip-file.zip*. This includes a comparison of the proposed changes against the MSPB clinician measure as currently specified. A measure justification form containing testing results for this measure with the proposed revisions is available on the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*. We are proposing to include the revised MSPB clinician measure with these specifications in the cost performance category beginning with the CY 2020 performance period.

(vi) Reliability

(A) Reliability for Episode-Based Measures

In the CY 2017 QPP final rule (81 FR 77169 through 77170), we finalized a reliability threshold of 0.4 for measures in the cost performance category. In the CY 2019 PFS final rule, we established at § 414.1350(c)(4) and (5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures and 10 episodes for procedural episode-based measures (83 FR 59773 through 59774). We examined the reliability of the proposed 10 episode-based measures listed in Table 38 at our established case minimums and found that all of these measures meet the reliability threshold of 0.4 for the majority of groups at a case minimum of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures. All of the proposed measures meet this standard at the individual clinician level as well, with the exception of the Lower Gastrointestinal Hemorrhage episode-based measure. In section III.K.3.c.(2)(b)(vi)(B) of this proposed rule, we discuss a proposal to limit our assessment of certain cost measures to groups (identified by a TIN) based on the results of our reliability analysis.

TABLE 38—PERCENT OF TINS AND TIN/NPIS THAT MEET 0.4 RELIABILITY THRESHOLD

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Acute Kidney Injury Requiring New Inpatient Dialysis	100.0	0.58	85.3	0.48
Elective Primary Hip Arthroplasty	100.0	0.85	100.0	0.78
Femoral or Inguinal Hernia Repair	100.0	0.86	100.0	0.81
Hemodialysis Access Creation	93.1	0.63	70.1	0.48
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	100.0	0.69	68.0	0.46
Lower Gastrointestinal Hemorrhage *	74.6	0.51	0.0	0.20
Lumbar Spine Fusion for Degenerative Disease, 1–3 Levels	100.0	0.77	100.0	0.69
Lumpectomy Partial Mastectomy, Simple Mastectomy	100.0	0.64	100.0	0.60
Non-Emergent Coronary Artery Bypass Graft (CABG)	100.0	0.82	100.0	0.74
Renal or Ureteral Stone Surgical Treatment	100.0	0.77	100.0	0.65

* This measure is being proposed only for groups. Please reference section III.K.3.c.(2)(b)(vi)(B) of the proposed rule.

(B) Limiting Assessment of Certain Measures to Groups

We have assessed clinicians and groups on cost measures when they meet the case minimum for a measure. As part of our efforts to ensure reliable measurement, we have examined the reliability of cost measures at the group and individual level, as clinicians are able to participate in MIPS in either way. However, for clinicians who participate in MIPS as individuals, we have found the proposed Lower Gastrointestinal Hemorrhage episode-based measure does not meet the reliability threshold of 0.4 that we established for measures in the cost performance category. While we considered not including the measure in MIPS for this reason, we do find that this measure meets the reliability threshold for those who participate in MIPS as part of a group. Therefore, we propose to include the measure in the cost performance category only for MIPS eligible clinicians who report as a group or virtual group. We will continue to assess the reliability of cost measures for group and individual participation as the measures are introduced or are revised. If we identify measures that are similarly found to meet our reliability threshold at the group level but not at the individual level, we would again consider limiting the assessment of the measure to groups.

(C) Reliability for Revised Cost Measures

In the CY 2017 Quality Payment Program final rule, we finalized a reliability threshold of 0.4 for measures in the cost performance category (81 FR 77169 through 77170). Additionally, we established a case minimum of 35 episodes for the MSPB clinician measure (81 FR 77171) and a case minimum of 20 beneficiaries for the total per capita cost measure (81 FR 77170). We codified these case minimums at § 414.1350(c)(1) and (2) in the CY 2019 PFS final rule (83 FR 59774). We based these case minimums on our interest in ensuring that the majority of clinicians and groups that were measured met the threshold of 0.4 reliability, which we felt best balanced our interest in ensuring moderate reliability without limiting participation. Given the significant changes to these measures that we are proposing in section III.K.3.c.(2)(b)(v), we again examined the reliability of the revised MSPB clinician and total per capita cost measures at these case minimums and found that the measures meet the reliability threshold of 0.4 for the majority of clinicians and groups at the existing case minimums, as shown in Table 39.

TABLE 39—PERCENT OF TINS AND TIN/NPIS THAT MEET 0.4 RELIABILITY THRESHOLD FOR THE REVISED MSPB CLINICIAN AND TOTAL PER CAPITA COST MEASURES

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Medicare Spending Per Beneficiary Clinician	100.0	0.77	100.0	0.69
Total Per Capita Cost	100.0	0.82	100.0	0.89

Based on this analysis, in this proposed rule we are not proposing any changes to the case minimums, which we previously finalized as 35 for the MSPB clinician measure, and 20 for the total per capita cost measure.

(vii) Request for Comments on Future Potential Episode-Based Measure for Mental Health

We plan to continue to develop episode-based measures and propose to adopt them for the cost performance category in future rulemaking. As a part of these efforts, we seek to expand the range of procedures and conditions covered to ensure that more MIPS eligible clinicians have their cost performance assessed under clinically relevant episode-based measures. In recognition of the importance of assessing mental health care, we developed an acute inpatient medical condition episode-based measure for the treatment of inpatient psychoses and related conditions through the same process involving extensive expert clinician input as the measures proposed in section III.K.3.c.(2)(b)(vii) of this proposed rule. The specifications for the Psychoses/Related Conditions episode-based measure are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip*. The Psychoses/Related Conditions episode-based measure represents an opportunity to incentivize improvement in the field of mental health, a CMS priority area.

The Psychoses/Related Conditions episode-based measure was reviewed by the MAP Clinician Workgroup in December 2018 as part of a group with the 10 episode-based measures in Table 40 that we are proposing and received a preliminary recommendation of ''Conditional support for rulemaking,'' on the condition of NQF endorsement. In January 2019, The MAP Coordinating Committee pulled this measure for separate discussion from the other 10 episode-based measures and voted to finalize a recommendation of ''Do not support for rulemaking.'' The MAP's concerns with this measure related to: (i) The attribution model and its potential to hold clinicians responsible for costs outside of their influence; (ii) geographic variation in community resource availability; (iii) effects of physical comorbidities on measure score; and (iv) the potential to exacerbate access issues in mental health care. More detail is available in the 2019 MAP Clinician Workgroup final report at *http://www.qualityforum.org/Publications/2019/03/MAP_Clinicians_2019_Considerations_for_Implementing_Measures_Final_Report.aspx*.

We appreciate the feedback from the MAP but believe that the measure already accounts for these concerns. The expert workgroup convened by the measure development contractor to provide input on the specifications carefully considered these and other issues unique to mental health care throughout the development process and field testing. The expert workgroup, which reconvened to consider the MAP's concerns, noted that they had addressed each of the MAP's concerns during development activities and that this measure could be a significant step towards mental health parity by including psychiatry with other specialties in a MIPS episode-based measure. In addition, the measure provides opportunities for innovation in care coordination, which the Person and Family Committee expressed as an improvement need. We are now seeking

comments on the Psychoses/Related Conditions episode-based measure. In future years, we may propose the use of this measure.

Regarding the MAP's first concern about clinician accountability, the Psychoses/Related Conditions measure is constructed to only capture costs within an attributed clinician's influence through judicious service assignment rules. That is, services are only included in the cost of an episode when they meet specific conditions defined by procedure, diagnosis, and timing within the episode window. Members of the expert workgroup also noted that the measure can incentivize improved care coordination across care settings by holding clinicians accountable for certain post-discharge care. This recognition of the potential for measures to incentivize systems care coordination aligns with the rationale for quality measures currently available for reporting in MIPS, which acknowledge the goal of promoting shared accountability and collaboration with patients, families, and providers. For example, NQF #0576/Quality #391 Follow-Up After Hospitalization for Mental Illness (81 FR 77645) holds clinicians accountable for certain follow-up care.

Regarding the MAP's second concern about geographic variation, empirical analyses indicate the impact of geographic variation has limited effect on measure score and is similar across episode-based measures. The measure development contractor conducted empirical analyses to examine the effect of adding variables to the current risk adjustment model to account for state differences to assess the impact of geographic variation. The analyses indicated that there is a high correlation between the measure using the current risk adjustment model and the model accounting for state differences. At the TIN level, the correlation between the Psychoses/Related Conditions base measure and state-augmented measure is 0.838. At the TIN–NPI level, the correlation between the Psychoses/Related Conditions base measure and state-augmented measure is 0.835.

Regarding the MAP's third concern about physical comorbidities, the measure's risk adjustment model includes variables to account for patient comorbidities, including variables for patient history of other physical or mental health issues that might affect outcomes for patients captured under this measure.

Regarding the MAP's fourth concern about mental healthcare access, the large number of beneficiaries covered by this measure mitigates the potential for clinicians to limit access for Medicare patients. The potential coverage of beneficiaries is high, as there are approximately 102,000 beneficiaries with at least one episode (for episodes ending between January 1, 2017 and December 31, 2017). Additionally, the measure is designed to account for complex case mix to preserve access to care: The patient cohort is divided into sub-groups to ensure meaningful clinical comparisons between homogenous patient populations. We believe that this measure has the potential to incentivize improved care coordination and team-based care, and encourage the use of use community resources, which would improve access to care.

The Psychoses/Related Conditions episode-based measure would bridge the measurement gap in the MIPS cost performance category by providing mental health clinicians an episode-based measure as a complement to the two broader, population cost measures currently in MIPS. Based on episodes ending between January 1, 2017 and December 31, 2017, approximately 97 percent of MIPS eligible TINs and 36 percent of MIPS eligible TIN/NPIs meeting the 20 episode-case minimum for the Psychoses/Related Conditions measure also meet the case minimum for the revised MSPB clinician measure. Similarly, approximately, 98 percent of MIPS eligible TINs and 23 percent of MIPS eligible TIN/NPIs meeting the case minimum for the Psychoses/Related Conditions measure also meet the case minimum for the revised total per capita cost measure. We believe that this measure accurately reflects cost associated with inpatient psychiatrists' care and can provide information about cost performance that is actionable for mental health clinical practice as they provide clinicians with feedback on the cost of services within their reasonable influence.

A key goal for cost measures is to assess provider variation due to practice differences rather than chance, which can be determined by the measure's reliability. The Psychoses/Related Conditions measure tests well for reliability. The measure has a mean reliability over 0.7, generally considered the threshold for high reliability, at both TIN and TIN–NPI levels at the 10, 20, and 30-episode case minima. At the 20-epsiode case minimum imposed for acute inpatient medical condition episode-based measures, mean reliability is 0.83 for TIN and 0.88 for TIN–NPI level reporting, with 100.0 percent of TINs and 100.0 percent of TIN–NPIs meeting or exceeding the 0.4 threshold for moderate reliability. A measure justification form with additional testing results for this measure is available at the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*.

We are seeking comments on the potential use of this new Psychoses/Related Conditions episode-based measure in the cost performance category in a future MIPS performance period.

(viii) Summary of Previously Established and Proposed Measures for the Cost Performance Category for the 2020 and Future Performance Periods

TABLE 40—SUMMARY TABLE OF COST MEASURES FOR THE 2020 PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS

Measure topic	Measure type	Measure Status
Total Per Capita Cost	Population-Based	Revised and proposed for 2020 performance period and beyond.
Medicare Spending Per Beneficiary Clinician	Population-Based	Revised and proposed for 2020 performance period and beyond.
Elective Outpatient Percutaneous Coronary Intervention (PCI).	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.
Knee Arthroplasty	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.
Revascularization for Lower Extremity Chronic Critical Limb Ischemia.	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.

TABLE 40—SUMMARY TABLE OF COST MEASURES FOR THE 2020 PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS—Continued

Measure topic	Measure type	Measure Status
Routine Cataract Removal with Intraocular Lens (IOL) Implantation.	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.
Screening/Surveillance Colonoscopy	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition episode-based.	Currently in use for 2019 Performance Period and Beyond.
Simple Pneumonia with Hospitalization	Acute inpatient medical condition episode-based.	Currently in use for 2019 Performance Period and Beyond.
ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI).	Acute inpatient medical condition episode-based.	Currently in use for 2019 Performance Period and Beyond.
Acute Kidney Injury Requiring New Inpatient Dialysis.	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Elective Primary Hip Arthroplasty	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Femoral or Inguinal Hernia Repair	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Hemodialysis Access Creation	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation.	Acute inpatient medical condition episode-based.	Proposed for 2020 Performance Period and Beyond.
Lower Gastrointestinal Hemorrhage *(at group level only)*.	Acute inpatient medical condition episode-based.	Proposed for 2020 Performance Period and Beyond.
Lumbar Spine Fusion for Degenerative Disease, 1–3 Levels.	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Lumpectomy, Partial Mastectomy, Simple Mastectomy.	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Non-Emergent Coronary Artery Bypass Graft (CABG).	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Renal or Ureteral Stone Surgical Treatment	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), and the CY 2019 PFS final rule (83 FR 59776 through 59777).

In this proposed rule, we are proposing to: (1) Modify the definition of rural area; (2) update § 414.1380(b)(3)(ii)(A) and (C) to remove the reference to the four listed accreditation organizations in order to be recognized as patient-centered medical homes and to remove the reference to the specific accrediting organization for comparable specialty practices; (3) increase the group reporting threshold to 50 percent; (4) establish factors to consider for removal of improvement activities from the Inventory; (5) remove 15, modify seven, and add two new improvement activities for the 2020 performance period and future years; and (6) conclude and remove the CMS Study on Factors Associated with Reporting Quality Measures. These proposals are discussed in more detail in this proposed rule.

(b) Small, Rural, or Health Professional Shortage Areas Practices

For our previously established policies regarding small, rural, or Health Professional Shortage Areas Practices, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77188), CY 2018 Quality Payment Program final rule (82 FR 53581), and § 414.1305. In the CY 2018 Quality Payment Program final rule (82 FR 53581 through 53582), we changed the definition of rural area at § 414.1305 to mean ZIP codes designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available.

It has come to our attention that the rural area definition at § 414.1305 includes the incorrect file name for the rural designation. While we used the correct file, we just referenced it incorrectly. Therefore, we are proposing to update the MIPS rural area definition by correcting the file name. In the CY 2017 Quality Payment Program final rule (81 FR 77188), we incorrectly referenced the file we used for rural designation as ''*the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available*'' instead of the correct file entitled ''*Federal Office of Rural Health Policy (FORHP) eligible ZIP codes*'' which may currently be found at *https://www.hrsa.gov/rural-health/about-us/definition/datafiles.html*. The HRSA Area Health Resources Files (AHRF) include data on Health Care Professions, Health Facilities, Population Characteristics, Economics, Health Professions Training, Hospital Utilization, Hospital Expenditures, and Environment at the county, state and national levels, from over 50 data sources [115] but does not contain specific data on rurality developed by HRSA's FORHP. To be clear, we have been using the more appropriate FORHP eligible ZIP code file in all previous 3 years of MIPS; we simply inadvertently listed the incorrect file name in the definition. Furthermore, the definition of rural in MIPS is based on the rural definition developed by HRSA's FORHP which may be found at *https://www.hrsa.gov/rural-health/about-us/definition/index.html*. The FORHP defines all non-Metro counties as rural and uses an additional method of determining rurality called the Rural-Urban

[115] *https://data.hrsa.gov/topics/health-workforce/ahrf.*

Commuting Area (RUCA) codes. The FORHP eligible ZIP codes are available in a file located at *https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/aboutus/definition/forhp-eligible-zips.xlsx*. Therefore, we are proposing to modify the definition of rural area at § 414.1305 to mean a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available. We invite public comment on our proposal as discussed in this proposed rule.

(c) Patient-Centered Medical Home and Comparable Specialty Practice Accreditation Organizations

In the CY 2017 Quality Payment Program final rule (81 FR 77179 through 77180), we finalized at § 414.1380(b)(3)(ii) an expanded definition of what is acceptable for recognition as a certified-patient-centered medical home or comparable specialty practice. Specifically, we finalized that one of the criteria, as stated at § 414.1380(b)(3)(ii)(A), is whether the practice has received accreditation from one of four accreditation organizations that are nationally recognized; (A)(1) through (A)(4) lists the four organizations with nationally recognized patient-centered medical home accreditation programs: (1) The Accreditation Association for Ambulatory Health Care; (2) the National Committee for Quality Assurance (NCQA) Patient-Centered Medical Home; (3) The Joint Commission Designation; or (4) the Utilization Review Accreditation Commission (URAC) (81 FR 77180). In addition, we finalized another criteria at § 414.1380(b)(3)(ii)(C), which states that the practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition (81 FR 77180). Further, we finalized that the criteria for being a nationally recognized accredited patient-centered medical home are that it must be national in scope and must have evidence of being used by a large number of medical organizations as the model for their patient-centered medical home (81 FR 77180).

Since finalizing these criteria, it has come to our attention that, we do not want to exclude other organizations. It was and is not our intention to limit patient-centered medical home or comparable specialty practice accreditation organizations to those listed. We realize that there may be additional accreditation organizations that have nationally recognized programs for accrediting patient-centered medical homes and comparable specialty practices that were not included. Therefore, we request comments on our proposal to update § 414.1380(b)(3)(ii)(A) and (C) to remove specific entity names.

(d) Improvement Activities Data Submission

We are proposing changes to the improvement activities data submission for group reporting requirements, as discussed below.

(i) Submission Mechanisms

For our previously established policies regarding improvement activities performance category submission mechanisms, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53650 through 53656), the CY 2019 PFS final rule (83 FR 59777), and § 414.1360(a)(1). We are not proposing any changes to these policies.

(ii) Submission Criteria

For our previously established policies regarding improvement activities performance category submission criteria, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77185), the CY 2018 Quality Payment Program final rule (82 FR 53651 through 53652), the CY 2019 PFS final rule (83 FR 59777 through 59778), and § 414.1380. We are not proposing any changes to these policies.

(iii) Group Reporting

In this proposed rule, we are making two proposals with respect to group reporting: (a) Increasing the group reporting threshold from at least one clinician to at least 50 percent of the group beginning with the 2020 performance year, and (b) at least 50 percent of a group's National Provider Identifiers (NPIs) must perform the same activity for the same continuous 90 days in the performance period beginning with the 2020 performance year. These are discussed in more detail below.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77181), in response to a public comment, we stated that if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period, the group may report on that activity. In addition, we specified that all MIPS eligible clinicians reporting as a group would receive the same score for the improvement activities performance category if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period (81 FR 77181).

In the CY 2018 Quality Payment Program proposed rule (82 FR 30053), we requested comment for future consideration on issues related to whether we should establish a minimum threshold (for example, 50 percent) of the clinicians (NPIs) that must complete an improvement activity in order for the entire group (Taxpayer Identification Number (TIN)) to receive credit in the improvement activities performance category in future years. Some commenters expressed concerns that setting a minimum threshold would add complexity or burden for clinicians. Other commenters supported the establishment of a minimum participation threshold in future years, noting that a minimum threshold will ensure scoring is reflective of care delivered by the group as a whole rather than one or a few high-performing clinicians.

We believe that by Year 4 (2020 performance year) of the Quality Payment Program, clinicians should be familiar with the improvement activities performance category. We believe that increasing the minimum threshold for a group to receive credit for the improvement activities performance category will not present additional complexity and burden for a group. With over 100 improvement activities available for eligible clinicians to choose from in the Improvement Activities Inventory, which may be found at the Quality Payment Program website *https://qpp.cms.gov/*, that provide a range of options for clinicians seeking to improve clinical practice that are not specific to practice size or specialty or practice setting, we believe that a group should be able to find applicable and meaningful activities to complete that would apply to at least 50 percent of individual MIPS eligible clinicians in a group.

Therefore, we are proposing to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent for the improvement activities performance category beginning with the 2020 performance year and future years. We would like to note that if finalized the proposed changes to the group threshold would have no impact on the previously finalized policy that eligible clinicians participating in an APM will receive full points for the improvement activities performance category as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260). This is an increase to the previously established requirement finalized in the CY 2017 Quality Payment Program final rule (81

FR 77181) that only one clinician within a TIN needs to attest to the completion of an improvement activity to get credit towards the MIPS final score. We believe a 50 percent threshold is achievable and appropriate because, if a group or virtual group has implemented an improvement activity, the activity should be recognized and adopted throughout much of the practice in order to improve clinical practice, care delivery, and outcomes. This aligns with our definition of an improvement activity at § 414.1305. In crafting our proposal, we also considered other thresholds, such as a lower threshold of 25 percent. However, we believe that improvement activities should be adopted throughout much of the practice to achieve improved outcomes. We do not believe that 25 percent group participation would reflect improved outcomes. We also considered a higher threshold of 100 percent, but have concerns that requiring every clinician within a group to perform improvement activities may be premature at this time because increasing the threshold by such a large amount may be considered burdensome to clinicians. However, we believe that 50 percent provides an appropriate balance between requiring at least half of the NPIs reporting as part of a group to participate in the improvement activities performance category and acknowledging the challenges to requiring every NPI in a group to perform the improvement activity for a group to receive credit. We also believe our proposal aligns with the 50 percent threshold for the number of practice sites that must be recognized for a TIN to receive full credit as a patient-centered medical home (82 FR 53655) and is both achievable and appropriate at this time.

Furthermore, we believe that requiring at least 50 percent of a group practice or TIN to perform an improvement activity for the same continuous 90-day performance period would facilitate improvement in clinical practice within a TIN. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77186), we considered setting the threshold for the minimum time required for performing an activity to longer periods up to a full calendar year. However, after researching several organizations we stated that we believed a minimum of 90 days is a reasonable amount of time (81 FR 77186). In addition, in response to comments we stated that we believed that each activity can be performed for a full 90 consecutive days by some, if not all, MIPS eligible clinicians, and that there are a sufficient number of activities included that any eligible clinician may select and perform for a continuous 90 days that will allow them to successfully report under this performance category (81 FR 77186).

Therefore, we are requesting comments on our proposal to revise § 414.1360(a)(2) to state that beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. To be clear, other submission requirements would remain the same. In other words, each TIN would need to submit an attestation for each improvement activity selected that at least 50 percent of its NPIs performed the same activity for the same continuous 90 days in the performance period. For example, TIN 1234 attests that at least 50 percent of its NPIs performed the improvement activity entitled: ''Participation in a QCDR that promotes use of patient engagement tools'' (IA_BE_7) for the same continuous 90-day period. Because IA_BE_7 is medium-weighted, the example TIN would receive 10 points toward the total possible improvement activities score. TIN 1234 also attests that at least 50 percent of its NPIs performed the improvement activity entitled: ''Implementation of formal quality improvement methods, practice changes, or other practice improvement processes'' (IA_PSPA_19) for the same continuous 90-day period. Because IA_PSPA_19 is medium-weighted, the example TIN would receive another 10 points toward the total possible improvement activities score. We refer readers to the CY 2019 Quality Payment Program final rule (83 FR 59753 through 59754) where we discuss the data submission deadline which was finalized at § 414.1325(e)(1) as follows: For the direct, login and upload, login and attest, and CMS Web Interface submission types, March 31 following the close of the applicable performance period or a later date as specified by CMS.

We invite public comments on our proposal as discussed above, as well as the alternatives considered.

(e) Improvement Activities Inventory

We are proposing changes to the Improvement Activities Inventory to: (1) Establish removal factors to consider when proposing to remove improvement activities from the Inventory; (2) remove 15 improvement activities for the 2020 performance period and future years contingent on our proposed removal factors being finalized; (3) modify seven existing improvement activities for the 2020 performance period and future years; and (4) add two new improvement activities for the 2020 performance period and future years. These proposals are discussed in more detail in this proposed rule.

(i) Proposed Factors for Consideration in Removing Improvement Activities

In the CY 2017 Quality Payment Program final rule (82 FR 53660 through 53661), we discussed that in future years, we anticipated developing a process and establishing factors for identifying activities for removal from the Improvement Activities Inventory through the Annual Call for Activities process. In the CY 2018 Quality Payment Program proposed rule (82 FR 30056), we invited public comments on what criteria should be used to identify improvement activities for removal from the Inventory. A few commenters did not support the idea of establishing removal factors for improvement activities, believing that many practices have made financial investments to perform these activities and that no activities should be removed. Some commenters suggested that we should remove activities that: Have become obsolete, are topped out, do not show demonstrated improvements over time, or are not attested to for three consecutive years. The commenters recommended that their removal should be conducted using an approach similar to what is used for the removal of quality measures. In our responses, we stated that we appreciate the commenters input. In addition, we understand that many practices may have made financial investments to perform these activities, but believe that over time, certain improvement activities should be considered for removal to ensure the list is robust and relevant. We will fully examine each activity prior to removal. In addition, we stated that commenters would have an opportunity to provide their input during notice-and-comment rulemaking. We agreed with commenters that we should remove activities as needed and should consider the removal criteria already established for quality measures. We continue to believe that having factors to consider in removing improvement activities would provide transparency and alignment with the removal of quality measures. Therefore, we are proposing to adopt the following factors for our consideration when

proposing the removal of an improvement activity:

- Factor 1: Activity is duplicative of another activity;
- Factor 2: There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice;
- Factor 3: Activity does not align with current clinical guidelines or practice;
- Factor 4: Activity does not align with at least one meaningful measures area;
- Factor 5: Activity does not align with the quality, cost, or Promoting Interoperability performance categories;
- Factor 6: There have been no attestations of the activity for 3 consecutive years; or
- Factor 7: Activity is obsolete.

These factors directly reflect those already finalized for quality measures found in the CY 2019 PFS final rule (83 FR 59765). The removal of improvement activities from the Inventory, including discussion of the removal factor(s) considered, would occur through notice-and-comment rulemaking. We note that these removal factors are considerations taken into account when deciding whether or not to remove improvement activities; but they are not firm requirements.

Therefore, we invite public comments on our proposal to implement factors to consider in removing improvement activities from the Inventory. In conjunction with this proposal, we are proposing a number of improvement activity removals as discussed in the next section and in Appendix 2 of this proposed rule. Those removals are contingent upon finalization of these removal factors.

(ii) New Improvement Activities and Modifications to and Removal of Existing Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would add new improvement activities or modifications to existing improvement activities to the Improvement Activities Inventory through notice-and-comment rulemaking. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), and Tables X and G in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303) for our previously finalized Improvement Activities Inventory. We also refer readers to the Quality Payment Program website at *https://qpp.cms.gov/* for a complete list of the most current list of improvement activities. In this proposed rule, we invite comments on our proposals to: (1) Remove 15 improvement activities from the Inventory beginning with the 2020 performance period, (2) modify seven existing improvement activities for 2020 performance period and future years, and (3) add two new improvement activities for 2020 performance period and future years. We refer readers to Appendix 2 of this proposed rule for further details. Our proposals to remove improvement activities are being made in conjunction with our proposal to adopt removal factors and are contingent upon finalization of that proposal.

(f) CMS Study on Factors Associated With Reporting Quality Measures

In this proposed rule, we are proposing to end this study and concurrently, remove the incentive under the improvement activity performance category that this study provided for study participants.

(i) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77195), we created the Study on Improvement Activities and Measurement. In our quest to create a culture of improvement using evidence-based medicine on a consistent basis, we believe fully understanding the strengths and limitations of the current processes of collecting and submitting quality measurement data is crucial to better understand and improve these current processes. We proposed to conduct a study on clinical improvement activities and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures (81 FR 77195). In the CY 2018 Quality Payment Program final rule (82 FR 53662) and CY 2019 PFS final rule (83 FR 59783), we finalized updates to the study.

Starting in CY 2017, this annual study was slated for a minimum period of 3 years, as stated in CY 2019 PFS final rule (83 FR 59776). Study participants were recruited every study year. The study population started in CY 2017 with a minimum of 42 individuals (81 FR 77195), grew to a minimum of 102 individuals for CY 2018 (82 FR 53662) and 200 individuals for CY 2019 (83 FR 59783). Each years' study population is comprised of the following categories: Urban versus non-urban, groups and individual clinicians; clinicians reporting quality measures in groups or reporting individually, different practice sizes; and different specialty groups (81 FR 77195). These changes to the study sample size over the years provided data for the study's analysis. The goals of the study are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians desiring: A more data driven approach to quality measurement, measure selection unconstrained by a CEHRT program or system, improving data quality submitted to CMS, enabling CMS get data more frequently and provide feedback more often (81 FR 77195). To encourage participation by clinicians and counterbalance clinician burden for anticipation of study, participating clinicians were incentivized with full improvement activity credit as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195 through 77197).

(ii) Proposal To End and Remove Study

We believe by the end of 2020 we will have reached the minimum sample size and have accrued the minimum data needed for the analysis to achieve the study goals. Therefore, we request comments on our proposal to conclude this study at the end of the CY 2019 performance period. In conjunction with our proposal to end the study, we are also proposing to remove the study and the incentive provided towards the improvement activity performance category beginning with the 2020 performance period. If the study is ended as proposed above, we are proposing to remove this activity because it would be obsolete (proposed removal factor 7). As a result, the full improvement activity credit given to participants as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195–77197), would no longer be available starting with the 2020 performance period.

(iii) Future Steps

After completing this data collection phase, we next plan to analyze the data gathered (which include lessons learned) and to make recommendations to improve outcomes, reduce burden, and enhance clinical care. We plan to finish the final data analysis by Spring 2020. This analysis would contain all the study years. It would show the trends and associations of all the factors we examined. It would also show the lessons learnt by study participants over the 3 years of the study. At the conclusion of this study and after analysis of the results, we plan to shift our focus to implementation of recommendations. We intend for this to include feedback to clinicians and stakeholders and educational and

outreach work. We plan to undertake education and outreach to the public. We would also include the results in other Quality Payment Program educational materials such as webinars.

(4) Promoting Interoperability

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of Certified Electronic Health Record Technology (CEHRT) as a performance category under the MIPS. In prior rulemaking, we referred to this performance category as the Advancing Care Information performance category, and it was reported by MIPS eligible clinicians as part of the overall MIPS program. In 2018, we renamed the Advancing Care Information performance category as the Promoting Interoperability performance category (83 FR 35912). As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the Promoting Interoperability performance category.

For the Promoting Interoperability performance category, our proposals include: (1) For the 2023 MIPS payment year, establishing a performance period of a minimum of a continuous 90-day period within CY 2021, up to and including the full calendar year; (2) making the Query of Prescription Drug Monitoring Program (PDMP) measure optional in CY 2020, and in the event we finalize this proposal, making the e-Prescribing measure worth up to 10 points in CY 2020; (3) removing the numerator and denominator for the Query of PDMP measure and instead requiring a ''yes/no'' response beginning in CY 2019; (4) removing the Verify Opioid Treatment Agreement measure beginning in CY 2020; (5) redistributing the points for the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients Access to Their Health Information measure if an exclusion is claimed, beginning in CY 2019; (6) revising the description of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure exclusion to more clearly and precisely capture our intended policy, beginning in CY 2019; (7) continuing the existing policy of reweighting the Promoting Interoperability performance category for certain types of non-physician practitioner MIPS eligible clinicians for the performance period in 2020; and (8) proposals related to hospital-based MIPS eligible clinicians and non-patient facing MIPS eligible clinicians in groups.

These proposals are discussed in more detail in this proposed rule.

We are also seeking input through Requests for Information as follows: (1) Potential Opioid Measures for Future Inclusion in the Promoting Interoperability performance category, (2) NQF and CDC Opioid Quality Measures, (3) a Metric to Improve Efficiency of Providers within EHRs, (4) the Provider to Patient Exchange Objective, (5) Integration of Patient-Generated Health Data into EHRs Using CEHRT, and (6) Engaging in Activities that Promote the Safety of the EHR.

(b) Goals of Proposed Changes to the Promoting Interoperability Performance Category

As we look toward the future of the Promoting Interoperability performance category, the general goals of our proposals in this proposed rule center on: (1) A priority of stability within the performance category after the recent changes made in the CY 2019 PFS final rule (83 FR 59785 through 59820) while continuing to further interoperability through the use of CEHRT; (2) reducing administrative burden; (3) continued use of the 2015 Edition CEHRT; (4) improving patient access to their EHRs so they can make fully informed health care decisions; and (5) continued alignment with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, where appropriate.

(c) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2019 PFS final rule at § 414.1320(e)(1) (83 FR 59745 through 59747), for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through December 31, 2020).

For the 2023 MIPS payment year, we are proposing to add § 414.1320(f)(1), which would establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year (CY 2021). This proposal aligns with the proposed EHR reporting period in CY 2021 for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs (84 FR 19554). We believe this would be an appropriate performance period because of the maturation needed within the performance category, including the changes to measures and other changes being proposed in this rule. In addition, it would offer stability and continuity for the Promoting Interoperability performance category after the performance category overhaul that was finalized in the CY 2019 PFS final rule (83 FR 59785 through 59820).

We are requesting comments on this proposal.

(d) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Proposed Changes to Measures for the e-Prescribing Objective

(A) Background

Beginning with the MIPS performance period in 2019, we adopted two new measures for the e-Prescribing objective that are based on electronic prescriptions for controlled substances: (1) Query of Prescription Drug Monitoring Program (PDMP) (83 FR 59800 through 59803); and (2) Verify Opioid Treatment Agreement (83 FR 59803 through 59806). These measures built upon the meaningful use of CEHRT, as well as the security of electronic prescribing of Schedule II controlled substances while preventing diversion. For both measures, we defined opioids as Schedule II controlled substances under 21 CFR 1308.12, as they are recognized as having a high potential for abuse with potential for severe psychological or physical dependence. Additionally, we noted the intent of the new measures was not to dissuade the prescribing or use of opioids for patients with medical diagnoses or conditions that benefit from their use, such as patients diagnosed with cancer or those receiving hospice.

During the comment period for the CY 2019 PFS proposed rule (83 FR 35921 through 35925), and subsequently through public forums and correspondence, we received extensive comments from stakeholders regarding the Query of PDMP measure and the Verify Opioid Treatment Agreement measure. While this feedback is the main catalyst for our proposals, there have also been significant legislative changes that have the potential to

positively impact the Promoting Interoperability performance category, specifically the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018). This legislation was enacted to address the opioid crisis and affects a wide range of HHS programs and policies. While this legislation is not the main reason for our proposals, we believe it may significantly affect the maturation, requirements, and use of PDMPs and State networks upon which the Query of PDMP measure is dependent.

In this proposed rule, we are aiming to be responsive to the comments that we have received from stakeholders since the CY 2019 PFS final rule was published and to take into account certain aspects of the SUPPORT Act that may have implications for the policy goals of the Promoting Interoperability performance category.

As explained in further detail below, we are proposing to make the Query of PDMP measure optional in CY 2020, remove the numerator and denominator that we established for the Query of PDMP measure and instead require a ''yes/no'' response beginning in CY 2019, and remove the Verify Opioid Treatment Agreement measure beginning in CY 2020. In section III.K.3.c.(4)(d)(i) of this proposed rule, we are also requesting information on potential new opioid use disorder (OUD) prevention and treatment-related measures. We believe the requests for information will help to inform future rulemaking and not only help prevent and treat substance use disorder, but allow us to adopt measures that enable flexibility without added burden for clinicians. We value stakeholders' continued interest in and support for combating the nation's opioid epidemic.

(B) Query of Prescription Drug Monitoring Program (PDMP) Measure

(aa) Query of PDMP Measure

As we stated in the CY 2019 PFS final rule (83 FR 59800 through 59803), the Query of PDMP measure is optional and available for bonus points for the 2019 performance period, and we will propose our policy for the Query of a PDMP measure for the 2020 performance period in future rulemaking. We afforded MIPS eligible clinicians' flexibility for implementing this measure, including the flexibility to query the PDMP in any manner allowed under their State law.

However, we have received substantial feedback from health IT vendors and specialty societies that this flexibility presents unintended challenges, such as the significant burden associated with IT system design and development needed to accommodate the measure and any future changes to it. During the CY 2019 PFS proposed rule comment period (83 FR 35922 through 35925) and after the final rule was published, these stakeholders stated that it is premature to require the Query of PDMP measure in the 2020 performance period especially given the maturation needed in PDMP development.

We agree with stakeholders that PDMPs are still maturing in their development and use. In addition there is considerable variation among state PDMP programs as many only operate within a state and are not linked to larger systems. For more information, we refer readers to the following: The National Alliance of Model State Drug Laws (*https://namsdl.org/topics/pdmp/*) and PDMP Training and Technical Assistance Center (*https://www.pdmpassist.org/content/pdmp-maps-and-tables*).

Stakeholders also mentioned the challenge posed by the current lack of integration of PDMPs into the EHR workflow. Historically, health care providers have had to go outside of the EHR workflow in order to separately log in to and access the State PDMP. In addition, stakeholders noted the wide variation in whether PDMP data can be stored in the EHR. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions. ONC is currently engaged in an assessment to better understand the current state of policy and technical factors impacting PDMP integration across States. This assessment is exploring factors like PDMP data integration, standards and hubs used to facilitate interstate PMDP data exchange, access permissions, and laws and regulations governing PDMP data storage.

In October 2018, the SUPPORT Act became law, signifying an important investment and approach for our nation in combating the opioid epidemic. The provisions of this law aim to provide for opioid use disorder prevention, recovery, and treatment and aim to increase access to evidence-based treatment and follow-up care included through legislative changes specific to the Medicare and Medicaid programs. Specifically, with respect to PDMPs, the SUPPORT Act includes new requirements and federal funding for PDMP enhancement, integration, and interoperability, and establishes mandatory use of PDMPs by certain Medicaid providers, in an effort to help reduce opioid misuse and overprescribing, and in an effort to help promote the overall effective prevention and treatment of opioid use disorder.

Section 5042(a) of the SUPPORT Act added section 1944 to the Act, titled ''Requirements relating to qualified prescription drug monitoring programs and prescribing certain controlled substances.'' This section increases federal Medicaid matching rates during FY 2019 and 2020 for certain state expenditures relating to qualified PDMPs administered by states. Under section 1944(b)(1) of the Act, to be a qualified PDMP, a PDMP must facilitate access by a covered provider to, at a minimum, the following information with respect to a covered individual, in as close to real-time as possible: Information regarding the prescription drug history of a covered individual with respect to controlled substances; the number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period; and the name, location, and contact information of each covered provider who prescribed a controlled substance to the covered individual during at the least the most recent 12-month period. Under section 1944(b)(2) of the Act, a qualified PDMP must also facilitate the integration of the information described in section 1944(b)(1) of the Act into the workflow of a covered provider, which may include the electronic system used by the covered provider for prescribing controlled substances.

Section 1944(f) of the Act establishes, for FY 2019 and FY 2020, a 100 percent federal Medicaid matching rate for state expenditures to design, develop, or implement a PDMP that meets the requirements outlined in section 1944(b)(1) and (2) of the Act, and to make connections to that PDMP. Section 1944(f)(2) of the Act specifies that, to qualify for the 100 percent federal matching rate, a state must have in place agreements with all contiguous states that, when combined, enable covered providers in all the contiguous states to access, through the PDMP, all information described in 1944(b)(1) of the Act.

Section 5042(b) of the SUPPORT Act requires CMS, in consultation with the Centers for Disease Control and Prevention (CDC), to issue guidance not later than October 1, 2019 on best practices on the uses of PDMPs required of prescribers and on protecting the

privacy of Medicaid beneficiary information maintained in and accessed through PDMPs. Furthermore, section 5042(c) of the SUPPORT Act requires that HHS develop and publish, not later than October 1, 2020, model practices to assist State Medicaid program operations in identifying and implementing strategies to utilize data-sharing agreements described in section 1944(b) of the Act for the following purposes: Monitoring and preventing fraud, waste, and abuse; and improving health care for individuals enrolled in Medicaid who transition in and out of Medicaid coverage, who may have sources of health care coverage in addition to Medicaid coverage, or who pay for prescription drugs with cash. We note that section 7162 of the SUPPORT Act also supports PDMP integration as part of the CDC's grant programs aimed at efficiency and enhancement by states, including improvement in the intrastate and interstate interoperability of PDMPs.

In addition, the explanatory statement that accompanied Title II of Division H of the Consolidated Appropriations Act, 2018 (Pub. L. 115–141),[116] encouraged the CDC to work with the ONC to enhance the integration of PDMPs and EHRs. As part of this effort, the CDC and ONC are collaborating to expand upon previous and leverage input from current federal efforts to advance and scale PDMP integration with health IT systems. This collaboration includes testing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs, and incorporating policy considerations, as relevant, to inform the implementation and success of integration approaches.

We understand that there is wide variation across the country in how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows, and that it could be burdensome for health care providers if we were to narrow the measure to allow only a single workflow. At the same time, we have heard extensive feedback from EHR developers that incorporating the ability to count the number of PDMP queries in CEHRT would require more robust certification specifications and standards. These stakeholders state that health IT developers may face significant cost burdens under the current flexibility allowed for health care providers if they fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Developers have indicated that the costs of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure.

Given the stakeholder concerns discussed above regarding the lack of integration, the recent enactment of the SUPPORT Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), and the activities funded by the CDC, we believe that additional time is needed to evaluate the changing PDMP landscape prior to requiring a Query of PDMP measure, or introducing requirements related to EHR–PDMP integration.

Therefore, we are proposing to make the Query of PDMP measure optional and eligible for 5 bonus points for the Electronic Prescribing objective in CY 2020. Making the measure optional in CY 2020 would allow time for further integration of PDMPs and EHRs to minimize the burden on MIPS eligible clinicians reporting this measure while still giving clinicians an opportunity to report on and earn points for the measure. We are proposing that, in the event we finalize this proposal for the Query of PDMP measure, the e-Prescribing measure would be worth up to 10 points in CY 2020.

In addition, beginning with the 2019 performance period, we are proposing to remove the numerator and denominator that we established for the Query of PDMP measure in the CY 2019 PFS final rule (83 FR 59800 through 59803) and instead require a ''yes/no'' response. Under this proposal, the measure description would remain the same (83 FR 59803), but instead of submitting numerator and denominator information for the measure, MIPS eligible clinicians would submit a ''yes/no'' response. A ''yes'' response would indicate that for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. We are proposing this change to give us more time to restructure the measure and develop a robust measure that meets the needs of both health care providers and other stakeholders. Because currently there are not standards-based interfaces between CEHRT and PDMPs, health care providers must manually track the number of times that they query a PDMP outside of CEHRT. We are proposing this change to reduce the burden on health care providers of having to manually keep track of information related to the measure and to mitigate the burden on health IT developers who would otherwise have to develop the measure's numerator and denominator calculations when we expect to propose changes to the measure in the near future. Therefore, health care providers and health IT developers have suggested that, given the current state, there would be a significant reduction in burden by allowing health care providers to satisfy the measure by submitting a ''yes/no'' response, rather than reporting a numerator and denominator. In addition, for the 2019 performance period, the Query of PDMP measure is not scored based on a clinician's performance as determined by a numerator and denominator; instead, it is an optional measure that is eligible for a full five bonus points regardless of how a clinician performs (83 FR 59794 through 59795). Thus, because the measure is not scored based on performance, requiring a ''yes/no'' response instead of a numerator and denominator would not affect the potential number of points that a clinician could earn by reporting on the measure.

We do not believe that these changes would result in additional costs (time or money) for health care providers, and instead would reduce the burden of manually tracking information needed to report on this measure in its current form. For CY 2019, we did not provide exclusions for the Query of PDMP and Verify Opioid Treatment Agreement measures because they were optional and eligible for bonus points, and similarly, we do not believe exclusions would be necessary for the Query of PDMP measure if we finalize our proposal to make the measure optional and eligible for bonus points in CY 2020.

We also welcome comments on future timing for requiring a measure that includes EHR–PDMP integration and on the value of the measure for advancing the effective prevention and treatment of opioid use disorder especially in relation to the requirements of the SUPPORT Act described above.

We also note that some stakeholders have requested that we define a value set for controlled substances for the opioid-related measures, Query of

[116] *https://www.govinfo.gov/content/pkg/CREC-2018-03-22/html/CREC-2018-03-22-pt3-PgH2697.htm.*

PDMP and Verify Opioid Treatment Agreement. In the CY 2019 PFS final rule (83 FR 59803), for the Query of PDMP and Verify Opioid Treatment Agreement measures, we defined opioids as Schedule II controlled substances under 21 CFR 1308.12. We recognize that some challenges remain related to electronic prescribing of controlled substances, including more restrictive state laws and lack of products both for health care providers and pharmacies that include the necessary functionalities. We anticipate working closely with the Drug Enforcement Administration (DEA) on future technical requirements that can better support measurement of adoption and use of electronic prescribing of controlled substances, which may include the definition of a value set related to such measures. As more information on developing technical requirements becomes available, we will provide additional information.

As we seek comment and continue to advance this measure, we are excited about future innovations that may help improve PDMPs and support the electronic prescribing of controlled substances. We envision a future state where PDMP data is integrated into the clinical workflow and where clinicians do not have to access multiple systems to find and reconcile the information. While we may have a long distance to go to get to this state, we believe that it is an achievable goal for the future of the Promoting Interoperability performance category.

We are inviting comments on these proposals.

(C) Verify Opioid Treatment Agreement Measure

In the CY 2019 PFS final rule (83 FR 59803 through 59806), we finalized the Verify Opioid Treatment Agreement measure as optional in both CYs 2019 and 2020. Since we proposed this measure, we have received feedback from stakeholders that this measure has presented significant implementation challenges and an increase in burden, and does not further interoperability. Below, we outline some of the ongoing concerns we heard since the measure was finalized in the CY 2019 PFS final rule (83 FR 59803 through 59806).

(aa) Lack of Certification Standards and Criteria

Stakeholders have continually expressed concern regarding the lack of defined data elements, structure, standards and criteria for the electronic exchange of opioid treatment agreements and how this impacts verifying whether there is an opioid treatment agreement to meet this measure. We acknowledged these concerns in the CY 2019 PFS final rule (83 FR 59803 through 59806).

In the CY 2019 PFS final rule (83 FR 59803 through 59806), we stated that there are a number of ways that certified health IT may be able to support the electronic exchange of opioid abuse-related treatment data such as the care plan template within the Consolidated-Clinical Document Architecture (C–CDA). We stated this information could be considered as part of an opioid treatment agreement, even though we did not define the elements of one. However, we understand that while such standards may include relevant information, the lack of clarity around a specific standard to support incorporation of an opioid treatment agreement presents an additional source of burden to clinicians seeking to report on the measure.

(bb) Calculating 30 Cumulative Day Look-Back Period

Another area where stakeholders have expressed concern is how to calculate 30 cumulative days of opioid prescriptions in a 6-month period. One possible solution we offered was to utilize the NCPDP 10.6 Medication History query. In the CY 2019 PFS final rule (83 FR 59803 through 59806), we noted that the Medication History query does not contain a discrete field for prescription days and relies on third party data that may not be discrete. Since the CY 2019 PFS final rule was published, stakeholders have continued to express this concern and impress upon us that the 30-cumulative day total in a 6-month look-back period cannot be automatically calculated, requiring health care providers to engage in a burdensome, manual calculation process if they wish to report on this measure.

In addition, we have heard concerns over which medications should be used to determine the 30-cumulative day threshold. For example, stakeholders were unsure if medications given while a patient is admitted to the hospital should count towards the 30 cumulative days and also how as needed, or PRN, medications should be addressed.

Stakeholders have also indicated that this measure could present timing challenges. For example, it may cause patients being discharged on opioids to be delayed in their discharge to account for the possible time-consuming nature of having to search for an opioid treatment agreement.

(cc) Unintended Burden Caused by Flexibility

In the CY 2019 PFS final rule (83 FR 59803 through 59806), we chose not to define what constitutes an opioid treatment agreement. While we believed that this would allow flexibility for health care providers to determine which elements they believed were most important to an opioid treatment agreement, we have heard from stakeholders that the lack of definition and standards around what would constitute an opioid treatment agreement has created an unintended burden. Specifically, some stakeholders indicated that we should define an opioid treatment agreement so that MIPS eligible clinicians would have a standardized definition of an opioid treatment agreement and the criteria to make up an opioid treatment agreement. However, other stakeholders indicated that given the lack of consensus within the industry on what should or should not be included in an opioid treatment agreement and on the clinical efficacy of various options for such agreements, that it would be inappropriate for us to define what should constitute an opioid treatment agreement at this time.

We have heard from stakeholders that the challenges described above result in a measure that is vague, burdensome to measure and does not necessarily offer a clinical value to the health care providers or support the clinical goal of supporting OUD treatment. Therefore, we are proposing to remove the Verify Opioid Treatment Agreement measure from the Promoting Interoperability performance category beginning with the performance period in CY 2020.

While we are proposing to remove the Verify Opioid Treatment Agreement measure, we believe there may be other opioid measures that would be more effective in combatting the opioid epidemic, offer value for health care providers in measuring the impacts of health IT-enabled resources on OUD prevention and treatment, and engage patients in care coordination and planning. We are seeking public comment on a series of question in requests for information regarding new opioid measures in section III.K.3.c(4)(d)(i) of this proposed rule.

We invite comments on this proposal.

(ii) Health Information Exchange Objective

There are two measures under the Health Information Exchange objective: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating

Health Information Measure. We are proposing minor modifications to both measures.

(A) Proposed Modification of the Support Electronic Referral Loops by Sending Health Information Measure

In the CY 2019 PFS final rule (83 FR 59807 through 59808), we renamed the Send a Summary of Care measure to the Support Electronic Referral Loops by Sending Health Information measure. Although an exclusion is available for this measure (83 FR 59808), we acknowledged that we did not address in the CY 2019 PFS proposed rule how the points for the measure would be redistributed in the event the exclusion is claimed, and stated that we intended to propose a redistribution policy in next year's rulemaking (83 FR 59795). Accordingly, we are proposing to redistribute the points for the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients Access to Their Health Information measure if an exclusion is claimed. We have chosen to redistribute the points to the Provide Patients Access to Their Health Information measure because we believe that many MIPS eligible clinicians may be eligible to claim exclusions for both measures under the Health Information Exchange objective. Under our existing policy (83 FR 59788), if an exclusion is claimed for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, the 20 points associated with it will be redistributed to the Support Electronic Referral Loops by Sending Health Information measure. Under our proposal, if exclusions are claimed for both the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the Support Electronic Referral Loops by Sending Health Information measure, the 40 points associated with these measures would be redistributed to the Provide Patients Access to Their Health Information measure. We are proposing that this redistribution policy would be applicable beginning with the 2019 performance period/2021 MIPS payment year.

We invite comments on this proposal.

(B) Modification of the Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

In the CY 2019 PFS final rule (83 FR 59808 through 59812), we replaced the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure with a new measure called the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. We established the following exclusion for the new measure: Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period would be excluded from this measure (83 FR 59812). We are proposing to revise this description of the exclusion to more clearly and precisely capture our intended policy. The Request/Accept Summary of Care measure, which as noted previously was replaced by the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, included the following exclusion: Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period (83 FR 59798, 82 FR 53679 through 53680). Our intention was to use that same exclusion from the Request/Accept Summary of Care measure for the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. Instead, the description of the exclusion that we included in the CY 2019 PFS final rule (83 FR 59812) did not precisely track the description of the Request/Accept Summary of Care measure exclusion, and could be construed in a way that would make the exclusion more difficult for a MIPS eligible clinician to meet. Specifically, it could be read to create two different sets of exclusion criteria: Receiving fewer than 100 transitions of care or referrals; or having fewer than 100 encounters with patients never before encountered. This was not our intention. Rather, as with the Request/Accept Summary of Care measure exclusion, our intention was that a combination of the two criteria must occur fewer than 100 times during the performance period for the exclusion to be applicable to a MIPS eligible clinician. Thus, we are proposing to revise the description of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure exclusion to track the description of the Request/Accept Summary of Care measure exclusion (83 FR 59798, 82 FR 53679 through 53680): Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period. For example, during the performance period, if a MIPS eligible clinician received 50 transitions of care, 50 referrals, and 50 patient encounters in which they have never before encountered the patient, the total sum of 150 would be above the threshold of fewer than 100 times, and therefore the MIPS eligible clinician would not be eligible for this exclusion. We are proposing that the revised description of the exclusion would be applicable beginning with the 2019 performance period/2021 MIPS payment year.

For ease of reference, Table 41 lists the objectives and measures for the Promoting Interoperability performance category for the 2020 performance period as revised to reflect the proposals made in this proposed rule. For more information on the 2015 Edition certification criteria required to meet the objectives and measures, we refer readers to Table 43 in the CY 2019 PFS final rule (83 FR 59817).

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TABLE 41: Objectives and Measures for the Promoting Interoperability Performance Category in 2020

Objective	Measure	Numerator	Denominator	Exclusion
e-Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
e-Prescribing: Generate and transmit permissible prescriptions electronically.	Query of PDMP (bonus): For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.				
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.	Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	transmit his or her health information; and 2.The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health	Syndromic Surveillance Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician 1.Is not in a category of health care providers from which ambulatory syndromic data is collected by their jurisdiction's syndromic surveillance system; OR 2.operates in a jurisdiction for which no public health

Objective	Measure	Numerator	Denominator	Exclusion
agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	surveillance data from an urgent care setting.			agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from MIPS eligible clinicians as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable	Public Health Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not diagnose or directly treat any disease or condition associated with a public health registry in the MIPS eligible clinician's jurisdiction during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no public health registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry

Objective	Measure	Numerator	Denominator	Exclusion
law and practice.				transactions as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Clinical Data Registry Reporting: The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician 1. Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the performance period; OR 2.operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no clinical data registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.

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(e) Scoring Methodology

(i) Proposed Changes to the Scoring Methodology for the 2020 Performance Period

In the CY 2019 PFS final rule (83 FR 59785 through 59796), we finalized a new performance-based scoring methodology for the Promoting Interoperability performance category beginning with the performance period in 2019. As previously discussed in section III.K.3.c.(4)(d)(i) of this proposed rule, we are proposing to: (1) Make the Query of PDMP measure optional and eligible for five bonus points in CY 2020; (2) make the e-Prescribing measure worth up to 10 points in CY 2020, in the event we finalize the proposal for the Query of PDMP measure; and (3) remove the Verify Opioid Treatment Agreement measure beginning in 2020. Table 42 reflects these proposals, although the maximum points available do not include points that would be redistributed in the event that an exclusion is claimed.

TABLE 42: Proposed Scoring Methodology for the Performance Period in 2020

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing**	10 points
	Query of PDMP	5 points (*bonus*)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information**	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information**	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: Immunization Registry Reporting** Electronic Case Reporting** Public Health Registry Reporting** Clinical Data Registry Reporting** Syndromic Surveillance Reporting**	10 points

** Exclusion available.

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(f) Additional Considerations

(i) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

In prior rulemaking (83 FR 59818 through 59819), we discussed our belief that certain types of MIPS eligible clinicians (NPs, PAs, CNSs, and CRNAs) may lack experience with the adoption and use of CEHRT. Because many of these non-physician clinicians were or are not eligible to participate in the Medicare or Medicaid EHR Incentive Program (now known as the Promoting Interoperability Program), we stated that we have little evidence as to whether there are sufficient measures applicable and available to these types of MIPS eligible clinicians under the advancing care information (now known as Promoting Interoperability) performance category. We established a policy at § 414.1380(c)(2)(i)(A)(5) for the performance periods in 2017, 2018, and 2019 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act. We stated our intention to use data from the first performance period (2017) to further evaluate the participation of these MIPS eligible clinicians in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians.

We have analyzed the data submitted for the 2017 performance period for the Promoting Interoperability performance category, and have discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. While we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For example, when a group of MIPS eligible clinicians chooses to report for MIPS as a group, the data submitted are representative of that entire group, as opposed to each individual MIPS eligible clinician in the group submitting data that exclusively reflect his/her own performance. Approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. Additionally, we are challenged because many of the measures that were available for submission for the 2017 performance period are now unavailable, due to our discontinuation of the Promoting Interoperability transition measure set, and the overhaul of the performance category that further reduced the number of available measures. For these reasons, we are unable to determine, at this time, whether the measures currently specified for the Promoting Interoperability performance category for the 2020 performance period are applicable and available for NPs, PAs, CRNAs, and CNSs. However, as more data beyond this first year become available, we plan to reevaluate the measures and consider how we could ensure that there are sufficient measures applicable and available for these types of MIPS eligible clinicians.

Thus, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2020, and to revise § 414.1380(c)(2)(i)(A)(*5*) to reflect this proposal. We are requesting public comments on this proposal.

(ii) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologist, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2019 PFS final rule (83 FR 59819 through 59820), we adopted a policy at § 414.1380(c)(2)(i)(A)(4) to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017–2019 to these new types of MIPS eligible clinicians (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the performance period in 2019. Because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category.

For the reasons discussed in section III.K.3.c.(4)(f)(i), for the performance period in 2020, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals, and to revise § 414.1380(c)(2)(i)(A)(4) to reflect this proposal. We invite comments on this proposal.

(iii) Hospital-Based MIPS Eligible Clinicians in Groups

We define a hospital-based MIPS eligible clinician under § 414.1305 as a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of services identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital (POS 21), on campus outpatient hospital (POS 22), off campus outpatient hospital (POS 19), or emergency room (POS 23) setting, based on claims for the MIPS determination period (81 FR 77238 through 77240, 82 FR 53686 through 53687, 83 FR 59727 through 59730). We established under § 414.1380(c)(2)(i)(C)(6) that a MIPS eligible clinician who is a hospital-based MIPS eligible clinician as defined in § 414.1305 will be assigned a zero percent weight for the Promoting Interoperability performance category, and the points associated with the Promoting Interoperability performance category will be redistributed to another performance category or categories (81 FR 77238 through 77240, 82 FR 53684, 83 FR 59871). However, if a hospital-based MIPS eligible clinician chooses to report on the Promoting Interoperability performance category measures, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score. We stated that this policy includes MIPS eligible clinicians choosing to report as part of a group or part of a virtual group (82 FR 53687).

Under § 414.1310(e)(2)(ii), individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN (81 FR 77058). For groups reporting on the Promoting Interoperability performance category,

we stated that group data should be aggregated for all MIPS eligible clinicians within the group (81 FR 77214 through 77216, 82 FR 53687). We stated that this includes those MIPS eligible clinicians who may qualify for a zero percent weighting of the Promoting Interoperability performance category due to circumstances such as a significant hardship or other type of exception, hospital-based or ASC-based status, or certain types of non-physician practitioners (82 FR 53687). We established at § 414.1380(c)(2)(iii) that for MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting (82 FR 53687, 83 FR 59871). We have heard from several stakeholders that our policy for groups that include hospital-based MIPS eligible clinicians sets a threshold that is too restrictive for a variety of reasons. Some stated that due to high turnover rates for hospital medicine groups, many such groups rely on locum tenens clinicians who may practice in multiple settings. They stated that if a hospital medicine group includes only one MIPS eligible clinician who does not meet the definition of a hospital-based MIPS eligible clinician, it could prevent the group from qualifying for reweighting because not all of the MIPS eligible clinicians in the group would be considered hospital-based. A few acknowledged that while hardship exceptions are available for MIPS eligible clinicians who lack control over CEHRT because they use the hospital's CEHRT, it is an administrative burden to have to submit a hardship exception application, especially if the clinician has a locum tenens relationship. We agree that hospital medicine groups may face unique circumstances due to the nature of their practice area and the staffing practices described by stakeholders. Thus, we are proposing to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We are proposing that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. We believe a threshold of more than 75 percent is appropriate because it is consistent with the thresholds for groups in the definitions of facility-based MIPS eligible clinician and non-patient facing MIPS eligible clinician under § 414.1305. We are proposing to revise § 414.1380(c)(2)(iii) to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the proposed revised definition of a hospital-based MIPS eligible clinician (or the definition of a non-patient facing MIPS eligible clinician, as proposed in section III.K.3.c.(4)(f)(iv), as defined in § 414.1305.

(iv) Non-Patient Facing MIPS Eligible Clinicians in Groups

We define a non-patient facing MIPS eligible clinician under § 414.1305 as an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician. We established under § 414.1380(c)(2)(i)(C)(5) that a MIPS eligible clinician who is a non-patient facing MIPS eligible clinician as defined in § 414.1305 will be assigned a zero percent weight for the Promoting Interoperability performance category, and the points associated with the Promoting Interoperability performance category will be redistributed to another performance category or categories (81 FR 77240 through 77243, 82 FR 53680–53682, 83 FR 59871). However, if a non-patient facing MIPS eligible clinician chooses to report on the Promoting Interoperability performance category measures, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score. We stated that this policy includes MIPS eligible clinicians choosing to report as part of a group or part of a virtual group (82 FR 53687).

As noted in section III.K.3.c.(4)(f)(iii) of the proposed rule in connection with our discussion of hospital-based MIPS eligible clinicians in groups, under § 414.1380(c)(2)(iii), for MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting. In that section, we are proposing to revise § 414.1380(c)(2)(iii) to account for groups and virtual groups that meet the proposed revised definition of a hospital-based MIPS eligible clinician under § 414.1305, which would only require the group or virtual group to meet a threshold of more than 75 percent instead of a threshold of all of the MIPS eligible clinicians in the group or virtual group. In an effort to more clearly and concisely capture our existing policy for non-patient facing MIPS eligible clinicians, we are proposing to revise § 414.1380(c)(2)(iii) to also account for a group or virtual group that meets the definition of a non-patient facing MIPS eligible clinician under § 414.1305, such that the group or virtual group only has to meet a threshold of more than 75 percent.

(g) Future Direction of the Promoting Interoperability Performance Category

(i) Request for Information (RFI) on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Performance Category

In the past, the Promoting Interoperability performance category measures focused on very general process focused actions supported by health IT. In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62766 through 62768), we sought to expand the potential for Medicare and Medicaid Promoting Interoperability Program measures to include more complex measures and closer relationships to high priority health outcomes.

In this RFI, we are seeking comment on Promoting Interoperability performance category measures that might be relevant to specific clinical priorities or goals related to addressing OUD prevention and treatment. As the Query of PDMP measure matures, we believe it will be essential in improving

prescribing practices. As outlined in section III.K.3.c.(4)(d).(i) of this proposed rule, stakeholders indicated that the Verify Opioid Treatment Agreement measure presented significant implementation challenges for MIPS eligible clinicians. Therefore, we are seeking comment on potential new measures for OUD prevention and treatment that could be included in future years of the Promoting Interoperability performance category. We welcome all comments, but we are seeking comment specifically on possible OUD prevention and treatment measures that include the following characteristics:

- Include evidence of positive impact on outcome-focused improvement activities, and the opioid crisis overall;
- Leverage the capabilities of CEHRT where possible, including: near-automatic calculation and reporting of numerator, denominator, exclusions and exceptions to minimize manual documentation required of the provider; and timing elements to reduce quality measurement and reporting burdens to the greatest extent possible;
- Are based on well-defined clinical concepts, measure logic and timing elements that can be captured by CEHRT in standard clinical workflow and/or routine business operations. Well-defined clinical concepts include those that can be discretely represented by available clinical and/or claims vocabularies such as SNOMED CT, LOINC, RxNorm, ICD–10 or CPT;
- Align with clinical workflows in such a way that data used in the calculation of the measure is collected as part of a standard workflow and does not require any additional steps or actions by the health care provider;
- Are applicable to all clinicians (for example, clinicians participating as individuals or as a group, or clinicians located in a rural area, designated health professional shortage area (HPSA), designated medically-underserved area (MUA), or urban area);
- Could potentially align with other MIPS performance categories; and
- Are represented by a measure description, numerator/denominator or yes/no attestation statement, and possible exclusions.

(ii) Request for Information (RFI) on NQF and CDC Opioid Quality Measures

We also are specifically seeking public comment on the development of potential measures for consideration for the Promoting Interoperability performance category that are based on existing efforts to measure clinical and process improvements specifically related to the opioid epidemic, including the opioid quality measures endorsed by the National Quality Forum (NQF) and the CDC Quality Improvement (QI) opioid measures discussed below. The NQF measures represent a reference point for evaluating opioid prescribing behaviors based on measures that have undergone the rigorous NQF measure endorsement process. The CDC guidelines ''encourage careful and selective use of opioid therapy in the context of managing chronic pain through . . . an evidence-based prescribing guideline.'' [117] The guidelines have led to the development of CDC measures on prescribing practices on which we are seeking comment. We believe these measures may help participants understand the relationship between the measure description and the use of health IT to support the actions of the measures.

For example, the measures may describe a clinical concept, such as the CDC Measure 12: Counsel on Risks and Benefits Annually. The actions for this activity can be supported by CEHRT through the use of standards to record key health information for the patient and to identify which patients should be included in the denominator based on information in the medication list, information gained through medication reconciliation of data received through health information exchange with another health provider of care, and/or information incorporated after a query of a PDMP is completed. The actions for the numerator could include leveraging CEHRT to provide patient-specific education, to capture or record Patient Generated Health Data (PGHD), to engage in secure messaging with the patient and ensure the patient is engaging with their record through a patient portal or an Application Programming Interface (API).

We believe that the clinical actions identified within both the NQF quality measures and the CDC QI opioid measures, can be supported by the standards and functionalities of certified health IT and we welcome public comment on the specific use cases for health IT implementation for the potential measure actions. We recognize that modifications to the NQF and CDC measures may be necessary to make the measures as applicable as possible to all participants of the Promoting Interoperability performance category, and are seeking comment on any modifications that would be necessary. In addition, we note that there is some overlap between some of the NQF quality measures and the CDC QI opioid measures and are seeking comment on whether there are ways in which the two sets of measures could be correlated to support potential new measures of the meaningful use of health IT for the Promoting Interoperability performance category. Finally, we are seeking comment on which measures might best advance the implementation and use of interoperable health IT and encourage information exchange between care teams and with patients.

(A) NQF Quality Measures

Three NQF-endorsed quality measures that were stewarded by the Pharmacy Quality Alliance (PQA) evaluate patients with prescriptions for opioids in combination with benzodiazepines, at high-dosage, or from multiple prescribers and pharmacies. Each measure was evaluated and recommended for endorsement by the NQF's Patient Safety Standing Committee [118] and endorsed by the Consensus Standards Approval Committee. These measures, NQF #2940, #2950, and #2951, were recommended by the NQF Measure Application Partnership for inclusion on the December 2018 Measures Under Consideration List for the Medicare Shared Savings Program.

We are seeking public comment on the development of potential measures for consideration for the Promoting Interoperability performance category that are based on existing efforts to measure clinical and process improvements specifically related to the opioid epidemic, including the opioid quality measures endorsed by the NQF above and the CDC QI opioid measures discussed below. The NQF measures represent a reference point for evaluating opioid prescribing behaviors based on measures that have undergone the rigorous NQF measure endorsement process. The CDC guidelines ''encourage careful and selective use of opioid therapy in the context of managing chronic pain through . . . an evidence-based prescribing guideline.'' [119] The guidelines have led to the development of CDC measures on prescribing practices on which are seeking comment. We are seeking comment on the following three NQF measures for possible inclusion in the Promoting Interoperability performance category and any modifications that may be

[117] *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC–DUIP-QualityImprovementAndCareCoordination-508.pdf.*

[118] *https://www.qualityforum.org/News_And_Resources/Press_Releases/2017/NQF_Statement_on_Endorsement_of_Opioid_Patient_Safety_Measures.aspx.*

[119] *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC–DUIP-QualityImprovementAndCareCoordination-508.pdf.*

necessary to maximize their use in the Promoting Interoperability performance category:

- Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940).
- Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950).
- Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951).

We believe these measures relate to activities that hold promise in combatting the opioid epidemic and can be supported using CEHRT to complete the actions of the measures. Therefore, we are seeking comment on how the Promoting Interoperability performance category can incorporate the description of the use of technology into measure guidance if these measures were considered for use by MIPS eligible clinicians. For example, the actions related to the Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950) measure could include using health IT to electronically prescribe the medication, to query a PDMP, to identify other care team members, to conduct medication reconciliation based on information received through health information exchange with other providers of care, and recording key health information in a structured format. Additional information regarding each measure is available using NQF's Quality Positioning System at *http://www.qualityforum.org/QPS/QPSTool.aspx*.

(B) CDC Quality Improvement Opioid Measures

We believe there may be promise in the CDC QI opioid measures based on the prescribing best practices found in Appendix B in the CDC document, ''Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain'' (Implementing the CDC Prescribing Guideline).[120] CDC developed the ''Implementing the CDC Prescribing Guideline'' document to help healthcare providers and systems integrate the CDC Prescribing Guideline [121] and the associated QI opioid measures found in the Implementing the CDC Prescribing Guideline document into their clinical practices. The CDC developed 16 QI opioid measures to align with the recommendations in the CDC Prescribing Guideline and to improve opioid prescribing. These measures are intended to measure implementation of the recommended practices.

Generally, we believe these guidelines and measures are consistent with the objective and measure concept of the Promoting Interoperability performance category where the recommendation in the CDC Prescribing Guideline is the overarching objective and an associated QI opioid measure is a description of the patient population focus (denominator) and the desired action (numerator). The ''Implementing the CDC Prescribing Guideline'' document, also, includes practice-level strategies to help organize and improve the management and coordination of long-term opioid therapy:

- Using an interdisciplinary team approach.
- Establishing practice policies and standards.
- Using EHR data to develop registries and track QI opioid measures.

These following measures address treatment guidelines for initial treatment practices and long-term treatment and outcomes. Examples of measures related to short term OUD prevention and treatment activities include:

- *CDC Measure 2:* Check PDMP Before Prescribing Opioids.
- *CDC Measure 4:* Evaluate Within Four Weeks of Starting Opioids.

Examples of measures related to long term OUD prevention and treatment activities include:

- *CDC Measure 11:* Check PDMP Quarterly.
- *CDC Measure 12:* Counsel On Risks and Benefits Annually.

The data sources from these measures include State PDMP data or the practice EHR data field.

The CDC and the Agency for Healthcare Research and Quality (AHRQ) are also developing electronic clinical decision support tools that can provide real-time clinical decision support for some of the best practices included in the Implementing the CDC Prescribing Guideline document based on well-defined clinical concepts.[122] Well-defined clinical concepts are those that can be discretely represented by available content standards or vocabularies such as SNOMED CT or LOINC. In the context of QI measures, these well-defined clinical concepts that are part of the clinical decision support artifacts, including the clinical conditions or prescribed medications that trigger the decision support, could also be used to develop measures for the Promoting Interoperability performance category related to OUD prevention and treatment. This can create a tight linkage between the guidelines, the recommended clinical actions based on the guidelines, and the improved outcomes based on the recommended clinical actions.

Therefore, we are seeking comment on which of the 16 CDC QI opioid measures have value for potential consideration for the Promoting Interoperability performance category. We are further seeking comment on whether we should consider a different type of measurement concept for OUD prevention and treatment, such as reporting on a set of cross-cutting activities and measures to earn credit in the Promoting Interoperability performance category (for example, a set of one clinical decision support, the related CDC QI opioid measure, and a potentially relevant clinical quality measure). While the CDC quality measures could be implemented for the Quality category, they are highlighted as under consideration for the PI category as they have been linked in the CDC work to the use of CDS artifacts through health IT, as discussed.

We refer readers to the ''Implementing the CDC Prescribing Guideline'' document, and the related measures, in Appendix B of that document, which is available at *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf*.

(iii) Request for Information (RFI) on a Metric To Improve Efficiency of Providers Within EHRs

One of the benefits of adopting EHRs is increasing the efficiency of health care processes and generating cost savings by eliminating time-consuming paper-based processes. Through the use of EHRs, health care providers are able to automate administrative aspects of delivery system management, such as coding and scheduling, easily locate patient information in electronic charts, and streamline communications with other health care providers through electronic means.

However, research, also, points to variable results from the implementation of health IT across practice settings, suggesting that health IT adoption is not a universal remedy for inefficient practice. Stakeholders continue to describe ways in which the potential benefits of EHRs have not been fully realized, and are pointing to non-optimized electronic workflows and poor system design that can increase, rather than reduce, administrative burden, which contributes to physician

[120] *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf*.

[121] *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm*.

[122] *https://cds.ahrq.gov/cdsconnect/topic/opioids-and-pain-management*.

burnout.[123] For instance, in many systems, stakeholders have identified EHR functionality associated with clinical documentation, order entry, and messaging as cumbersome. It is our understanding that in order to achieve true EHR efficiency gains in today's healthcare environment, the way forward must include reductions in the persistent sources of technology-related burden, an increased allowance for ancillary medical staff to assist in medical documentation, and through the more effective use of technology.

In November 2018, the Office of the National Coordinator for Health Information Technology (ONC) released the draft report ''Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs,'' [124] as required by section 4001 of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016). In the draft report, ONC described a variety of factors that may contribute to EHR-related burden, and provided draft recommendations for how HHS, as well as other stakeholders may be able to address these factors. Specifically, the draft report discussed processes where adoption of improved electronic processes could reduce the EHR-related burden, such as processes related to prior authorization requests. The draft report, also, discussed EHR usability and design challenges which may contribute to EHR-related burden, and identified best practices for design, as well as a variety of emerging system features which may improve efficiency in health IT usage. We believe further adoption of more efficient workflows and technologies, such as those identified in the draft report, will help health care providers with overall improvements in patient care and interoperability, and we are seeking comment on how such implementation of such processes can be effectively measured and encouraged as part of the Promoting Interoperability performance category.

We also are interested in how to measure and incentivize efficiency as it relates to the meaningful use of CEHRT and the furthering of interoperability. In 2017, the NQF released, ''A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy,'' [125] which included discussion of measure concepts of productivity and efficiency that can result from the use of health IT, specifically the health information exchange. For instance, the NQF report identifies a measure concept for the ''percentage of reduction of duplicate labs and imaging over time,'' which can capture the impact of electronic availability of imaging studies on duplicative studies that are often conducted when health care providers do not have the ability to locate an existing study. However, we recognize that there are challenges associated with tying such measures of economic efficiency to a single factor, such as electronic workflow improvements.[126]

Consistent with our commitment to reducing administrative burden, increasing efficiencies, and improving beneficiary experience via the ''Patients over Paperwork initiative,'' [127] we are seeking stakeholder feedback on a potential metric to evaluate health care provider efficiency using EHRs. Specifically, we are requesting information on the following questions:

- What do stakeholders believe would be useful ways to measure the efficiency of health care processes due to the use of health IT? What are measurable outcomes demonstrating greater efficiency in costs or resource use that can be linked to the use of health IT-enabled processes? This includes measure description, numerator/denominator or yes/no reporting, and exclusions.
- What do stakeholders believe may be hindering their ability to achieve greater efficiency (for example, product, measures, CMS regulations)? Please, provide examples.
- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability performance category) that can increase the efficiency of provider interactions with technology systems; for instance, alternate authentication technologies that can simplify provider logon? How could we reward providers for adoption and use of these technologies?
- What are key administrative processes that can benefit from more efficient electronic workflows; for instance, conducting prior authorization requests? How can we measure and reward providers for their uptake of more efficient electronic workflows?
- Could CMS successfully incentivize efficiency? What role should CMS play in improving efficiency in the practice of medicine? The underlying goal is to move to a more streamlined, efficient, easier user experience, whereby providers can input and access a patient's data in a reliable, timely manner. Having not yet reached this point, we are seeking feedback on the best way(s) to get there.

(iv) Request for Information (RFI) on the Provider to Patient Exchange Objective

In March 2018, the White House Office of American Innovation and the CMS Administrator announced the launch of MyHealthEData and CMS' role in improving patient access and advancing interoperability. As part of the MyHealthEData initiative, we are taking a patient-centered approach to health information access and moving to a system in which patients have immediate access to their computable health information and can be assured that their health information will follow them as they move throughout the health care system from provider to provider, payer to payer. To accomplish this, we have launched several initiatives related to data sharing and interoperability to empower patients and encourage plan and provider competition. One example is our overhaul of the Advancing Care Information performance category under MIPS to transform it into the new Promoting Interoperability performance category, which put a heavy emphasis on patient access to their health information through the Provide Patients Electronic Access to Their Health Information measure.

Through the Provide Patients Electronic Access to Their Health Information measure, we are ensuring that patients have access to their information through any application of their choice that is configured to meet the technical specifications of the API in the MIPS eligible clinician's CEHRT. To make these APIs fully useful to patients, they should provide immediate access to updated information whenever the patient needs that information, should be always available, configured using standardized technology and contain the information a patient needs to make informed decisions about their care.

In the CY 2019 PFS proposed rule (83 FR 35932), we introduced a potential future Promoting Interoperability performance category concept that explored creating a set of priority health IT activities that would serve as alternatives to the traditional Promoting

[123] *https://www.ahrq.gov/professionals/clinicians-providers/ahrq-works/burnout/index.html.*

[124] *https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf.*

[125] *https://www.qualityforum.org/Publications/2017/09/Interoperability_2016-2017_Final_Report.aspx.*

[126] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699907/.*

[127] *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html.*

Interoperability performance category measures. We requested public comment on whether MIPS eligible clinicians should earn credit in the Promoting Interoperability performance category by attesting to health IT or interoperability activities in lieu of reporting on specific measures. We identified specific health IT activities and sought public comment on those and additional activities that would add value for patients and health care providers, are relevant to patient care and clinical workflows, support alignment with existing objectives, promote flexibility, are feasible for implementation, are innovative in the use of health IT, and promote interoperability. We received feedback in support of this future concept.

One such activity that we specifically requested comment on was a health IT activity in which MIPS eligible clinicians may obtain credit in the Promoting Interoperability performance category if they maintain an ''open API,'' or standards-based API, which allows patients to access their health information through a preferred third-party application. An API can be thought of as a set of commands, functions, protocols, or tools published by one software developer (''Developer A'') that enables other software developers to create programs (applications or ''apps'') that can interact with developer A's software without needing to know the internal workings of developer A's software, all while maintaining consumer privacy data standards. This is how API technology creates a seamless user experience that is, typically, associated with other applications that are used in more common aspects of consumers' daily lives, such as travel and personal finance. Standardized, transparent, and pro-competitive API technology can enable similar benefits to consumers of health care services.[128]

We received feedback from several commenters regarding concerns that an ''open'' API may open the door to patient data without security, leaving MIPS eligible clinicians' EHR systems open for cyber-attacks. However, we wish to note that the term ''open API'' does not imply that any and all applications or application developers would have unfettered access to individuals' personal or sensitive information nor would it allow for any reduction in the required protections for privacy and security of patient health information. Additionally, with respect to patient access, a patient will need to authenticate him/herself to a health care organization that is the steward of their data (for example, username and password) and the access provided to an app will be for that one patient. The overall HIPAA Security Rule, HIPAA Privacy Rule, and other cybersecurity obligations that apply to HIPAA covered entities remain the same and would need to be applied to an API in the same way they are currently applied to any and all other interfaces a health care organization deploys in production.

ONC's 21st Century Cures Act proposed rule (84 FR 7424 through 7610) includes new proposals that focus on how certified health IT can use APIs to allow health information to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law. For instance, ONC has proposed to adopt a new criterion for a standards-based API at § 170.315(g)(10). This standards-based API criterion would replace the existing API criterion with one that requires the use of the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard. ONC has also proposed a series of requirements for the standards-based API that would improve interoperability by focusing on standardized, transparent, and pro-competitive API practices.

ONC has proposed to make the standards-based API criterion part of the 2015 Edition base EHR definition (84 FR 7427), which would ensure that this functionality is ultimately included in the CEHRT definition required for participation in the Promoting Interoperability performance category. If finalized, health IT developers would have 24 months from the publication of the final rule to implement these changes to certified health IT products.

(A) Immediate Access

The existing Provide Patients Electronic Access to Their Health Information measure specifies that the MIPS eligible clinicians provide the patient timely access to view online, download, and transmit his or her health information, and further specifies that patient health information must be made available to the patient within 4 business days of its availability to the MIPS eligible clinicians. We believe it is critical for patients to have access to their health information when making decisions about their care. In the recently published proposed rule titled, ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers proposed rule'' (84 FR 7610 through 7680) (hereinafter referred to as the ''CMS Interoperability and Patient Access proposed rule''), we proposed that certain health plans and payers be required to make patient health information available through an open, standards-based API no later than one business day after it is received by the health plan or payer.

Recognizing the importance of patients having access to their complete health information, including clinical information from the MIPS eligible clinicians' CEHRT, and appreciating the new technical flexibility a standards-based API would provide, we are seeking comment on whether MIPS eligible clinicians should make patient health information available immediately through an open, standards-based API, no later than one business day after it is available to the MIPS eligible clinicians in their CEHRT. We seek comment on the barriers to more immediate access to patient information. Additionally, we seek comment on whether there are specific data elements that may be more or less feasible to share no later than one business day. We also seek comment as to when implementation of such a requirement is feasible.

(B) Persistent Access and Standards-Based APIs

As discussed above, the ONC 21st Century Cures Act proposed rule (84 FR 7479) includes a proposal for adoption of API conditions of certification that ensure a standards-based API is implemented in a manner that provides unimpeded access to technical documentation, is non-discriminatory, preserves rights of access, and minimizes costs or other burdens that could result in special effort. The ONC 21st Century Cures Act proposed rule (84 FR 7575), also, includes requirements for the standardized API related to privacy and security to ensure that patient health information is protected.

The existing Provide Patients Electronic Access to Their Health Information measure does not specify the overall operational expectations associated with enabling patients' access to their health information. For instance, the measure only specifies that

[128] ONC has made available a succinct, non-technical overview of APIs in context of consumers' access to their own medical information across multiple providers' EHR systems, which is available at the *HealthIT.gov* website at *https://www.healthit.gov/api-education-module/story_html5.html*.

access must be ''timely.'' As a result, we request public comment on whether we should revise the measure to be more specific with respect to the experience patients should have regarding their access. For instance, in the ONC 21st Century Cures Act proposed rule (84 FR 7481 through 7484), there is a proposal regarding requirements around persistent access to APIs, which would accommodate a patient's routine access to their health information without needing to reauthorize their application and re-authenticate themselves. We seek comment on whether the Promoting Interoperability performance category measure should be updated to accommodate this proposed technical requirement for persistent access.

As we work to advance interoperability and empower patients through access to their health information, we continue to explore the role of APIs. We support the ONC 21st Century Cures Act proposed rule (84 FR 7424) proposal to move to an HL7 FHIR®-based API under 2015 Edition certification (84 FR 7479). Health care providers committed to a standards-based API could benefit from joining in on the industry's new FHIR standards framework to reduce burden in, and improve on, quality measurement through automation and simplification. Use of FHIR-based APIs could help push forward interoperability regardless of EHR systems used providing standardized way to share information.

Understanding this, we are, specifically, seeking public comments on the following question:

- If ONC's proposed FHIR-based API certification criteria is finalized, would stakeholders support a possible bonus under the Promoting Interoperability performance category for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs?

(C) Available Data

Recognizing the overall burden that switching EHR systems places on health care providers, ONC has introduced a new proposal that seeks to minimize that burden. In the ONC 21st Century Cures Act proposed rule, ONC proposed to adopt a new 2015 Edition certification criterion for the EHI export at 45 CFR 170.315(b)(10). The purpose of this criterion is to provide patients and health IT users the ability to securely export the entire EHR for a single patient, or all patients, in a computable, electronic format, and facilitate receiving the health IT system's interpretation, and use of the EHI, to the extent that is reasonably practicable using the existing technology of developers. This patient-focused export capability complements other provisions of the proposed rule that support patients' access to their EHI, including information that may eventually be accessible via the proposed standardized API in 45 CFR 170.215. It is also complementary to the proposals in the CMS Interoperability and Patient Access proposed rule, which proposed to require certain health plans and issuers to provide patients access to their health data through a standardized API.

Building on these proposals, we are seeking comment on an alternative measure under the Provider to Patient Exchange objective that would require clinicians to use technology certified to the EHI criterion to provide the patient(s) their complete electronic health data contained within an EHR.

Specifically, we are seeking comment on the following questions:

- Do stakeholders believe that incorporating this alternative measure into the Provider to Patient Exchange objective will be effective in encouraging the availability of all data stored in health IT systems?
- In relation to the Provider to Patient Exchange objective, as a whole, how should a required measure focused on using the proposed total EHI export function in CEHRT be scored?
- If this certification criterion is finalized and implemented, should a measure based on the criterion be established as a bonus measure? Should this measure be established as an attestation measure?
- In the long term, how do stakeholders believe such an alternative measure would impact burden?
- If stakeholders do not believe this will have a positive impact on burden, in what other way(s) might an alternative measure be implemented that may result in burden reduction? Please, be specific.
- Which data elements do stakeholders believe are of greatest clinical value or would be of most use to health care providers to share in a standardized electronic format if the complete record was not immediately available?

In addition to the above questions, we have some general questions that are related to health IT activities, for which we are, also, seeking public comment:

- Do stakeholders believe that we should consider including a health IT activity that promotes engagement in the health information exchange across the care continuum that would encourage bi-directional exchange of health information with community partners, such as post-acute care, long-term care, behavioral health, and home and community based services to promote better care coordination for patients with chronic conditions and complex care needs? If so, what criteria should we consider when implementing a health information exchange across the care continuum health IT activity in the Promoting Interoperability performance category?
- What criteria should we employ, such as specific goals or areas of focus, to identify high priority health IT activities for the future of the performance category?
- Are there additional health IT activities we should consider recognizing in lieu of reporting on existing measures and objectives that would most effectively advance priorities for nationwide interoperability and spur innovation?

(D) Patient Matching

ONC has stated that patient matching is critically important to interoperability and the nation's health IT infrastructure as health care providers must be able to share patient health information and accurately match a patient to his or her data from a different health care provider in order for many anticipated interoperability benefits to be realized. We continue to support ONC's work promoting the development of patient matching initiatives. Per Congress' guidance, ONC is looking at innovative ways to provide technical assistance to private sector-led initiatives to further develop accurate patient matching solutions in order to promote interoperability without requiring a unique patient identifier (UPI). We understand the significant health information privacy and security concerns raised around the development of a UPI standard and the current prohibition against using HHS funds to adopt a UPI standard (84 FR 7656).

Recognizing Congress' statement regarding patient matching and stakeholder comments stating that a patient matching solution would accomplish the goals of a UPI, we are seeking comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. We are also seeking comment on how we may leverage our authority to provide support to those working to improve patient matching. We note that we intend to use comments we receive for

the development of policy and future rulemaking.

- Do stakeholders believe that CMS and ONC patient matching efforts impact burden? Please, explain.
- If stakeholders believe that patient matching is leading to increased burden, what suggestions might stakeholders have to promote interoperability securely and accurately, without the requirement of a UPI, that may result in burden reduction? Please, be specific.

(v) Request for Information (RFI) on Integration of Patient-Generated Health Data Into EHRs Using CEHRT

The Promoting Interoperability performance category is continuously seeking ways to prioritize the advanced use of CEHRT functionalities, encourage movement away from paper-based processes that increase health care provider burden, and empower individual beneficiaries to take a more impactful role in managing their health to achieve their goals. Increased availability of patient-generated health data (PGHD) [129] offers providers an opportunity to monitor and track a patient's health-related data from information that is provided by the patient and not the provider. Increasingly affordable wearable devices, sensors, and other technologies capture PGHD, providing new ways to monitor and track a patient's healthcare experience. Capturing important health information through devices and other tools between medical visits could help improve care management and patient outcomes, potentially resulting in increased cost savings. Although many types of PGHD are being used in clinical settings today, the continuous collection and integration of patients' health-data into EHRs to inform clinical care has not been widely achieved across the health care system.

In the 2015 Edition Health IT Certification Criteria final rule (80 FR 62661; 45 CFR 170.315(e)(3)), ONC finalized a criterion for patient health information capture functionality within certified health IT that allows a user to identify, record, and access information directly and electronically shared by a patient. We finalized a PGHD measure requiring health care providers to incorporate PGHD or data from a nonclinical setting into CEHRT (80 FR 62851). However, we removed this measure in the CY 2019 PFS final rule (83 FR 59813), due to concerns that the measure was not fully health IT-based and could include paper-based actions, an approach which did not align with program priorities to advance the use of CEHRT. Stakeholder comments regarding this measure also noted that manual processes to conduct actions associated with the measure could increase health care provider reporting burden and that there was confusion over which types of data would be applicable and the situations in which the patient data would apply. At the same time, there was ample support from the public for ONC and CMS to continue to advance certified health IT capabilities to capture PGHD.

However, we continue to believe that it is important for the Promoting Interoperability performance category to explore new ways to incentivize health care providers who take proactive steps to advance the emerging use of PGHD. As relevant technologies and standards continue to evolve, there may be new approaches through which we can address challenges related to emerging standards for PGHD capture, appropriate clinical workflows for receiving and reviewing PGHD, and advance the technical architecture needed to support PGHD use.

In 2018, ONC released the white paper, ''Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024,'' [130] which described key challenges, opportunities and enabling actions for different stakeholders, including clinicians, to advance the use of PGHD. For instance, the report identified an enabling action around supporting ''clinicians to work within and across organizations to incorporate prioritized PGHD use cases into their workflows.'' This action urges clinicians and care teams to identify priority use cases and relevant PGHD types that would be valuable to improving care delivery for patient populations. It, also, highlights the importance of developing clinical workflows that avoid overwhelming the care team with extraneous data by encouraging care teams to develop management strategies for shared responsibilities around collecting, verifying, and analyzing PGHD. A second enabling action the white paper identifies for clinicians is, ''collaboration between clinicians and developers to advance technologies supporting PGHD interpretation and use.'' This enabling action highlights feedback for developers about prioritized use cases and application features as critical to ensuring that the necessary refinements are made to technology solutions to effectively support the capture and use of PGHD. Finally, the report encourages ''clinicians in providing patient education to encourage PGHD capture and use in ways that maximize data quality,'' recognizing the important role that clinicians can play in helping patients understand how to share PGHD, the differences between solicited and unsolicited PGHD, and how PGHD are relevant for the patient's care.

Considering the enabling actions for clinicians identified in the white paper, we are interested in ways that the Promoting Interoperability performance category could adopt new elements related to PGHD that: (1) Represent clearly defined uses of health IT; (2) are linked to positive outcomes for patients; and (3) advance the capture, use, and sharing of PGHD. In considering how the Promoting Interoperability performance category could continue to advance the use of PGHD, we also note that a future element related to PGHD would not necessarily need to be implemented as a traditional measure requiring reporting of a numerator and denominator. For instance, in the CY 2019 PFS proposed rule (83 FR 35932), we requested comment on the concept of ''health IT'' or ''interoperability'' activities to which a health care provider could attest, potentially in lieu of reporting on measures associated with certain objectives. By addressing the use of PGHD through such a concept, rather than traditional measure reporting, we could potentially reduce the reporting burden associated with a new PGHD-related element.

We are inviting stakeholder comment on these concepts, and the specific questions below:

- What specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings are most promising for improving patient outcomes? For instance, use of PGHD for capturing advanced directives and pre/post-operation instructions in surgery units.
- Should the Promoting Interoperability performance category explore ways to reward providers for engaging in activities that pilot promising technical solutions or approaches for capturing PGHD and incorporating it into CEHRT using standards-based approaches?
- Should health care providers be expected to collect information from their patients outside of scheduled appointments or procedures? What are the benefits and concerns about doing so?
- Should the Promoting Interoperability performance category

[129] For more information, we refer readers to *https://www.healthit.gov/topic/scientific-initiatives/patient-generated-health-data.*

[130] *https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf.*

explore ways to reward health care providers for implementing best practices associated with optimizing clinical workflows for obtaining, reviewing, and analyzing PGHD?

We believe the bi-directional availability of data, meaning that both patients and their health care providers have real-time access to the patient's electronic health record, is critical. This includes patients being able to import their health data into their medical record and have it be available to health care providers. We welcome input on how we can encourage, enable, and reward health care providers to advance capture, exchange, and use of PGHD.

(vi) Request for Information (RFI) on Engaging in Activities That Promote the Safety of the EHR

The widespread adoption of EHRs has transformed the way health care is delivered, offering improved availability of patient health information, supporting more informed clinical decision making, and reduce medical errors.[131] However, many stakeholders have identified risks to patient safety as one of the unintended consequences that may result from the implementation of EHRs. By disrupting established workflows and presenting clinicians with new challenges, EHR implementation may increase the incidence of certain errors, resulting in harm to patients.

As we continue to advance the use of CEHRT in health care, we are seeking comment on how to further mitigate the specific safety risks that may arise from technology implementation. Specifically, we are seeking comment on ways that the Promoting Interoperability performance category may reward MIPS eligible clinicians for engaging in activities that can help to reduce the errors associated with EHR implementation.

For instance, we are requesting comment on a potential future change to the performance category under which MIPS eligible clinicians would receive points towards their Promoting Interoperability performance category score for attesting to performance of an assessment based on one of the ONC SAFER Guides. The SAFER Guides (available at *https://www.healthit.gov/topic/safety/safer-guides*) are designed to help healthcare organizations conduct self-assessments to optimize the safety and safe use of EHRs in nine different areas: High Priority Practices, Organizational Responsibilities, Contingency Planning, System Configuration, System Interfaces, Patient Identification, Computerized Provider Order Entry, Test Results Reporting and Follow-Up, and Clinician Communication.

Each of the SAFER Guides is based on the best evidence available, including a literature review, expert opinion, and field testing at a wide range of healthcare organizations, from small ambulatory practices to large health systems. A number of EHR developers currently utilize the SAFER Guides as part of their health care provider training modules.

Specifically, we might consider offering points towards the Promoting Interoperability performance category score to MIPS eligible clinicians that attest to conducting an assessment based on the High Priority Practices [132] and/or the Organizational Responsibilities [133] SAFER Guides which cover many foundational concepts from across the guides. Alternatively we might consider awarding points for review of all nine of the SAFER Guides. We are also inviting comments on alternatives to the SAFER Guides, including appropriate assessments related to patient safety, which should also be considered as part of any future bonus option.

We are requesting comment on the ideas above, as well as inviting stakeholders to suggest other approaches we may take to rewarding activities that promote reduction of safety risks associated with EHR implementation as part of the Promoting Interoperability performance category.

(5) APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

As codified at § 414.1370(a), the APM scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified on the Participation List for the of an APM Entity participating in a MIPS APM for the applicable MIPS performance period.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77246), the APM scoring standard is designed to reduce reporting burden for such clinicians by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and MIPS.

We established at § 414.1370(c) that the MIPS performance period under § 414.1320 applies for the APM scoring standard. We finalized under § 414.1370(f) that the MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity, and the MIPS payment adjustment is applied at the TIN/NPI level for each MIPS eligible clinician in the APM Entity group. Under § 414.1370(f)(2), if the APM Entity group is excluded from MIPS, all eligible clinicians within that APM Entity group are also excluded from MIPS.

As finalized at § 414.1370(h)(1) through (4), the performance category weights used to calculate the MIPS final score for an APM Entity group for the APM scoring standard performance period are: Quality at 50 percent; cost at 0 percent; improvement activities at 20 percent; and Promoting Interoperability at 30 percent.

(b) MIPS APM Criteria

We established at § 414.1370(b) that for an APM to be considered a MIPS APM, it must satisfy the following criteria: (1) APM Entities must participate in the APM under an agreement with CMS or by law or regulation; (2) the APM must require that APM Entities include at least one MIPS eligible clinician on a Participation List; (3) the APM must base payment on quality measures and cost/utilization; and (4) the APM must be neither a new APM for which the first performance period begins after the first day of the MIPS performance year nor an APM in the final year of operation for which the APM scoring standard is impracticable. In the CY 2019 PFS final rule (59820 through 59821), we clarified that we consider whether each distinct track of an APM meets the criteria to be a MIPS APM and that it is possible for an APM to have tracks that are MIPS APMs and tracks that are not MIPS APMs. We also clarified that we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.

Based on the MIPS APM criteria, we expect that the following 10 APMs will satisfy the requirements to be MIPS APMs for the 2020 MIPS performance period:

- Comprehensive ESRD Care Model (all Tracks).
- Comprehensive Primary Care Plus Model (all Tracks).
- Next Generation ACO Model.
- Oncology Care Model (all Tracks).

[131] *https://www.healthit.gov/topic/health-it-basics/improved-patient-care-using-ehrs.*

[132] *https://www.healthit.gov/sites/default/files/safer/guides/safer_high_priority_practices.pdf.*

[133] *https://www.healthit.gov/sites/default/files/safer/guides/safer_organizational_responsibilities.pdf.*

- Medicare Shared Savings Program (all Tracks).
- Medicare ACO Track 1+ Model.
- Bundled Payments for Care Improvement Advanced.
- Maryland Total Cost of Care Model (Maryland Primary Care Program).
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).
- Primary Care First (All Tracks).

Final CMS determinations of MIPS APMs for the 2020 MIPS performance period will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*. Further, we make these determinations based on the established MIPS APM criteria as specified in § 414.1370(b).

(c) Calculating MIPS APM Performance Category Scores

(i) Quality Performance Category

As noted, the APM scoring standard is designed to reduce reporting burden for MIPS eligible clinicians participating in MIPS APMs by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and MIPS. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77246), due to operational constraints, we did not require MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program and the Next Generation ACO Model to submit data on quality measures for purposes of MIPS for the 2017 MIPS performance period. As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53695), we designed a means of overcoming these operational constraints and required MIPS eligible clinicians participating in such MIPS APMs to submit data on APM quality measures for purposes of MIPS beginning with the 2018 MIPS performance period. We also finalized a policy to reweight the quality performance category to zero percent in cases where an APM has no measures available to score for the quality performance category for a MIPS performance period, such as where none of the APM's measures would be available for calculating a quality performance category score by the close of the MIPS submission period because measures were removed from the APM measure set due to changes in clinical practice guidelines. Although we anticipated different scenarios where quality would need to be reweighted, we did not anticipate at that time that the quality performance category would need to be reweighted regularly.

After several years of implementation of the APM scoring standard, we have found that for participants in certain MIPS APMs (as defined in § 414.1305), it often is not operationally possible to collect and score performance data on APM quality measures for purposes of MIPS because these APMs run on episodic or yearly timelines that do not always align with the MIPS performance periods and deadlines for data submission, scoring, and performance feedback. In addition, although we anticipated different scenarios where quality would need to be reweighted, we do not believe the quality performance category should be reweighted regularly.

To achieve the aims of the APM scoring standard, we believe it is necessary to consider new approaches to quality performance category scoring.

(A) Allowing MIPS Eligible Clinicians Participating in MIPS APMs To Report on MIPS Quality Measures

We propose to allow MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures in a manner similar to our established policy for the Promoting Interoperability performance category under the APM scoring standard for purposes of the MIPS quality performance category beginning with the 2020 MIPS performance period.

Similar to our approach for the Promoting Interoperability performance category, we would allow MIPS eligible clinicians in MIPS APMs to receive a score for the quality performance category either through individual or TIN-level reporting based on the generally applicable MIPS reporting and scoring rules for the quality performance category. Under such an approach, we would attribute one quality score to each MIPS eligible clinician in an APM Entity by looking at both individual and TIN-level data submitted for the eligible clinician and using the highest reported score, excepting scores reported by a virtual group. Thus, we would use the highest individual or TIN-level score attributable to each MIPS eligible clinician in an APM Entity in order to determine the APM Entity score based on the average of the highest scores for each MIPS eligible clinician in the APM Entity.

As with Promoting Interoperability performance category scoring, each MIPS eligible clinician in the APM Entity group would receive one score, weighted equally with that of the other MIPS eligible clinicians in the APM Entity group, and we would calculate one quality performance category score for the entire APM Entity group. If a MIPS eligible clinician has no quality performance category score—if the individual's TIN did not report and the individual did not report—that MIPS eligible clinician would contribute a score of zero to the aggregate APM Entity group score.

We would use only scores reported by an individual MIPS eligible clinician or a TIN reporting as a group; we would not accept virtual group level reporting because a virtual group level score is too far removed from the eligible clinician's performance on quality measures for purposes of the APM scoring standard.

We request comment on this proposal.

(B) APM Quality Reporting Credit

We are also proposing to apply a minimum score of 50 percent, or an ''APM Quality Reporting Credit'' under the MIPS quality performance category for certain APM entities participating in MIPS, where APM quality data cannot be used for MIPS purposes as outlined below. Several provisions of the statute address the possibility of considerable overlap between the requirements of MIPS and those of an APM. Most notably, section 1848(q)(1)(C)(ii) of the Act excludes QPs and partial QPs that do not elect to participate in MIPS from the definition of a MIPS eligible clinician. In addition, section 1848(q)(5)(C)(ii) of the Act requires that participation by a MIPS eligible clinician in an APM (as defined in section 1833(z)(3)(C) of the Act) earn such MIPS eligible clinician a minimum score of one-half of the highest potential score for the improvement activities performance category.

In particular, we believe that section 1848(q)(5)(C)(ii) of the Act reflects an understanding that APM participation requires significant investment in improving clinical practice, which may be duplicative with the requirements under the improvement activities performance category. We believe that MIPS APMs require an equal or greater investment in quality, which, due to operational constraints, cannot always be reflected in a MIPS quality performance category score. Accordingly, we are proposing to apply a similar approach to quality performance category scoring under the APM scoring standard. Specifically, we are proposing that APM Entity groups participating in MIPS APMs receive a minimum score of one-half of the highest potential score for the quality performance category, beginning with the 2020 MIPS performance period.

To the extent possible, we would calculate the final score by adding to the credit any additional MIPS quality score received on behalf of the individual NPI or the TIN. For the purposes of final

scoring this credit would be added to any MIPS quality measure scores we receive. All quality category scores would be capped at 100 percent. For example, if the additional MIPS quality score were 40 percent, that would be added to the 50 percent credit for a total of 90 percent; if the quality score were 70 percent, that would be added to the 50 percent credit and because the result is 120 percent, the cap would be applied for a final score of 100 percent.

We request comment on this proposal.

(i) Exceptions From APM Quality Reporting Credit

Under this proposal, we would not apply the APM Quality Reporting Credit to the APM Entity group's quality performance score for those APM Entities reporting only through a MIPS quality reporting mechanism according to the requirements of their APM, such as the Medicare Shared Savings Program, which requires participating ACOs to report through the CMS Web Interface and the CAHPS for ACOs survey measures. In these cases, no burden of duplicative reporting would exist, and there would not be any additional unscored quality measures for which to give credit.

In the case where an APM Entity group is in an APM that requires reporting through a MIPS quality reporting mechanism under the terms of participation in the APM, should the APM Entity group fail to report on required quality measures, the individual eligible clinicians and TINs that make up that APM Entity group would still have the opportunity to report quality measures to MIPS for purposes of calculating a MIPS quality performance category score as finalized in they would in any Other MIPS APM in accordance with § 414.1370(g)(1)(ii). However, as in these cases no burden of duplicative reporting would exist, they would remain ineligible for the APM Quality Reporting credit.

(C) Additional Reporting Option for APM Entities

We recognize that some APM Entities may have a particular interest in ensuring that MIPS eligible clinicians in the APM Entity group perform well in MIPS, or in reducing the overall burden of joining the entity. Likewise, we recognize that some APMs, such as the CMS Web Interface reporters already require reporting on MIPS quality measures as part of participation in the APM. Therefore, we are proposing that, in instances where an APM Entity has reported quality measures to MIPS through a MIPS submission type and using MIPS collection type on behalf of the APM Entity group, we would use that quality data to calculate an APM Entity group level score for the quality performance category. We believe this approach best ensures that all participants in an APM Entity group receive the same final MIPS score while reducing reporting burden to the greatest extent possible.

We request comment on this proposal.

(D) Bonus Points and Caps for the Quality Performance Category

In the 2018 Quality Payment Program final rule (82 FR 53568, 53700), we finalized our policies to include bonus points in the performance category score calculation when scoring quality at the APM Entity group level. Because these adjustments would, under the proposals discussed in section[s] III.J.3.d.(1)(b) of this proposed rule, already be factored in when calculating an individual or TIN-level quality performance category score before the quality scores are rolled-up and averaged to create the APM Entity group level score, we believe it would be inappropriate to continue to calculate these adjustments at the APM Entity group level in the case where an APM Entity group's quality performance score is reported by its composite individuals or TINs. However, in the case of an APM Entity group that chooses to or is required by its APM to report on MIPS quality measures at the APM Entity group level, we would continue to apply any bonuses or adjustments that are available to MIPS groups for the measures reported by the APM Entity and to calculate the applicability of these adjustments at the APM Entity group level.

We request comment on this proposal.

(E) Special Circumstances

In prior rulemaking, with regard to the quality performance category, we did not include MIPS eligible clinicians who are subject to the APM scoring standard in the automatic extreme and uncontrollable circumstances policy or the application-based extreme and uncontrollable circumstances policy that we established for other MIPS eligible clinicians (82 FR 53780–53783, 53895–53900; 83 FR 59874–59875). However, in section III.J.3.c.(5)(c)(i)(c) of this proposed rule, we are proposing to allow MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures and be scored for the MIPS quality performance category based on the generally applicable MIPS reporting and scoring rules for the quality performance category. In light of this proposal, we believe that the same extreme and uncontrollable circumstances policies that apply to other MIPS eligible clinicians with regard to the quality performance category should also apply to MIPS eligible clinicians participating in MIPS APMs who would report on MIPS quality measures as proposed. Therefore, beginning with the 2020 MIPS performance period/2022 MIPS payment year and only with regard to the quality performance category, we propose to apply the application-based extreme and uncontrollable circumstances policy (82 FR 53780–53783) and the automatic extreme and uncontrollable circumstances policy (83 FR 59874–59875) that we previously established for other MIPS eligible clinicians and codified at § 414.1380(c)(2)(i)(A)(6) and (8), respectively, to MIPS eligible clinicians participating in MIPS APMs who are subject to the APM scoring standard and would report on MIPS quality measures as proposed in section III.J.3.c.(5)(c)(i). We would limit the proposed application of these policies to the quality performance category because our proposal in section III.J.3.c.(5)(c)(i) pertains to reporting on MIPS quality measures.

Under the previously established policies, MIPS eligible clinicians who are subject to extreme and uncontrollable circumstances may receive a zero percent weighting for the quality performance category in the final score (82 FR 53780–53783, 83 FR 59874–59875). Similar to the policy for MIPS eligible clinicians who qualify for a zero percent weighting of the Promoting Interoperability performance category (82 FR 53701 through 53702), we propose that if a MIPS eligible clinician who qualifies for a zero percent weighting of the quality performance category in the final score is part of a TIN reporting at the TIN level that includes one or more MIPS eligible clinicians who do not qualify for a zero percent weighting, we would not apply the zero percent weighting to the qualifying MIPS eligible clinician. The TIN would still report on behalf of the entire group, although the TIN would not need to report data for the qualifying MIPS eligible clinician. All MIPS eligible clinicians in the TIN who are participants in the MIPS APM would count towards the TIN's weight when calculating the aggregated APM Entity score for the quality performance category.

However, in this circumstance, if the MIPS eligible clinician was a solo practitioner and qualified for a zero percent weighting, if the MIPS eligible clinician's TIN did not report at the group level and the MIPS eligible

clinician was individually eligible for a zero percent weighting, or if all MIPS eligible clinicians in a TIN qualified for the zero percent weighting, neither the TIN nor the individual would be required to report on the quality performance category and would be assigned a weight of zero when calculating the APM Entity's quality performance category score.

If quality performance data were reported by or on behalf of one or more TIN/NPIs in an APM Entity group, a quality performance category score would be calculated for, and would be applied to, all MIPS eligible clinicians in the APM Entity group. If all MIPS eligible clinicians in all TINs of an APM Entity group qualify for a zero percent weighting of the quality performance category, the quality performance category would be weighted at zero percent of the MIPS final score.

We welcome comments from the public in this discussion of how best to address the technical infeasibility of scoring quality for many of our MIPS APMs, and whether the above described policy or some other approach may be an appropriate path forward for the APM entity group scoring standard in CY 2020.

We request comment on this proposal.

(d) Request for Comment on APM Scoring Beyond 2020

We are also seeking comment on potential policies to be included in next year's rulemaking to further address the changing incentives for APM participation under MACRA. We want the design of the APM scoring standard to continue to encourage appropriate shifts of MIPS eligible clinicians into MIPS APMs and eventually into Advanced APMs while ensuring fair treatment for all MIPS eligible clinicians.

We note that the QP threshold will be increasing in future years, potentially resulting in larger proportions of Advanced APM participants being subject to MIPS under the APM scoring standard. At the same time the MIPS performance threshold will be increasing annually, gradually reducing the impact of the APM scoring standard on participants' ability to achieve a neutral or positive payment adjustment under MIPS.

(F) Excluding Virtual Groups From APM Entity Group Scoring

Due to concerns that virtual groups could be used to calculate APM Entity group scores, we have excluded virtual group MIPS scores when calculating APM Entity group scores. Previously, we have effectuated this exclusion through the use and application of terms defined in § 414.1305, specifically, ''APM Entity,'' ''APM Entity group,'' ''group,'' and ''virtual group.'' To improve clarity around the exclusion of virtual group scores in calculating APM Entity group scores, we now are proposing to effectuate this exclusion more explicitly, by amending § 414.1370(e)(2) to state that the score calculated for an APM Entity group, and subsequently the APM Entity, for purposes of the APM scoring standard does not include MIPS scores for virtual groups.

(i) Sunsetting the APM Quality Reporting Credit for APM Entities

One proposal we may consider beginning in the 2021 performance year would be to apply the APM Quality Reporting Credit described above, if finalized, to specific APM Entities for a maximum number of MIPS performance years; this may be set for all APMs or tied to the end of each APM's initial agreement period.

We believe that this proposal would create an incentive for new APM Entity groups to continue to form and join new MIPS APMs while maintaining the incentive for APM Entity groups and MIPS eligible clinicians to continue to strive to achieve QP status. This proposal also would complement the shift we are seeing within APMs, such as the Shared Savings Program, to require APM participants to move into two-sided risk tracks and Advanced APMs within 2 to 5 years of joining the model or program.

(ii) Sunsetting the APM Quality Reporting Credit for Non-Advanced APMs

Similar to the first proposal, we may consider an approach whereby we would implement the above approach to quality scoring and then phase out the APM Quality Reporting Credit for MIPS APMs that are not also Advanced APM tracks.

We would have the option to implement this change by removing the APM Reporting Credit for non-Advanced MIPS APMs entirely at the end of a set number of years for all non-Advanced APMs (for example, 2 years).

Alternatively we could tie this sunsetting of the APM Quality Reporting Credit for a non-Advanced APM to the initial agreement period of each APM, creating a well-timed incentive for movement into Advanced APM tracks of an APM after the initial agreement period after the start of the APM.

(iii) Sunsetting the APM Quality Reporting Credit for APM Entities in One-Sided Risk Tracks

One possible way of acknowledging the uncertainty involved with joining an APM without extending the APM Reporting Credit to all APM participants would be to retain the APM Quality Reporting Credit for all two-sided risk APM tracks but to remove this credit for participants in all one-sided risk tracks except for those APM Entities in the first 2 years—or first agreement period—of a MIPS APM.

We believe this approach would help ease the transition from MIPS to APM participation and ultimately into Advanced APM participation. However, this proposal would continue to provide the APM Quality Reporting Credit for participants in two-sided risk APMs who have not reached the QP threshold. In this way, we could create an incentive for APM participants to move towards Advanced APMs, even in situations where it is unlikely the participant would be able to reach the QP threshold.

(iv) Retain Different APM Quality Reporting Credits for Advanced APMs and MIPS APMs

Another available option would be to apply an APM Reporting Credit, as described above to all MIPS APM participants but base the available credit on the level of risk taken on by the MIPS APM. For example, the maximum 50 percent credit may continue to be available to APM Entities in Advanced APM tracks while the value of the credit may be limited to 25 percent for participants in one-sided risk tracks. We are soliciting comments on how we might best divide these tracks and address the advent of two-sided risk MIPS APMs that do not meet the nominal amount and financial risk standards in order to be considered an Advanced APM, and what an appropriate reporting credit would be for these tracks.

(v) Other Options

We seek comments and suggestions on other ways in which we could modify the APM scoring standard to continue to encourage MIPS eligible clinicians to join APMs, with an emphasis on encouraging movement toward participation in two-sided risk APMs that may qualify as Advanced APMs.

(e) MIPS APM Performance Feedback

As we discussed in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77270, and 82 FR 53704 through 53705, respectively), MIPS

eligible clinicians who are scored under the APM scoring standard will receive performance feedback under section 1848(q)(12) of the Act.

Regarding access to performance feedback, whereas split-TIN APM Entities and their participants can only access their performance feedback at the APM Entity group or individual MIPS eligible clinician level, MIPS eligible clinicians participating in the Shared Savings Program, which is a full-TIN APM, were able to access their performance feedback at the ACO participant TIN level for the 2017 performance period. However, due to confusion caused by the policy in cases, where not all eligible clinicians in a Shared Savings Program participant TIN received the APM Entity score, for example eligible clinicians that terminate before the first snapshot, we intend to better align treatment of Shared Savings Program ACOs and their participant TINs with other APM Entities and, where appropriate, with other MIPS groups. We will continue to allow ACO participant TIN level access to the APM Entity group level final score and performance feedback, as well as provide the APM Entity group level final score and performance feedback to individual MIPS eligible clinicians who bill through the TINs identified on the ACO's ACO participant list. However, we will also provide TIN level performance feedback to ACO participant TINs that will include the information that is available to all TINs participating in MIPS, including the applicable final scores for MIPS eligible clinicians billing under the TIN, regardless of their MIPS APM participation status.

d. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the 2022 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. The rationale for our scoring methodology continues to be grounded in the understanding that the MIPS scoring system has many components and various moving parts. As we transform MIPS through the MIPS Value Pathways (MVP) Framework as discussed in section III.K.3.a. of this proposed rule, we may propose modifications to our scoring methodology in future rulemaking as we continue to develop a methodology that emphasizes simplicity and that is understandable for MIPS eligible clinicians.

In this proposed rule, we are proposing policies to help eligible clinicians as they participate in the 2020 performance period/2022 MIPS payment year, and as we move beyond the transition years of the program.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to § 414.1380(b)(1) for our policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category percent score, including achievement and improvement points, and the small practice bonus.

As we move towards the transformation of the program through the MVP Framework discussed in section III.K.3.a.(2) of this proposed rule, we anticipate we will revisit and remove many of our scoring policies such as the 3-point floor, bonus points, and assigning points for measures that cannot be scored against a benchmark through future rulemaking. As we propose to transform the MIPS program through MVPs, our goal is to incorporate ways to address these issues without developing special scoring policies. We refer readers to section III.K.3.a.(3)(d) of this proposed rule, for further discussion on scoring of MVPs.

In section III.K.3.d.(1) of this proposed rule, we discuss the limited proposals for our scoring policies as we anticipate future changes as we work to transform MIPS through MVPs. Specifically, we are proposing to: (1) Maintain the 3-point floor for measures that can be scored for performance; (2) develop benchmarks based on flat percentages in specific cases where we determine the measure's otherwise applicable benchmark could potentially incentivize inappropriate treatment; (3) continue the scoring policies for measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria; (4) maintain the cap on measure bonus points for high-priority measures and end-to-end reporting; and (5) continue the improvement scoring policy. In addition, we are requesting comment on future approaches to scoring the CAHPS for MIPS survey measure if new questions are added to the survey. These proposals are discussed in more detail in this section of the proposed rule.

(i) Assigning Quality Measure Achievement Points

We refer readers to § 414.1380(b)(1) for more on our policies for scoring performance on quality measures.

(A) Scoring Measures Based on Achievement

We established at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable). MIPS eligible clinicians receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77282), we established that measures with a benchmark based on the performance period (rather than on the baseline period) would continue to receive between 3 and 10 measure achievement points for performance periods after the first transition year. For measures with benchmarks based on the baseline period, we stated that the 3-point floor was for the transition year and that we would revisit the 3-point floor in future years.

For the 2022 MIPS payment year, we are proposing to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. As we move towards the proposed MVPs discussed in section III.K.3.a. of this proposed rule, we anticipate we will revisit and possibly remove the 3-point floor in future years. As a result, we will wait until there is further policy development under the proposed framework before proposing to remove the 3-point floor. Accordingly, we are proposing to amend § 414.1380(b)(1)(i) to remove the years 2019, 2020, and 2021 and adding in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. The number of measure achievement points received for each measure is determined based on the applicable benchmark decile category and the percentile distribution.

MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(B) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

We refer readers to § 414.1380(b)(1)(i)(A) and (B) for more on our scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement. A summary of the proposed policies for the CY 2020 MIPS performance period is provided in Table 43.

TABLE 43—QUALITY PERFORMANCE CATEGORY: PROPOSED SCORING POLICIES FOR THE CY 2020 MIPS PERFORMANCE PERIOD *

Measure type	Description	Scoring rules
Class 1	For the 2020 MIPS performance period: Measures that can be scored based on performance. Measures that are submitted or calculated that meet all the following criteria: (1) Has a benchmark; (2) Has at least 20 cases; and (3) Meets the data completeness standard (generally 70 percent for 2020.) ** ** We refer readers to section III.K.3.c.(1)(c) for our proposal to increase data completeness.	For the 2020 MIPS performance period: 3 to 10 points based on performance compared to the benchmark.
Class 2	For the 2020 MIPS performance period: Measures that are submitted and meet data completeness, but do not have either of the following: (1) A benchmark (2) At least 20 cases.	For the 2020 MIPS performance period: 3 points.
Class 3	For the 2020 MIPS performance period: Measures that are submitted, but do not meet data completeness threshold, even if they have a measure benchmark and/or meet the case minimum	Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero measure achievement points. Small practices will continue to receive 3 points.

* The Class 2 and 3 measure scoring policies are not applicable to CMS Web Interface measures or administrative claims-based measures.

For the 2022 MIPS payment year, we are proposing to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark or meet the case minimum requirement. Accordingly, we are proposing to amend § 414.1380(b)(1)(i)(A)(*1*) to remove the years 2019, 2020, and 2021 and adding in its place the years 2019 through 2022 to provide that except as provided in paragraph (b)(1)(i)(A)(2) (which relates to CMS Web Interface measures and administrative claims-based measures), for the 2019 through 2022 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

(C) Modifying Benchmarks To Avoid the Potential for Inappropriate Treatment

We established at § 414.1380(b)(1)(ii) that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period. We also established at § 414.1380(b)(1)(i) that the number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution.

We believe all the measures in the MIPS program are of high standard as they have undergone extensive review prior to their inclusion in the program. MIPS measures go through the rulemaking process, and QCDR measures have an approval process before they are included in MIPS. We also believe our benchmarking generally provides an objective way to compare performance differences across different types of quality measures. However, we have heard concerns from stakeholders that for a few measures, the benchmark methodology may incentivize the inappropriate treatment of certain patients, in order for a clinician to achieve a score in the highest decile. Our scoring system already provides some protection from inappropriate treatment because all clinicians in the top 10 percent of the distribution receive the same 10-point score, thus a clinician with performance in the 90th percentile has no incentive to go higher. However, for certain measures with benchmarks set at very high or maximum performance in the top decile, we are concerned that these levels may not be representative and may not provide the most appropriate incentives for clinicians. Specifically, there are some measures that may have the potential to encourage clinicians to alter the clinical interaction with patients inappropriately, regardless of the individual patient's circumstances, in order to achieve that top decile performance level, for example, intermediate outcome measures that may encourage clinicians to over treat patients in order to achieve the highest performance level. Patient safety is our primary concern; therefore, we are proposing to establish benchmarks based on flat percentages in specific cases where we determine the measure's

otherwise applicable benchmark could potentially incentivize treatment that could be inappropriate for a particular patient type. Rather than develop benchmarks based on the distribution of scores we would base them on flat percentages such that any performance rate at or above 90 percent would be in the top decile and any performance rate above 80 percent would be in the second highest decile, and this would continue for the remaining deciles. We believe the measures that would fall under this methodology are high-priority or outcome measures for clinicians to focus on. However, we want to ensure that benchmarks are set to incentivize the most appropriate behavior, and ensure that our method for scoring against a benchmark accurately reflects performance and does not result in clinicians receiving low scores, despite adherence to the most appropriate treatment.

For the measures identified, we are proposing to use a flat percentage, similar to how the Shared Savings Program uses flat percentages to set benchmarks for measures with high performance. We selected this methodology for the following reasons: First, it is a straight-forward and simple methodology that currently exists for some MIPS measures that are collected through the CMS Web Interface. Second, because we are applying this methodology to measures with very high performance, we believe this approach is consistent with the Shared Saving Program approach established at § 425.502(b)(2)(ii) of using flat percentages to set benchmarks when many reporters demonstrate high achievement on a measure. The Shared Savings Program uses this method to avoid penalizing high ACO performance; however, in this case, we would be applying the flat percentages to ensure that the benchmark does not result in inappropriate and potentially harmful patient treatment. We believe this adjustment would provide additional protection to patients and reduce the potential incentive for inappropriate treatment of patients.

We propose that to determine whether a measure benchmark may not provide the most appropriate incentives for treatment, thus creating the potential for inappropriate treatment based on the patient's circumstances, CMS medical officers would assess if there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure benchmark. This assessment will include reviews of factors such as whether the measure specifications allow for clinical judgment to adjust for inappropriate outcomes, if the benchmarks for any of the impacted measure's collection types could put these patients at risk by setting a potentially harmful standard for top decile performance, or whether the measure is topped out. The intent of the assessment is to have CMS medical officers determine whether certain measure benchmarks may have unintended consequences that put patients at risk and the measure benchmark should therefore move to a flat percentage. The assessment will take into account all available information, including from the medical literature, published practice guidelines, and feedback from clinicians, groups, specialty societies, and the measure steward. Before applying the flat percentage benchmarking methodology to any recommended measure, we would propose the modified benchmark for the applicable MIPS payment year through rulemaking. This policy would be effective beginning with the CY 2020 MIPS performance period (and thus the 2022 MIPS payment adjustment year). We also seek comment on future actions we should take to help us in determining which measures to apply the flat percentage benchmarking to; for example, convening a technical expert panel.

We have identified two measures for which we believe we need to apply benchmarks based on flat percentages to avoid potential inappropriate treatment—MIPS #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (9%) and MIPS #236 (NQF 0018): Controlling High Blood Pressure. Although there are protections built into both of these measures, such as the use of less stringent requirements than current clinical guidelines, they lack comprehensive denominator exclusions and risk-adjustment or risk-stratification, which can lead to the possible over treatment of patients in order to meet numerator compliance. Overtreatment could lead to instances where the patient's blood sugar or blood pressure is lowered to a level that meets the measure standard but is too low for their optimum health given other coexisting medical conditions.

Because the factors for determining if a measure benchmark has the potential to cause inappropriate treatment may include both measure and benchmark considerations, we are concerned that all the benchmarks associated with the different collection types of a measure could be affected. Therefore, we are proposing to use the flat percentage benchmarks as an alternative to our standard method of calculating benchmarks by a percentile distribution of measure performance rates under for all collection types where the top decile for any measure benchmark is higher than 90 percent under the performance-based benchmarking methodology at § 414.1380(b)(1)(ii). We are limiting the application of the flat percentage methodology to all collection types where the top decile for any measure benchmark is higher than 90 percent so that our flat percentage methodology will actually reduce or remove the incentive for inappropriate care. If the top decile was originally below 90 percent, using the flat percentages would actually raise the level up to 90 percent and therefore provide a stronger incentive to provide inappropriate care in order to get the top score. We also seek comment on whether we should use a criteria different than applying it to collection types where the top decile would be higher than 90 percent if the benchmark was based on a distribution. For the two measures we are proposing to modify, we would not know which benchmarks and their associated collection types are impacted until we run our analysis; however, based on the benchmarks for the 2019 MIPS performance period, we would anticipate using the modified benchmarks for the Medicare Part B claims and the MIPS CQM collection types.

We considered whether we should rerun the benchmarks excluding those in the top decile but are concerned that the approach would add complexity to the program overall. We seek comment on whether we should consider different methodologies for the modified benchmarks such as excluding the top decile or increasing the required data completeness for the measure to a very high level (for example, 95 to 100 percent) and use performance period benchmarks rather than historical benchmarks.

We are proposing to add paragraph § 414.1380(b)(1)(ii)(C) to state that beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines has the potential to result in inappropriate treatment, CMS will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at § 414.1380(b)(1)(ii). We also propose to revise the text at § 414.1380(b)(1)(ii) to provide exceptions and to clarify the requirement that benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(ii) Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure

We refer readers to § 414.1380(b)(1)(vii)(B) for more on our policy on reducing the total available measure achievement points for the quality performance category by 10 points for groups that submit 5 or fewer quality measures and register for the CAHPS for MIPS survey, but do not meet the minimum beneficiary sampling requirements.

In this proposed rule, we are not proposing any changes to the scoring of the CAHPS for MIPS survey Measure. However, to the extent consistent with our authority to collect such information under section 1848(q) of the Act, we are considering expanding the information collected in the CAHPS for MIPS survey measure, described in section III.K.3.c.(1) of this proposed rule, and seek comment on scoring. One consideration is adding narrative questions to the CAHPS for MIPS survey measure, which would invite patients to respond to a series of questions in free text, such as responding to open ended questions and describing their experience with care in their own words. We believe narratives from patients about their health care experiences would be helpful to other patients when selecting a clinician and can provide a valuable complement to standardized survey scores, both to help clinicians understand what they can do to improve care and to engage and inform patients about differences among their experiences of care. On the other hand, there may be concerns about the accuracy and usefulness of narrative information reported by patients. For more information on the rationale for adding narrative questions, we refer readers to section III.K.3.c.(1)(c)(i) of this proposed rule. In addition, we are interested in learning from organizations with experience scoring narrative information, including methodologies. We would work with stakeholders on user testing before proposing any such methodology in future rulemaking. We are also considering adding an additional CAHPS for MIPS survey question allowing patients to provide a score for their overall experience and satisfaction rating with a recent health care encounter, to capture the patient ''voice'' and provide patients with information useful to making a decision on clinicians, as detailed in section III.I.3.a.(1) of this proposed rule. We are interested in feedback regarding how to score this measure. The new questions could potentially be added to the calculation for a score for the CAHPS for MIPS survey measure. We would consider any changes for future notice and comment rulemaking.

(iii) Scoring for MIPS Eligible Clinicians That Do Not Meet Quality Performance Category Criteria

In the CY 2019 PFS final rule (83 FR 35950), we finalized our proposal to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen.

In this proposed rule, we do not propose any changes to this policy. However, we refer readers to section III.K.3.d.(2)(b)(ii)(A) of this proposed rule for discussion on the rare circumstances when we are unable to calculate a quality performance category score for a MIPS eligible clinician because they do not have applicable or available quality measures. If we are unable to score the quality performance category for a MIPS eligible clinician, then we will reweigh the clinician's quality performance category score according to the reweighting policies described in sections III.K.3.d.(2)(b)(iii) of this proposed rule.

(iv) Incentives To Report High-Priority Measures

We refer readers to § 414.1380(b)(1)(v)(A) for more on the cap on high-priority measure bonus points for the first 3 years of MIPS at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category.

In the CY 2019 PFS final rule (83 FR 59851), we finalized technical updates to § 414.1380(b)(1) to more clearly and concisely capture previously established policies in the section. During this effort we inadvertently added that a high priority measure must have a benchmark. This was not intended to be a policy change. We are clarifying that in order for a measure to qualify for high priority bonus points it must meet case minimum and data completeness and not have a zero percent performance. The measure does not need to have a benchmark. Accordingly, we propose to revise § 414.1380(b)(1)(v)(A)(*1*)(*i*) to provide that each high priority measure must meet the case minimum requirement at (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

We also removed high priority bonus points for CMS Web interface reporters in the CY 2019 PFS final rule (83 FR 59850 through 59851). We refer readers to the CY 2019 PFS final rule for further discussion on this policy.

In this proposed rule, we propose to maintain the cap on measure points for reporting high priority measures for the 2022 MIPS payment year. Accordingly, we propose to revise § 414.1380(b)(1)(v)(A)(*1*)(*ii*) to remove the years 2019, 2020, and 2021 and adding in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

(v) Incentives To Use CEHRT To Support Quality Performance Category Submissions

We refer readers to § 414.1380(b)(1)(v)(B) for more on our policy assigning one bonus point for each quality measure submitted with end-to-end electronic reporting, under certain criteria.

In this proposed rule, we propose to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2022 MIPS payment year. We believe with the proposed framework for transforming MIPS through the MVPs discussed in section III.K.3.a. of this proposed rule, we can find ways in future years to incorporate eCQM measures without needing to incentivize end-to-end reporting with bonus points. As a result, we will wait until there is further policy development under the proposed framework before proposing to remove our policy of assigning bonus points for end-to-end electronic reporting. Accordingly, we propose to revise § 414.1380(b)(1)(v)(B)(*1*)(*i*) to remove the years 2019, 2020, and 2021 and add in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

(vi) Improvement Scoring for the MIPS Quality Performance Category Percent Score

We refer readers to § 414.1380(b)(1)(vi)(C)(*4*) for more on our policy stating that for the 2020 and 2021 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

In this proposed rule, we propose to continue our previously established

policy for the 2022 MIPS payment year and to revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 and 2021 MIPS payment year'' and adding in its place the phrase ''2019 through 2022 MIPS payment years'' to provide that for the 2020 through 2022 MIPS payment years, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. Specifically, for the 2022 MIPS payment year, we will compare the MIPS eligible clinician's quality performance category achievement percent score for the 2020 MIPS performance period to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent for the 2019 MIPS performance period.

(c) Facility-Based Measurement Scoring Option for the Quality and Cost Performance Categories for the 2022 MIPS Payment Year

(i) Background

For our previously established policies regarding the facility-based measurement scoring option, we refer readers to both the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767) and the CY 2019 PFS final rule (83 FR 59856 through 59867). In the CY 2019 PFS proposed rule (83 FR 35962 through 35963), we requested comments on a number of issues and topics related to whether we should expand the facility-based scoring option to other facilities and programs in future years, particularly the use of end-stage renal disease (ESRD) and post-acute care (PAC) settings as the basis for facility-based measurement and scoring. We appreciate the many comments we received in response to this request. We are not proposing an expansion to other facility types as part of this rule but may consider addressing this issue in future rulemaking.

(ii) Facility-Based Measurement Eligibility

In the CY 2019 PFS final rule (83 FR 59856 through 59860), we established the policies that determine eligibility for scoring for facility-based measurement as an individual and as a group. In the CY 2019 PFS final rule, we established at § 414.1380(e)(2)(i)(C) that a MIPS eligible clinician is facility-based if the clinician can be attributed, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period. While we do not propose any changes to the eligibility of facility-based measurement for individuals or groups, we are proposing to amend § 414.1380(e)(2)(i)(C) to improve clarity. Specifically, we propose to amend § 414.1380(e)(2)(i)(C) to state that a MIPS eligible clinician is facility-based if the clinician can be assigned, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period. We hope to avoid any ambiguity as we have used the term ''attribute'' and ''attribution'' in two ways. We have used the term to refer to the use of the facility's performance in place of the clinician's own performance (83 FR 59857). We have also used the term at § 414.1380(e)(2)(i)(C) to reference our method of connecting clinicians to a facility and indicate that the facility score will be the clinician's score. We believe these are related but distinct concepts; therefore, we are proposing to revise § 414.1380(e)(2)(i)(C) to use the term ''assign'' instead of ''attribute.'' We believe this change in language more clearly describes how a clinician receives a score under facility-based measurement while avoiding making any changes to our methods in determining eligibility for facility-based measurement or their score. This does not constitute a change in policy.

(iii) Facility-Based Measures for CY 2020 MIPS Performance Period/2022 MIPS Payment Year

For informational purposes, we are providing in Table 44 a list of the measures included in the FY 2021 Hospital VBP Program measure set that will be used in determining the quality and cost performance category scores for the CY 2020 MIPS performance period/ 2022 MIPS payment year. The FY 2021 Hospital VBP Program has adopted 12 measures covering 4 domains (83 FR 20412 through 20413). The performance period for measures in the Hospital VBP Program varies depending on the measure, and some measures include multi-year performance periods. These measures are determined through separate rulemaking; the applicable rulemaking is usually the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) rule. We are using these measures, benchmarks, and performance periods for the purposes of facility-based measurement in accordance with § 414.1380(e)(1). The measures for FY 2021 Hospital VBP Program were summarized in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 41454 through 41455).

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TABLE 44: FY 2021 Hospital VBP Program Measures

Short Name	Domain/Measure Name	NQF #	Performance Period
Person and Community Engagement Domain			
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)	January 1, 2019-December 31, 2019
Clinical Outcomes Domain			
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization	0230	July 1, 2016-June 30, 2019
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization	0229	July 1, 2016-June 30, 2019
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468	September 1, 2017-June 30, 2019
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893	July 1, 2016-June 30, 2019
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550	April 1, 2016-March 31, 2019
Safety Domain			
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138	January 1, 2019-December 31, 2019
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139	January 1, 2019-December 31, 2019
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753	January 1, 2019-December 31, 2019
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716	January 1, 2019-December 31, 2019
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717	January 1, 2019-December 31, 2019
Efficiency and Cost Reduction Domain			
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158	January 1, 2019-December 31, 2019

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(d) Scoring the Improvement Activities Performance Category

For our previously established policies regarding scoring the improvement activities performance category, we refer readers to § 414.1380(b)(3), the CY 2018 Quality Payment Program final rule (82 FR 53767 through 53769), and the CY 2019 PFS final rule (83 FR 59867 through 59868). We also refer readers to § 414.1355 and the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53662), and the CY 2019 PFS final rule (83 FR 59776 through 59785) for our previously established policies regarding the improvement activities performance category generally and section III.K.3.c.(3) of this proposed rule, where we discuss our proposals for the improvement activities performance category.

(e) Scoring the Promoting Interoperability Performance Category

We refer readers to section III.K.3.c.(4) of this proposed rule, where we discuss our proposals for the Promoting Interoperability performance category.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to § 414.1380(c) and the discussion in the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329), CY 2018 Quality Payment Program final rule (82 FR 53769 through 53785), and CY 2019 PFS final rule (83 FR 59868 through 59878). In this proposed rule, we are proposing to continue the complex patient bonus for the 2022 MIPS payment year and to establish performance category reweighting policies for the 2022, 2023, and 2024 MIPS payment years.

(a) Complex Patient Bonus for the 2022 MIPS Payment Year

In the CY 2019 PFS final rule (83 FR 59869 through 59870), under the authority in section 1848(q)(1)(G) of the Act, we finalized at § 414.1380(c)(3) to maintain the complex patient bonus, which we previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776), of up to five points to be added to the final score for the 2021 MIPS payment year. The complex patient bonus was developed as a short-term solution to address the impact patient complexity

may have on MIPS scoring that we would revisit on an annual basis while we continue to work with stakeholders on methods to account for patient risk factors. Our overall goal for the complex patient bonus was twofold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. For a detailed description of the complex patient bonus finalized for prior MIPS payment years, please refer to the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776) and CY 2019 PFS final rule (83 FR 59869 through 59870).

For the 2020 MIPS performance period/2022 MIPS payment year, we propose to continue the complex patient bonus as finalized for the 2019 MIPS performance period/2021 MIPS payment year and to revise § 414.1380(c)(3) to reflect this policy. Although we intend to maintain the complex patient bonus as a short-term solution, we do not believe we have sufficient information available at this time to develop a long-term solution to account for patient risk factors in MIPS such that we would be able to include a different approach in this proposed rule. Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology for MIPS. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, enacted October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. ASPE completed its first report [134] in December 2016, which examined the effect of individuals' socioeconomic status on quality, resource use, and other measures under the Medicare program, and included analyses of the effects of Medicare's current value-based payment programs on providers serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. The second ASPE report is expected in October 2019 as required by the IMPACT Act, and will examine additional risk factors and data. We expect the second report will build on the analyses included in initial report and may provide additional insight for a long-term solution to addressing risk factors in MIPS. At this time, we do not believe additional data sources are available that would be feasible to use as the basis for a different approach to account for patient risk factors in MIPS. We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

With newly available data from the Quality Payment Program, we considered whether the data still support the complex patient bonus at the final score level. We have replicated analyses similar to the ones presented in Table 27 of the CY 2018 Quality Payment Program final rule (82 FR 53776). However, our latest analyses use the data submitted for the Quality Payment Program for the 2017 MIPS performance period and assess eligibility and final scores based on the proposals we are making for the 2020 MIPS performance period/2022 MIPS payment year using the methodology described in the Regulatory Impact Analysis in section VI. of this proposed rule.

[134] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs (2016). Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

In the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776), when considering approaches for a complex patient bonus, we reviewed evidence to identify how indicators of patient complexity have an impact on performance under MIPS, as well as availability of data to implement the bonus. Specifically, we identified two potential indicators for complexity: Medical complexity as measured through Hierarchical Condition Category (HCC) risk scores; and social risk as measured through the proportion of patients with dual eligible status.

We identified these indicators because they are common indicators of patient complexity in the Medicare program and the data is readily available. Both of these indicators have been used in CMS programs to account for risk and both data elements are already publicly available for individual NPIs in the Medicare Physician and Other Supplier Public Use File (referred to as the Physician and Other Supplier PUF).

We divided clinicians and groups into quartiles based on average HCC risk score and percentage of dual eligible patients. To assess whether there was a difference in MIPS simulated scores by these two variables, we analyzed the effect of average HCC risk score and dual eligible ratio separately for groups and individuals. When looking at individuals, we focused on individuals that reported 6 or more measures (removing individuals who reported no measures or who reported less than 6 measures). We restricted our analysis to individuals who reported 6 or more measures because we wanted to look at differences in performance for those who reported the 6 measures which are generally required under MIPS if there are six measures that apply to the MIPS eligible clinician, rather than differences in scores due to MIPS eligible clinicians not fully reporting for MIPS.

We also ranked MIPS eligible clinicians by proportion of patients with dual eligibility as previously done in Table 27 of the CY 2018 Quality Payment Program final rule (82 FR 53776). We have updated the analysis by using the components of the complex patient bonus and dividing clinicians into quartiles. The preliminary results are shown in Table 45.

TABLE 45—MIPS SIMULATED AVERAGE FINAL SCORE * BY HCC RISK QUARTILE AND DUAL ELIGIBLE RATIO QUARTILE

HCC risk score	Estimated 2022 MIPS payment year final scores using data submitted for the quality payment program for the 2017 MIPS performance period	
	Individuals with 6+ measures *	Groups
Quartile 1—Lowest Average HCC	72.32	70.3
Quartile 2	72.58	77.59
Quartile 3	73.2	73.93
Quartile 4—Highest Average HCC	72.68	67.66
Dual Eligible Ratio		
Quartile 1—Low Proportion of Dual Status	73.51	73.04
Quartile 2	72.37	76.28
Quartile 3	72.16	72.21
Quartile 4—Highest Proportion of Dual Status	70.7	68.79

* We restricted our analysis to individuals who reported 6 or more measures because we wanted to look at differences in performance for those who reported the 6 measures which are generally required under MIPS if there are six measures that apply to the MIPS eligible clinician, rather than differences in scores due to MIPS eligible clinicians not fully reporting for MIPS.

Table 45 illustrates the average estimated MIPS final scores for individual MIPS eligible clinicians who submitted at least 6 measures (generally, those who fully report for MIPS quality) and for group reporters, stratified by the average HCC risk score and dual eligible ratio quartiles. For more detail on the original analysis, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53776).[135]

Overall, the analysis of preliminary data shows a consistent relationship between the dual eligible ratio quartiles and the average MIPS final scores only for individuals, where the average MIPS final score decreases as the quartile increases. We see slight differences in the average HCC risk score and dual eligible ratio quartiles for groups, but virtually no difference for average HCC risk score for individuals. However, we have only 1 year of data and more recent data may bring different results. In addition, we are awaiting a second report from ASPE in October 2019 that we expect will provide more direction for our approach to accounting for risk factors in MIPS. We are concerned that without the information from ASPE and without observing a clear trend that would require a change in our methodology, making any changes beyond our proposal to continue this policy would be premature at this time.

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77320 through 77329 and 82 FR 53779 through 53785, respectively), as well as the CY 2019 PFS final rule (83 FR 59870 through 59878). Under our proposals in section III.K.3.c.(2)(a) of this proposed rule, the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year. Under our proposals in section III.K.3.c.(1)(b) of this proposed rule, the quality performance category would thus make up 40 percent of a MIPS eligible clinician's final score the 2022 MIPS payment year, 35 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year. Table 46 summarizes the weights proposed for each performance category.

TABLE 46—PROPOSED WEIGHTS BY MIPS PERFORMANCE CATEGORY FOR THE 2022 THROUGH 2024 MIPS PAYMENT YEARS

Performance category	2022 MIPS payment year (proposed)	2023 MIPS payment year (proposed) (percent)	2024 MIPS payment year (proposed) (percent)
Quality	40	35	30
Cost	20	25	30
Improvement Activities	15	15	15
Promoting Interoperability	25	25	25

[135] Data submitted for 2017 MIPS performance period was subject to different policies than later years of MIPS (due to the ''pick-your-pace'' approach in the first year of MIPS and the much lower performance threshold of 3 points).

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity for each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Assigning a scoring weight of zero percent and redistributing the weight to the other performance categories differs from the scenario of a MIPS eligible clinician failing to report on an applicable measure or activity that is required to be reported. For a description of our existing policies for reweighting performance categories, please refer to § 414.1380(c)(2) and the CY 2019 PFS final rule (83 FR 59871 through 59876).

(A) Reweighting Performance Categories Due to Data That Are Inaccurate, Unusable, or Otherwise Compromised

Under current regulations at § 414.1380(c)(2), we assign different weights to the performance categories and redistribute weight from one category to another under specified circumstances where we have determined reweighting is appropriate. These circumstances do not currently include cases where a MIPS eligible clinician submits data that are inaccurate, unusable, or otherwise compromised (referred to in this section as ''compromised data''). If we determine a MIPS eligible clinician has submitted compromised data, we assign the clinician a score of zero for the performance category. Because compromised data is not currently a basis for reweighting, the determination that data are inaccurate, unusable or otherwise compromised is likely to reduce the clinician's final score and therefore may reduce the clinician's payment adjustments. However, we believe that reweighting of the applicable performance categories may be appropriate in rare cases. Specifically, we believe reweighting may be appropriate when a MIPS eligible clinician's data are inaccurate, unusable or otherwise compromised due to circumstances that are outside of the control of the MIPS eligible clinician or its agents.

In the CY 2018 Quality Payment Program final rule, we discussed our belief that extreme and uncontrollable circumstances, such as natural disasters, could cause the MIPS measures and activities to be unavailable to a MIPS eligible clinician (82 FR 53780 through 53783). For similar reasons, we believe that the measures and activities may not be available to a MIPS eligible clinician for the quality, cost, and improvement activities performance categories under section 1848(q)(5)(F) of the Act when data related to the measures and activities are inaccurate, unusable or otherwise compromised due to circumstances that are outside of the control of the MIPS eligible clinician or its agents. In addition, we believe data that are inaccurate, unusable or otherwise compromised due to circumstances that are outside of the control of the MIPS eligible clinician or its agents could constitute a significant hardship for purposes of the Promoting Interoperability performance category under section 1848(o)(2)(D) of the Act. Therefore, we are proposing a new policy to allow reweighing for any performance category if, based on information we learn prior to the beginning of a MIPS payment year, we determine data for that performance category are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the MIPS eligible clinician or its agents.

For purposes of this reweighting policy, we propose that reweighting take into account both what control the clinician had directly over the circumstances and what control the clinician had indirectly through its agents. The term agent as used in this proposal is intended to include any individual or entity, including a third party intermediary as described in § 414.1400, acting on behalf of or under the instruction of the MIPS eligible clinician We believe that reweighting is not appropriate if a clinician could exert influence over a third party intermediary or another party to prevent or remediate compromised data and does not do so. However, we believe reweighting is appropriate in certain circumstances that may be within the control of the clinician's third party intermediary if the clinician cannot alter that party's conduct. Such circumstances would exist if a clinician's third party intermediary could correct the clinician's compromised data and despite requests from the clinician the third party intermediary chose not to do so. In this example, the decision by the third party intermediary not to make the correction would demonstrate that the third party intermediary was not acting as an agent of the clinician and the third party intermediary's conduct would not preclude reweighting. We solicit comments on this approach and possible alternatives for balancing efforts to allow reweighting in circumstances in which clinicians are not culpable for compromised data while maintaining financial incentives for clinicians, third party intermediaries and other parties to prevent and correct compromised data.

We propose that our determination of whether reweighing will be applied under this policy can take into account any information known to the agency and we will consider the information we obtain on a case-by-case basis for reweighting. We anticipate considering information provided to us through routine communication channels for the Quality Payment Program by any submitter type as defined under § 414.1305, as well as other relevant information sources of which we are aware. We request that third party intermediaries, to the extent feasible, inform MIPS eligible clinicians if the third party intermediary believes their data may have been compromised. To the extent third party intermediaries believe that MIPS data may be compromised, we encourage them to provide us with a list of or other identifying information for all MIPS eligible clinicians who may have been affected by such issues, so that we may evaluate the circumstances in a timely manner. We also encourage MIPS eligible clinicians to contact us and self-identify if they believe they have compromised data; they should not rely solely on a third party intermediary to do so. We recognize that there may be scenarios when a MIPS eligible clinician or one or more of its agents becomes aware of potential data issues prior to submission of data. We solicit comment on whether and how our proposed reweighting policy should apply to these circumstances. We note that compromised data are not true, accurate or complete for purposes of § 414.1390(b) or § 414.1400(a)(5) and knowing submission of compromised

data may result in remedial action against the submitter. A MIPS eligible clinician should not submit data and should not allow the submission of his or her data if the MIPS eligible clinician knows that the data are inaccurate, unusable, or otherwise compromised.

We propose to determine whether the requirements for reweighting are met by assessing if: (1) The MIPS eligible clinician's data are inaccurate, unusable, or otherwise compromised; and (2) the data are compromised due to circumstances outside of the control of the MIPS eligible clinician or agent. We would make the determination of whether the clinician's data are inaccurate, unusable or otherwise compromised based on documentation of the issue and its demonstrated effect on data of the particular MIPS eligible clinician. As noted above, we propose to limit this policy to cases where data are compromised outside the control of the clinician or its agent because we do not want to create incentives for clinicians or third party intermediaries to knowingly submit compromised data and want to encourage clinicians and their agents to take reasonable efforts to correct data that they believe maybe not compromised. Factors relevant to whether the circumstances were outside the control of the clinician and its agents include: Whether the affected MIPS eligible clinician or its agents knew or had reason to know of the issue; whether the affected MIPS eligible clinician or its agents attempted to correct the issue; and whether the issue caused the data submitted to be inaccurate or unusable for MIPS purposes. We solicit feedback on these factors and whether there are additional factors we should consider to determine if there should be reweighing based on compromised data. If we determine that a MIPS eligible clinician's data were compromised and the conditions for reweighting are met, we propose to notify the clinician of this determination through the performance feedback that we provide under section 1848(q)(12) of the Act if feasible, or through routine communication channels for the Quality Payment Program. We emphasize that this proposed reweighting policy is solely intended to mitigate the potential adverse financial impact of compromised data on the MIPS eligible clinician; a determination under this proposed policy that data are compromised due to circumstances outside of the control of the MIPS eligible clinician and its agent and therefore that reweighting will occur for that clinician does not indicate and should not be interpreted to suggest that a third party intermediary or other individual or entity could not be held liable for the compromised data.

We are proposing to apply reweighting only in cases when we learn of the compromised data before the beginning of the associated MIPS payment year because we want to encourage MIPS eligible clinicians and their agents to inform us of these concerns in a timely basis so we can update our data sets timely, while minimizing the impacts to other stakeholders who utilize MIPS data. For example, the Physician compare website utilizes MIPS data to provide information to patients, consumers and other stakeholders when selecting a clinician or group. We are concerned that without the appropriate incentive to notify us in a timely manner, clinicians and their agents may delay disclosures that data may be compromised and with these delays the MIPS data could be in an increased state of flux which will reduce the usefulness of the data to stakeholders. We are interested in feedback on whether there are other factors we should consider when adopting a timeline for reweighting due to compromised data and whether the period should be broader. We seek comment on whether we should restrict our reweighting due to compromised data to instances when we learn the relevant information prior to the beginning of the MIPS payment year and whether there are other incentives for MIPS eligible clinicians to alert us to concerns about compromised data. We emphasize that if we determine a MIPS eligible clinician has submitted compromised data for a performance category during the associated payment year or at a later point, the MIPS eligible clinician would not qualify for reweighting under this proposal, instead for the performance categories with compromised data the clinician's performance category score would be zero and the scoring weight for the category would not be redistributed.

In sum, under the authority in sections 1848(q)(5)(F) and 1848(o)(2)(D) of the Act, we are proposing at § 414.1380(c)(2)(i)(A)*(9),* and (c)(2)(i)(C)*(10),* beginning with the 2018 MIPS performance period and 2020 MIPS payment year, to reweight the performance categories for a MIPS eligible clinician who we determine has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents if we learn the relevant information prior to the beginning of the associated MIPS payment year. In addition, we are proposing to amend § 414.1380(c)(2)(i)(C) to ensure that the reweighting proposed at § 414.1380(c)(2)(i)(C)*(10),* would not be voided by the submission of data for the Promoting Interoperability performance category as is the case with other significant hardship exceptions. We solicit comment in this proposal and alternatives to potentially mitigate the impact on MIPS eligible clinicians who through no fault of their own have data in a performance category that are inaccurate, unusable or are otherwise compromised.

We note that we previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77326 through 77328 and 82 FR 53778 through 53779). Therefore, if a MIPS eligible clinician is scored on fewer than two performance categories as a result of reweighting due to compromised data, he or she would receive a final score equal to the performance threshold.

(iii) Redistributing Performance Category Weights

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77325 through 77329 and 82 FR 53783 through 53785, 53895 through 53900), in the CY 2019 PFS final rule (83 FR 59876 through 59878), and at § 414.1380(c)(2)(ii) we established policies for redistributing the weights of performance categories for the 2019, 2020, and 2021 MIPS payment years in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories. Under these policies, we generally redistribute the weight of a performance category or categories to the quality performance category because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs.

Because the cost performance category was zero percent of a MIPS eligible clinician's final score for the 2017 MIPS performance period, we stated in the CY 2019 PFS proposed rule (83 FR 35970) that it is not appropriate to redistribute weight to the cost performance category for the 2019 MIPS performance period because MIPS eligible clinicians have limited experience being scored on cost measures for purposes of MIPS. In addition, we were concerned that there would be limited measures in the cost performance category under our proposals for the 2019 MIPS performance period and stated that it

may be appropriate to delay shifting additional weight to the cost performance category until additional measures are developed. However, we also noted that cost is a critical component of the Quality Payment Program and believe placing additional emphasis on the cost performance category in future years may be appropriate. Therefore, we solicited comment on redistributing weight to the cost performance category in future years.

Several commenters expressed the belief that the weight of other performance categories should not be redistributed to the cost performance category. One commenter stated that the cost performance category weight should not be increased until additional cost measures are available and additional results of the episode-based cost measures are available. Another commenter expressed the belief that the cost performance category does not yet accurately assess the impact of a clinician's care on the total cost of care for a patient.

We do not believe it would be appropriate to redistribute weight from the other performance categories to the cost performance category for the 2022 MIPS payment year, except in scenarios in which the only other scored performance category is the improvement activities performance category. As described in section III.K.3.c.(2)(b)(v) of this proposed rule, we are proposing substantial changes to the MSPB and total per capital cost measures, as well as proposing to add 10 new episode-based measures. We believe it is appropriate to provide MIPS eligible clinicians additional time to adjust to these changes prior to redistributing weight to the cost performance category. Under the proposals we are making in this proposed rule, we would begin to redistribute more weight to the cost performance category beginning with the 2023 MIPS payment year, because MIPS eligible clinicians will have had more experience being scored on cost measures at that point, and will have had time to adjust to the changes to existing measures and new episode-based measures that we are proposing.

Under our existing policies, we redistribute weight from the other performance categories to the improvement activities performance category in certain scenarios. However, we have generally redistributed performance category weights more to the quality performance category to incentivize reporting on quality measures, and because MIPS eligible clinicians have had more experience with quality measure reporting from other CMS programs. Beginning with the 2022 MIPS payment year, we propose to not redistribute performance category weights to the improvement activities performance category in any scenario. For the improvement activities performance category, we are only assessing whether a MIPS eligible clinician completed certain activities (83 FR 59876 through 59878). Because MIPS eligible clinicians will have had several years of experience reporting under MIPS, we believe it is important to prioritize performance on measures that show a variation in performance, rather than the activities under the improvement activities performance category, which are based on attestation of completion. Therefore, we believe it is no longer appropriate to increase the weight of the improvement activities performance category above 15 percent under our redistribution policies. We note that in situations where the weights of both the quality and Promoting Interoperability performance categories are redistributed, cost would be weighted at 85 percent and improvement activities would be weighted at 15 percent. We believe this would help to reduce incentives to not report measures for the quality performance category in circumstances when a clinician may be able to report but chooses not to do so. For example, when a clinician may be able to report on quality measures, but chooses not to report because they are located in an area affected by extreme and uncontrollable circumstances as identified by CMS and qualify for reweighting under § 414.1380(c)(2)(i)(A)(8).

For the 2022 MIPS payment year, we propose at § 414.1380(c)(2)(ii)(D) similar redistribution policies to our policies finalized for the 2021 MIPS payment year (83 FR 59876 through 59878), with minor modifications, as shown in Table 47. First, we have adjusted our redistribution policies to account for a cost performance category weight of 20 percent for the 2022 MIPS payment year. We are also proposing, in scenarios when the cost performance category weight is redistributed while the Promoting Interoperability performance category weight is not, to redistribute a portion of the cost performance category weight to the Promoting Interoperability performance category as well as to the quality performance category. We believe this is appropriate given our current focus on working with the Office of the National Coordinator for Health IT (ONC) on implementation of the interoperability provisions of the 21st Century Cures Act (the Cures Act) (Pub. L. 115–233, enacted December 13, 2016) to ensure seamless but secure exchange of health information for clinicians and patients. While we have previously redistributed all of the cost performance category weight to the quality performance category (83 FR 59876 through 59878), we propose to redistribute 15 percent to the quality performance category and 5 percent to the Promoting Interoperability performance category for the 2022 MIPS payment year (*see* Table 47). This proposed change would emphasize the importance of interoperability without overwhelming the contribution of the quality performance category to the final score. We also propose to weight the improvement activities performance category at 15 percent and to weight the Promoting Interoperability performance category at 85 percent for the 2022 MIPS payment year when the quality and cost performance categories are each weighted at zero percent, to align with our focus on interoperability and pursuant to our proposal of not redistributing weight to the improvement activities performance category.

TABLE 47—PERFORMANCE CATEGORY REDISTRIBUTION POLICIES PROPOSED FOR THE 2022 MIPS PAYMENT YEAR

Reweighting scenario	Quality (percent)	Cost (percent)	Improvement activities (percent)	Promoting interoperability (percent)
No Reweighting Needed:				
—Scores for all four performance categories	40	20	15	25
Reweight One Performance Category:				
—No Cost	55	0	15	30
—No Promoting Interoperability	65	20	15	0
—No Quality	0	20	15	65

TABLE 47—PERFORMANCE CATEGORY REDISTRIBUTION POLICIES PROPOSED FOR THE 2022 MIPS PAYMENT YEAR—Continued

Reweighting scenario	Quality (percent)	Cost (percent)	Improvement activities (percent)	Promoting interoperability (percent)
—No Improvement Activities	55	20	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	15	85
—No Cost and no Improvement Activities	70	0	0	30
—No Promoting Interoperability and no Quality	0	85	15	0
—No Promoting Interoperability and no Improvement Activities	80	20	0	0
—No Quality and no Improvement Activities	0	20	0	80

In section III.K.3.c.(2)(a) of this proposed rule, we have proposed weights for the cost performance category of 25 and 30 percent for the 2023 and 2024 MIPS payment years, respectively. Because MIPS eligible clinicians will have had more experience being scored on cost measures, we believe it would be appropriate to begin redistributing even more of the performance category weights to the cost performance category beginning with the 2023 MIPS payment year. While we have proposed to redistribute weight to the cost performance category for the 2022 MIPS payment year in scenarios in which only the cost and improvement activities performance categories are scored, we believe that we should redistribute weight to the cost performance category in other scenarios beginning with the 2023 MIPS payment year. In general, we would redistribute performance category weights so that the quality and cost performance categories are almost equal. For simplicity, we would redistribute the weight in 5-point increments. If the redistributed weight cannot be equally divided between quality and cost in 5-point increments, we would redistribute slightly more weight to quality than cost. We believe that redistributing weight equally to quality and cost is consistent with our goal of greater alignment between the quality and cost performance categories as described in section III.K.3.c.(2) of this proposed rule. We would also continue to redistribute weight to the Promoting Interoperability performance category, but we would ensure that if the quality and cost performance categories are scored, they would have a higher weight than the Promoting Interoperability performance category. For example, beginning with the 2024 MIPS payment year, if the improvement activities performance category is the only performance category to be reweighted to zero percent, quality and cost would be 40 and 35 percent, respectively, and we would not increase the weight of the Promoting Interoperability performance category (weighted at 25 percent) so that it would not exceed the weight of the quality or cost performance categories. Our proposed redistribution polices for the 2023 and 2024 MIPS payment years, which we propose to codify at §§ 414.1380(c)(2)(ii)(E) and (F), are presented in Tables 47 and 48.

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TABLE 48: Performance Category Redistribution Policies Proposed for the 2023 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	35%	25%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	50%	35%	15%	0%
-No Quality	0%	40%	15%	45%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	65%	0%	0%	35%
-No Promoting Interoperability and no Quality	0%	85%	15%	0%
-No Promoting Interoperability and no Improvement Activities	55%	45%	0%	0%
-No Quality and no Improvement Activities	0%	45%	0%	55%

TABLE 49: Performance Category Redistribution Policies Proposed for the 2024 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	45%	40%	15%	0%
-No Quality	0%	45%	15%	40%
-No Improvement Activities	40%	35%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	60%	0%	0%	40%
-No Promoting Interoperability and no Quality	0%	85%	15%	0%
-No Promoting Interoperability and no Improvement Activities	50%	50%	0%	0%
-No Quality and no Improvement Activities	0%	60%	0%	40%

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e. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score used in MIPS payment adjustment calculations, we refer readers to the CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799) and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343).

We are proposing to: (1) Set the performance threshold for the 2022 and 2023 MIPS payment years and (2) set the additional performance threshold for exceptional performance for the 2022 and 2023 MIPS payment years.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act includes a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional

MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies. The performance thresholds for the first 3 years of MIPS are presented in Table 50.

TABLE 50—PERFORMANCE THRESHOLDS FOR THE 2019 MIPS PAYMENT YEAR, 2020 MIPS PAYMENT YEAR, AND 2021 MIPS PAYMENT YEAR

	2019 MIPS payment year (points)	2020 MIPS payment year (points)	2021 MIPS payment year (points)
Performance Threshold	3	15	30

To determine a performance threshold to propose for the fourth year of MIPS (2020 MIPS performance period/2022 MIPS payment year) and the fifth year of MIPS (2021 MIPS performance period/2023 MIPS payment year), we are again relying upon the special rule in section 1848(q)(6)(D)(iii) of the Act, as amended by 51003(a)(1)(D) of the Bipartisan Budget Act of 2018.

As required by section 1848(q)(6)(D)(iii) of the Act, we considered data available from a prior period with respect to performance on measures and activities that may be used under the MIPS performance categories. In accordance with clause (iv) of section 1848(q)(6)(D) of the Act, we also considered which data could be used to estimate the performance threshold for the 2024 MIPS payment year to ensure a gradual and incremental transition from the performance threshold we would establish for the 2022 MIPS payment year. In accordance with section 1848(q)(6)(D)(i) of the Act, the performance threshold for the 2024 MIPS payment year would be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

To estimate the performance threshold for the 2024 MIPS payment year, we considered the actual MIPS final scores for MIPS eligible clinicians for the 2019 MIPS payment year and the estimated MIPS final scores for the 2020 MIPS payment year and 2021 MIPS payment year. As referenced in the CY 2019 PFS final rule, we analyzed the actual final scores for the first year of MIPS (the 2019 MIPS payment year) and found the mean final score was 74.01 points and the median final score was 88.97 points (83 FR 59881). In the Regulatory Impact Analysis (RIA) of the CY 2019 PFS final rule, we used data submitted for the first year of MIPS (2017 MIPS performance period/2019 MIPS payment year) and applied the scoring and eligibility policies for the third year of MIPS (2019 MIPS performance period/2021 MIPS payment year) to estimate the potential final scores for the 2021 MIPS payment year. The estimated mean final score for the 2021 MIPS payment year was 69.53 points and the median final score was 78.72 points (83 FR 60048). We also estimated mean and median final scores for the 2020 MIPS payment year of 80.3 points and 90.91 points, respectively, based on information in the regulatory impact analysis in the CY 2018 Quality Payment Program final rule (82 FR 53926 through 53950). Specifically, we used 2015 and 2016 PQRS data, 2014 and 2015 CAHPS for PQRS data, 2014 and 2015 VM data, 2015 and 2016 Medicare and Medicaid EHR Incentive Program data, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility, the initial QP determination file for the 2019 payment year, the 2017 MIPS measure benchmarks, and other available data to model the final scores for clinicians estimated to be MIPS eligible in the 2020 MIPS payment year (82 FR 53930). We considered using the actual final scores for the 2020 MIPS payment year; however, the data used to calculate the final scores was submitted through the first quarter of 2019, and final scores for MIPS eligible clinicians were not available in time for us to use in our analyses for purposes of this proposed rule (although we intend to include those results in the final rule if available). We believe the data points based on actual data from the 2017 MIPS performance period/2019 MIPS payment year would be appropriate to use in our analysis in projecting the estimated performance threshold for the 2024 MIPS payment year. However, after we analyze the actual final scores for the 2020 MIPS payment year, if we see the mean or median final scores significantly increasing or decreasing, we would consider modifying our estimation of the performance threshold for the 2024 MIPS payment year accordingly.

We refer readers to Table 51 for potential values for estimating the performance threshold for the 2024 MIPS payment year based on the mean or median final score from prior periods.

TABLE 51—POTENTIAL VALUES FOR ESTIMATED PERFORMANCE THRESHOLD FOR THE 2024 MIPS PAYMENT YEAR BASED ON THE MEAN OR MEDIAN FINAL SCORE FOR THE 2019 MIPS PAYMENT YEAR; 2020 MIPS PAYMENT YEAR; AND 2021 MIPS PAYMENT YEAR

	2019 MIPS payment year * (points)	2020 MIPS payment year ** (points)	2021 MIPS payment year *** (points)
Mean Final Score	74.01	80.30	69.53
Median Final Score	88.97	90.91	78.72

Source: CY 2019 PFS final rule RIA * *** (83 FR 60048); CY 2018 Quality Payment Program final rule RIA ** (82 FR 53926 through 53950).
* Mean and median final scores based on actual final scores for 2019 MIPS payment year.
** Mean and median final scores based on information available in the RIA because actual final scores for the 2020 MIPS payment year were not available in time for this proposed rule.
*** Mean and median final scores based on estimated final scores from 2021 MIPS payment year.

We are choosing the mean final score of 74.01 points for the 2019 MIPS payment year as our estimate of the performance threshold for the 2024 MIPS payment year because it represents a mean based on actual data; is more representative of clinician performance because all final scores are considered in the calculation; is more achievable for clinicians, particularly for those that are new to MIPS; and is a value that falls generally in the middle of potential values for the performance threshold referenced in Table 51. In the CY 2019 PFS proposed rule, we requested comment on our approach to estimating the performance threshold for the 2024 MIPS payment year, which was based on the estimated mean final score for the 2019 MIPS payment year, and whether we should use the median instead of the mean (83 FR 35972). A few commenters supported the use of the mean rather than the median for determining the performance threshold because they believed this approach and the statutory requirement of a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year would provide a clear path and certainty and would allow for clinicians to budget, plan, and develop a long-term strategy for successful participation in MIPS.

We note that estimating the performance threshold for the 2024 MIPS payment year based on the mean final score for the 2019 MIPS payment year is only an estimation that we are providing in accordance with section 1848(q)(6)(D)(iv) of the Act. We are proposing to use data from the 2019 MIPS payment year because it is the only MIPS final score data available and usable in time for the publication of this proposed rule. We acknowledge that via the 2020 MIPS payment year performance feedback, we have provided to MIPS eligible clinicians their calculated final scores. However, the mean and median of final scores for the 2020 MIPS payment year are not yet published. We anticipate that the mean and median data points for the 2020 MIPS payment year will be available for consideration prior to publication of the final rule and seek comment on whether and how we should use this information to update our estimates. We understand that using final scores from the early years of MIPS has numerous limitations and may not be similar to the distribution of final scores for the 2024 MIPS payment year. Eligibility and scoring policies changed in the initial years of the program. For example, beginning with the 2020 MIPS payment year, we increased the low-volume threshold compared to the 2019 MIPS payment year. We also added incentives for improvement scoring for the quality performance category and bonuses for complex patients and small practices, which could increase scores. Starting with the 2021 MIPS payment year, we modified our eligibility to include new clinician types and an opt-in policy, revised the small practice bonus, significantly revised the Promoting Interoperability performance category scoring methodology, and added a topped-out cap for certain topped out quality measures. As illustrated in Table 51, we estimated that the mean and median final scores for the 2020 MIPS payment year will be higher than for the 2019 MIPS payment year; however, we anticipate the final scores for the 2021 MIPS payment year will be lower. Recognizing the limitations of data for the 2019 MIPS payment year and the 2020 MIPS payment year, we are requesting comments on whether we should update or modify our estimates. We will propose the actual performance threshold for the 2024 MIPS payment year in future rulemaking.

Based on these analyses, we are proposing a performance threshold of 45 points for the 2022 MIPS payment year and a performance threshold of 60 points for the 2023 MIPS payment year to be codified at § 414.1405(b)(7) and (8), respectively. A performance threshold of 45 points for the 2022 MIPS payment year and 60 points for the 2023 MIPS payment year would be an increase that is consistent with the increase in the performance threshold from the 2020 MIPS payment year (15 points) to the 2021 MIPS payment year (30 points), and we believe it would allow for a consistent increase over time that provides a gradual and incremental transition to the performance threshold we will establish for the 2024 MIPS payment year, which we have estimated to be 74.01 points.

For example, if in future rulemaking we were to set the performance threshold for the 2024 MIPS payment year at 75 points (which is close to the mean final score for the 2019 MIPS payment year), this would represent an increase in the performance threshold of approximately 45 points from the 2021 MIPS payment year (that is, the difference from the Year 3 performance threshold of 30 points to a Year 6 performance threshold of 75 points). We believe an increase of approximately 15 points each year, from Year 3 through Year 6 of the MIPS program, would provide for a gradual and incremental transition toward a performance threshold that must be set at the mean or median final score for a prior period in Year 6 of the MIPS program.

We also believe this increase of 15 points per year could incentivize higher performance by MIPS eligible clinicians and that a performance threshold of 45 points for the 2022 MIPS payment year, and a performance threshold of 60 points for the 2023 MIPS payment year, represent a meaningful increase compared to 30 points for the 2021 MIPS payment year, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold. In section III.K.3.e.(4) of this proposed rule, we provide examples of the ways clinicians can meet or exceed the proposed performance threshold for the 2022 MIPS payment year.

We recognize that some MIPS eligible clinicians may not exceed the proposed performance thresholds either due to poor performance or by failing to report on an applicable measure or activity that is required. We also recognize the unique challenges for small practices and rural clinicians that could prevent them from meeting or exceeding the proposed performance thresholds and refer readers to sections III.K.3.a.(3)(b)(i) and III.K.3.a.(3)(b)(i)(A) of this proposed rule for a discussion of the participation of small and rural practices in MVPs and a request for feedback on small and rural practices participation in MVPs, respectively.

We invite public comment on our proposals to set the performance threshold for the 2022 MIPS payment year at 45 points and to set the performance threshold for the 2023 MIPS payment year at 60 points. We also seek comment on whether we should adopt a different performance threshold in the final rule if we determine that the actual mean or median final scores for the 2020 MIPS payment year are higher or lower than our estimated performance threshold for the 2024 MIPS payment year of 74.01 points. For example, if the actual mean or median final score for the 2020 MIPS payment year is closer to 85 points, should we finalize a higher performance threshold than currently proposed? Or if the mean or median values are lower, should we finalize a lower performance threshold? We anticipate the data will change over time and that the distribution of final scores will differ from one year to the next. We also seek comment on whether the increase should be more gradual for the 2022 MIPS payment year, which would mean a lower performance threshold (for example, 35 instead of 45 points), or whether the increase should be steeper (for example, 50 points). We also seek comment on alternative numerical values for the performance threshold for the 2022 MIPS payment year. For the 2023 MIPS payment year, we alternatively considered whether the performance threshold should be set at a lower or higher number, for example, 55 points or 65 points, and also seek comment on alternative numerical values for the performance threshold for the 2023 MIPS payment year.

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act. Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500 million of funding available for the year under section 1848(q)(6)(F)(iv) of the Act.

As we discussed in section III.K.3.e.(2) of this proposed rule, we are relying on the special rule under section 1848(q)(6)(D)(iii) of the Act to propose a performance threshold of 45 points for the 2022 MIPS payment year and to propose a performance threshold of 60 points for the 2023 MIPS payment year. As we also discussed in section III.K.3.e.(2) of this proposed rule, for the initial 5 years of MIPS, the special rule under section 1848(q)(6)(D)(iii) of the Act also applies for purposes of establishing an additional performance threshold for a year. For the 2022 MIPS payment year and the 2023 MIPS payment year, we are relying on the discretion afforded by the special rule and proposing to again decouple the additional performance threshold from the performance threshold.

For illustrative purposes, we considered what the numerical values would be for the additional performance threshold under one of the methods described in section 1848(q)(6)(D)(ii) of the Act: The 25th percentile of the range of possible final scores above the performance threshold. With a proposed performance threshold of 45 points, the range of total possible points above the performance threshold is 45.01 to 100 points and the 25th percentile of that range is 58.75, which is just more than one-half of the possible 100 points in the MIPS final score. We do not believe it would be appropriate to lower the additional performance threshold to 58.75 points because it is below the mean and median final scores for each of the prior performance periods that are referenced in Table 51. Similarly, with a proposed performance threshold for the 2023 MIPS payment year of 60 points, the range of possible points above the performance threshold is 60.01 to 100 points and the 25th percentile of that range is 69.99 points. We do not believe it would be appropriate to lower the additional performance threshold to 69.99 points because it is below or close to the mean and median final scores for each of the prior performance periods that are referenced in Table 51.

We are relying on the special rule under section 1848(q)(6)(D)(iii) of the Act to propose at § 414.1405(d)(6) to set the additional performance threshold for the 2022 MIPS payment year at 80 points and to propose at § 414.1405(d)(7) to set the additional performance threshold for the 2023 MIPS payment year at 85 points. These values are higher than the 25th percentile of the range of the possible final scores above the proposed performance threshold for the 2022 and 2023 MIPS payment years.

We originally proposed 80 points for the additional performance threshold for the 2021 MIPS payment year in the CY 2019 PFS proposed rule (83 FR 35973) although we finalized 75 points in the CY 2019 PFS final rule (83 FR 59886). In the CY 2019 PFS final rule, we noted the impact that proposed policy changes for the 2021 MIPS payment year could have on final scores as clinicians are becoming familiar with these changes and noted our belief that 75 points was appropriate for Year 3 of MIPS (83 FR 59883 through 59886). We also signaled our intent to increase the additional performance threshold in future rulemaking. (83 FR 59886).

We believe that 80 points and 85 points are minimal and incremental increases over the additional performance threshold of 75 points for the 2021 MIPS payment year. We also believe it is appropriate to raise the bar on what is rewarded as exceptional performance for Year 4 and for Year 5 of the MIPS program and that increasing the additional performance threshold each year will encourage clinicians to increase their focus on value-based care and enhance the delivery of high quality care for Medicare beneficiaries.

An additional performance threshold of 80 points and 85 points would each require a MIPS eligible clinician to participate and perform well in multiple performance categories. Generally, under the proposed performance category weights for the 2022 MIPS payment year discussed as section III.K.3.d.(2)(b) of this proposed rule, a MIPS eligible clinician who is scored on all four performance categories could receive a maximum of 40 points towards the final score for the quality

performance category or a maximum score of 65 points for participating in the quality performance category and Promoting Interoperability performance category, which are both below the proposed 80-point and 85-point additional performance thresholds. In addition, 80 points and 85 points are at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target.

For example, if a MIPS eligible clinician gets a perfect score for the improvement activities (15 percent), cost (20 percent), and Promoting Interoperability (25 percent) performance categories, but does not submit quality measures data, then the MIPS eligible clinician would only receive 60 points (0 points for quality performance category + 20 points for the cost performance category + 15 points for improvement activities performance category + 25 points for Promoting Interoperability performance category), which is below the proposed additional performance thresholds. We believe setting the additional performance threshold at 80 points and 85 points could increase the incentive for exceptional performance while keeping the focus on quality performance.

We note that under section 1848(q)(6)(F)(iv) of the Act, funding is available for additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act only through the 2024 MIPS payment year, which is the sixth year of the MIPS program. We believe it is appropriate to further incentivize clinicians whose performance meets or exceeds the additional performance threshold for the fourth and fifth years of the MIPS program. We recognize that setting a higher additional performance threshold may result in fewer clinicians receiving additional MIPS payment adjustments. We also note that a higher additional performance threshold could increase the maximum additional MIPS payment adjustment that a MIPS eligible clinician potentially receives if the funds available (up to $500 million for each year) are distributed over fewer clinicians that have final scores at or above the higher additional performance threshold.

We invite public comment on our proposals to set the additional performance threshold at 80 points for the 2022 MIPS payment year and at 85 points for the 2023 MIPS payment year. Alternatively, for the 2022 MIPS payment year, we considered whether the additional performance threshold should remain at 75 points or be set at a higher number, for example, 85 points, and also seek comment on alternative numerical values for the additional performance threshold for the 2022 MIPS payment year. We refer readers to sections VI.E.10.c.(3) and VI.F.2. of the RIA for the estimated maximum payment adjustments when the additional performance threshold is set at 80 points and at 85 points, respectively, for the 2022 MIPS payment year.

Alternatively, for the 2023 MIPS payment year, we also considered whether the additional performance threshold should remain at 80 points as proposed for the 2022 MIPS payment year or whether a different numerical value should be adopted for the 2023 MIPS payment year, and also seek comment on alternative numerical values for the additional performance threshold for the 2023 MIPS payment year. Additionally, in the event that we adopt different numerical values for the performance threshold in the final rule than proposed in section III.K.3.e.(2) of this proposed rule, we seek comment on whether we should adopt different numerical values for the additional performance threshold and how we should set those values. We also seek comment on how the distribution of the additional MIPS payment adjustments across MIPS eligible clinicians may impact exceptional performance by clinicians participating in MIPS. For example, the distribution of the additional MIPS payment adjustments could result in a higher additional MIPS payment adjustment available to fewer clinicians or could result in a lower additional MIPS payment adjustment available to a larger number of clinicians. We also remind readers that we anticipate the data will change over time and that the distribution of final scores will differ from one year to the next.

(4) Example of Adjustment Factors

In the CY 2019 PFS proposed rule (83 FR 35978 through 35981) and the CY 2019 PFS final rule (83 FR 59891 through 59894), we provided a figure and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our proposed policies for the 2021 MIPS payment year. We are updating the figure and tables based on the policies we are proposing in this proposed rule.

Figure 1 provides an example of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on the policies proposed for the 2022 MIPS payment year in this proposed rule. In Figure 1, the performance threshold is 45 points. The applicable percentage is 9 percent for the 2022 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the 2022 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 11.25 points based on the performance threshold of 45 points for the 2022 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 9 percent for the 2022 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 9 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be higher than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 45 points (which is the performance threshold in this example) would receive a neutral MIPS payment adjustment. Because the performance threshold is 45 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 9 percent.

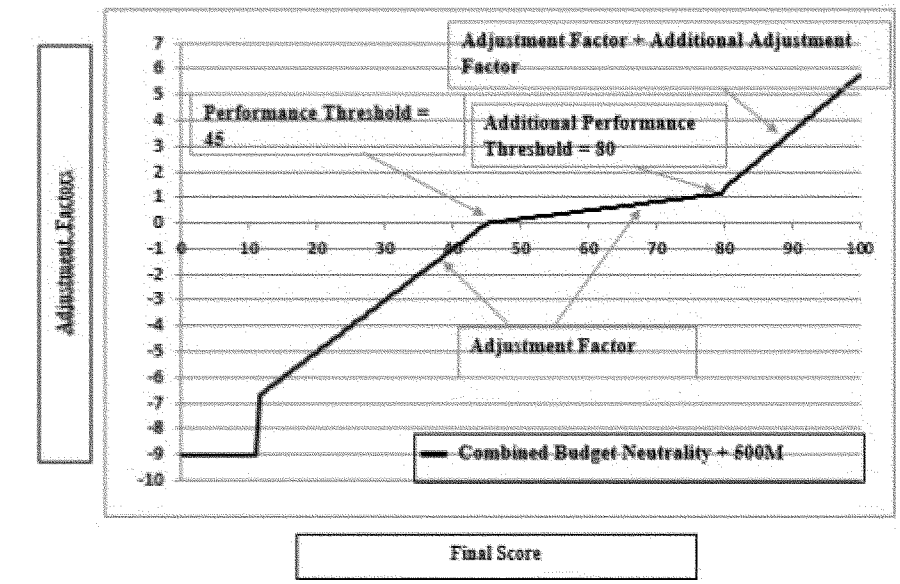
Figure 1 illustrates an example of the slope of the line for the linear adjustments for the 2022 MIPS payment year, but it could change considerably as new information becomes available. In this example, the scaling factor for the MIPS payment adjustment factor is 0.203. In this example, MIPS eligible clinicians with a final score equal to 100 would have a MIPS payment adjustment factor of 1.823 percent (9 percent ×

0.2026). (Note that this is prior to adding the additional payment adjustment for exceptional performance, which is explained below.)

The proposed additional performance threshold for the 2022 MIPS payment year is 80 points. An additional MIPS payment adjustment factor of 0.5 percent starts at the additional performance threshold and increases on a linear sliding scale up to 10 percent. This linear sliding scale line is also multiplied by a scaling factor that is greater than zero and less than or equal to 1.0. The scaling factor will be determined so that the estimated aggregate increase in payments associated with the application of the additional MIPS payment adjustment factors is equal to $500 million. In Figure 1, the example scaling factor for the additional MIPS payment adjustment factor is 0.395. Therefore, MIPS eligible clinicians with a final score of 100 would have an additional MIPS payment adjustment factor of 3.95 percent (10 percent × 0.395). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be 1 + 0.0182 + 0.0395 = 0.0578, for a total positive MIPS payment adjustment of 5.78 percent.

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FIGURE 1: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Proposed Performance Threshold and Proposed Additional Performance Threshold for the 2022 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. MIPS clinicians with a final score of at least 80 points would also receive an additional adjustment factor for exceptional performance. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent and is also multiplied by a scaling factor that is greater than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

The final MIPS payment adjustments will be determined by the distribution of final scores across MIPS eligible clinicians and the performance threshold. More MIPS eligible clinicians above the performance threshold means the scaling factors would decrease because more MIPS eligible clinicians receive a positive MIPS payment adjustment factor. More MIPS eligible clinicians below the performance threshold means the scaling factors would increase because more MIPS eligible clinicians would receive a negative MIPS payment adjustment factor and relatively fewer MIPS eligible clinicians would receive a positive MIPS payment adjustment factor.

Table 52 illustrates the changes in payment adjustments based on the final policies for the 2020 and 2021 MIPS payment years, and the proposed policies for the 2022 and 2023 MIPS payment years discussed in this proposed rule, as well as the statutorily required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.

TABLE 52: Illustration of Point System and Associated Adjustments Comparison between the 2020 MIPS Payment Year, the 2021 MIPS Payment Year, and the Proposed Policies for the 2022 MIPS Payment Year and the 2023 MIPS Payment Year

2020 MIPS payment year		2021 MIPS payment year		2022 MIPS payment year (proposed)		2023 MIPS payment Year (proposed)	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-3.75	Negative 5%	0.0-7.5	Negative 7%	0.0-11.25	Negative 9%	0.0-15.0	Negative 9%
3.76-14.99	Negative MIPS payment adjustment greater than negative 5% and less than 0% on a linear sliding scale	7.51-29.99	Negative MIPS payment adjustment greater than negative 7% and less than 0% on a linear sliding scale	11.26-44.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	15.01-59.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
15.0	0% adjustment	30.0	0% adjustment	45.0	0% adjustment	60.0	0% adjustment
15.01-69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	30.01-74.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	45.01-79.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	60.01-84.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
70.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for final scores from 15.00 to 100.00. This sliding scale is multiplied by a	75.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for final scores from 30.00 to 100.00. This sliding scale is multiplied by a	80.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final	85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges

2020 MIPS payment year		2021 MIPS payment year		2022 MIPS payment year (proposed)		2023 MIPS payment Year (proposed)	
Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment
	scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 80.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		from 0 to 9% for final scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionatel y distribute the available funds for exceptional performance

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We have provided updated examples below with the policies proposed for the 2022 MIPS payment year to demonstrate scenarios in which MIPS eligible clinicians can achieve a final score above the proposed performance threshold of 45 points based on our final policies.

Example 1: MIPS Eligible Clinician in Small Practice Submits 5 Quality Measures and 1 Improvement Activity

In the example illustrated in Table 53, a MIPS eligible clinician in a small practice reporting individually exceeds the performance threshold by performing at the median level for 5 quality measures via Part B claims collection type and one medium-weight improvement activity. The practice does not submit data for the Promoting Interoperability performance category, but does submit a significant hardship exception application which is approved; therefore, the weight for the Promoting Interoperability performance

category is redistributed to the quality performance category under the proposed reweighting policies discussed in section III.K.3.d.(2)(b)(iii) of this proposed rule. We also assumed the small practice has a cost performance category percent score of 50 percent. Finally, we assumed a complex patient bonus of 3 points which represents the average HCC risk score for the beneficiaries seen by the MIPS eligible clinician, as well as the proportion of Medicare beneficiaries that are dual eligible. There are special scoring rules for the improvement activities performance category which affect MIPS eligible clinicians in a small practice.

- Six measure achievement points for each of the 5 quality measures submitted at the median level of performance. We refer readers to § 414.1380(b)(1)(i) for further discussion of the quality performance category scoring policy. Because the measures are submitted via Part B claims, they do not qualify for the end-to-end electronic reporting bonus, nor do the measures submitted qualify for the high-priority bonus. The small practice bonus of 6 measure bonus points apply because at least 1 measure was submitted. Because the MIPS eligible clinician does not meet full participation requirements, the MIPS eligible clinician does not qualify for improvement scoring. We refer readers to § 414.1380(b)(1)(vi) for the full participation requirements for improvement scoring. Therefore, the quality performance category is (30 measure achievement points + 6 measure bonus points)/60 total available measure points + zero improvement percent score which is 60 percent.
- The Promoting Interoperability performance category weight is redistributed to the quality performance category so that the quality performance category score is worth 65 percent of the final score. We refer readers to section III.K.3.d.(2)(b)(iii) of this proposed rule for a discussion of this policy.
- MIPS eligible clinicians in small practices qualify for special scoring for improvement activities so a medium weighted activity is worth 20 points out of a total 40 possible points for the improvement activities performance category. We refer readers to § 414.1380(b)(3) for further detail on scoring policies for small practices for the improvement activities performance category.
- This MIPS eligible clinician exceeds the performance threshold of 45 points (but does not exceed the additional performance threshold). This score is summarized in Table 53.

TABLE 53—SCORING EXAMPLE 1, MIPS ELIGIBLE CLINICIAN IN A SMALL PRACTICE

[A] Performance category	[B] Performance score	[C] Category weight	[D] Earned points ([B] * [C] * 100)
Quality	60%	65%	39
Cost	50%	20%	10
Improvement Activities	20 out of 40 points—50%	15%	7.5
Promoting Interoperability	N/A	0% (redistributed to quality)	0
Subtotal (Before Bonuses)			56.5
Complex Patient Bonus			3
Final Score (not to exceed 100).			59.5

Example 2: Group Submission Not in a Small Practice

In the example illustrated in Table 54, a MIPS eligible clinician in a medium size practice participating in MIPS as a group receives performance category scores of 75 percent for the quality performance category, 50 percent for the cost performance category, and 100 percent for the Promoting Interoperability and improvement activities performance categories. There are many paths for a practice to receive a 75 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated at this amount. Again, for simplicity, we assume a complex patient bonus of 3 points. The final score is calculated to be 83 points, and both the performance threshold of 45 and the additional performance threshold of 80 are exceeded. In this example, the group practice exceeds the additional performance threshold and will receive the additional MIPS payment adjustment.

TABLE 54—SCORING EXAMPLE 2, MIPS ELIGIBLE CLINICIAN IN A MEDIUM PRACTICE

[A] Performance category	[B] Performance score	[C] Category weight (%)	[D] Earned points ([B] * [C] * 100)
Quality	75%	40	30
Cost	50%	20	10
Improvement Activities	40 out of 40 points—100%	15	15
Promoting Interoperability	100%	25	25
Subtotal (Before Bonuses)			80
Complex Patient Bonus			3
Final Score (not to exceed 100)			83

Example 3: Non-Patient Facing MIPS Eligible Clinician

In the example illustrated in Table 55, an individual MIPS eligible clinician that is non-patient facing and not in a small practice receives performance category scores of 50 percent for the quality performance category, 50 percent for the cost performance category, and 50 percent for 1 medium-weighted improvement activity. Again, there are many paths for a practice to receive a 50 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated. Because the MIPS eligible clinician is non-patient facing, they qualify for special scoring for improvement activities and receive 20 points (out of 40 possible points) for the medium weighted activity. Also, this individual did not submit Promoting Interoperability measures and qualifies for the automatic redistribution of the Promoting Interoperability performance category weight to the quality performance category. Again, for simplicity, we assume a complex patient bonus of 3 points.

In this example, the final score is 53 and the performance threshold of 45 points is exceeded while the additional performance threshold of 80 points is not.

TABLE 55—SCORING EXAMPLE 3, NON-PATIENT FACING MIPS ELIGIBLE CLINICIAN

[A] Performance category	[B] Performance score	[C] Category weight	[D] Earned points ([B] * [C] * 100)
Quality	50%	65%	32.5
Cost	50%	20%	10
Improvement Activities	20 out of 40 points for 1 medium weight activity—50%.	15%	7.5
Promoting Interoperability	0%	0% (redistributed to quality)	0
Subtotal (Before Bonuses)			50
Complex Patient Bonus			3
Final Score (not to exceed 100).			53

We note that these examples are not intended to be exhaustive of the types of participants in MIPS nor the opportunities for reaching and exceeding the performance threshold.

f. Targeted Review and Data Validation and Auditing

For previous discussions of our policies for targeted review, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358).

We are proposing to: (1) Identify who is eligible to request a targeted review; (2) revise the timeline for submitting a targeted review request; (3) add criteria for denial of a targeted review request; (4) update requirements for requesting additional information; (5) state who will be notified of targeted review decisions and require retention of documentation submitted; and (6) codify the policy on scoring recalculations. These proposals are discussed in more detail in this proposed rule.

(1) Targeted Review

(a) Who Is Eligible To Request Targeted Review

In the CY 2017 Quality Payment Program final rule, we established at § 414.1385(a) that MIPS eligible clinicians and groups may submit a targeted review request and that these submissions could be with or without the assistance of a third party intermediary (81 FR 77353). In our efforts to minimize burden on MIPS eligible clinicians and groups, we believe it is important to allow designated support staff and third party intermediaries to submit targeted review requests on their behalf. To expressly acknowledge the role of designated support staff and third party intermediaries in the targeted review process, we are proposing to revise § 414.1385(a)(1) to state that a MIPS eligible clinician or group (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review. MIPS eligible clinicians and groups (including their designated support staff) can request a targeted review by logging into the QPP website at *qpp.cms.gov*, and after reviewing their performance feedback for the relevant performance period and MIPS payment year, they can submit a request for targeted review. An authorized third party intermediary as defined at § 414.1305, such as a qualified registry, health IT vendor, or QCDR, that does not have access to their clients' performance feedback still would be able to request a targeted review on behalf of their clients. Third party intermediaries do not have access to the performance feedback of MIPS eligible clinicians and groups; therefore, we will share an URL link to the Targeted Review Request Form with these designated entities. In the CY 2017 Quality Payment Program final rule, we established at § 414.1385(a)(2) that CMS will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted (81 FR 77353). We are proposing to redesignate this provision as § 414.1385(a)(4).

(b) Timeline for Targeted Review Requests

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(1) that MIPS eligible clinicians and groups have a 60-day period to submit a request for targeted review, which begins on the day we make available the MIPS payment adjustment factor, and if applicable the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors), for the MIPS payment year and ends on September 30 of the year prior to the MIPS payment year or a later date specified by CMS. During the first year of targeted review for MIPS, we allowed MIPS eligible clinicians and groups 90 days, with an additional 14-day extension, to submit a targeted review request. In response to user feedback, in December 2018, we made available revised performance feedback to MIPS eligible clinicians and groups who had filed a targeted review request. We believe it is important to ensure MIPS eligible clinicians and groups have an opportunity to review their revised

performance feedback prior to the application of the MIPS payment adjustment factors. We anticipate that by limiting the targeted review period to 60 days, we would be able to make available the revised performance feedback during October of the year prior to the MIPS payment year, which would be approximately 2 months earlier than what we were able to do for the first year of targeted review. Therefore, we are proposing to revise § 414.1385(a)(2) to state that all requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year, and to state that the targeted review request submission period may be extended as specified by CMS. We are proposing this change would apply beginning with the 2019 performance period.

(c) Denial of Targeted Review Requests

Each targeted review request is carefully reviewed based upon the information provided at the time the request is submitted. During the first year of targeted review, CMS received many targeted review requests that were duplicative. We continue to seek opportunities to limit burden and improve the efficiency of our processes. Therefore, we are proposing to revise § 414.1385(a)(3) to state that a request for a targeted review may be denied if: The request is duplicative of another request for targeted review; the request is not submitted during the targeted review request submission period; or the request is outside of the scope of targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year. Notification will be provided to the individual or entity that submitted the targeted review request as follows:

- If the targeted review request is denied; in this case, there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician or group.
- If the targeted review request is approved; in this case, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician or group.

(d) Request for Additional Information

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(3) that the MIPS eligible clinician or group may include additional information in support of their request for targeted review at the time the request is submitted, and if CMS requests additional information from the MIPS eligible clinician or group, it must be provided and received by CMS within 30 days of the request, and that non-responsiveness to the request for additional information may result in the closure of the targeted review request, although the MIPS eligible clinician or group may submit another request for targeted review before the deadline. Supporting documentation is a critical component of evaluating and processing a targeted review request. We may need to request supporting documentation, as each targeted review request is reviewed individually and by category. Therefore, we are proposing to add § 414.1385(a)(5) to state that a request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS's request. Non-responsiveness to CMS's request for additional information may result in a final decision based on the information available, although another request for a targeted review may be submitted before the end of the targeted review request submission period. Documentation can include, but is not limited to:

- Supporting extracts from the MIPS eligible clinician or group's EHR.
- Copies of performance data provided to a third party intermediary by the MIPS eligible clinician or group.
- Copies of performance data submitted to CMS.
- QPP Service Center ticket numbers.
- Signed contracts or agreements between a MIPS eligible clinician/group and a third party intermediary.

(e) Notification of Targeted Review Decisions

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(4) that decisions based on the targeted review are final, and there is no further review or appeal. We are proposing to renumber this provision as § 414.1385(a)(7) and to add text to § 414.1385(a)(7) to state that CMS will notify the individual or entity that submitted the request for a targeted review of the final decision. To align with policies finalized at § 414.1400(g) regarding the auditing of entities submitting MIPS data, we are also proposing to add § 414.1385(a)(8) to state that documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.

(f) Scoring Recalculations

In the CY 2017 Quality Payment Program final rule (81 FR 77353), we stated that if a request for targeted review is approved, the outcome of such review may vary. We stated, for example, we may determine that the clinician should have been excluded from MIPS, re-distribute the weights of certain performance categories within the final score (for example, if a performance category should have been weighted at zero), or recalculate a performance category score in accordance with the scoring methodology for the affected category, if technically feasible (81 FR 77353). Therefore, we are proposing to add § 414.1385(a)(6) to state that if a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to the measures, activities, performance categories, and final score, as well as the MIPS payment adjustment factors.

(2) Data Validation and Auditing

For previous discussions of our policies for data validation and auditing at § 414.1390, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77358 through 77362). Among other requirements, § 414.1390(b) establishes that all MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS must certify to the best of their knowledge that the data submitted is true, accurate and complete. MIPS data that are inaccurate, incomplete, unusable or otherwise compromised can result in improper payment. Despite these existing obligations, we have received inquiries regarding perceived opportunities to selectively submit data that are unrepresentative of the MIPS performance of the clinician or group. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period, commonly referred to as ''cherry-picking,'' results in data submissions that are not true, accurate or complete. A clinician or group cannot certify that data submitted to CMS are true, accurate and complete to the best of its knowledge if they know the data submitted is not representative of the clinician's or group's performance. Accordingly, a clinician or group that submits a certification under § 414.1390(b) in connection with the

submission of data they know is cherry-picked has submitted a false certification in violation of existing regulatory requirements. If CMS believes cherry-picking of data may be occurring, we may subject the MIPS eligible clinician or group to auditing in accordance with § 414.1390(a) and in the case of improper payment a reopening and revision of the MIPS payment adjustment in accordance with § 414.1390(c).

g. Third Party Intermediaries

We refer readers to §§ 414.1305 and 414.1400, the CY 17 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), and the CY 2019 PFS final rule (83 FR 59894 through 59910) for our previously established policies regarding third party intermediaries.

In this proposed rule, we propose to make several changes. We propose to establish new requirements for MIPS performance categories that must be supported by QCDRs, qualified registries, and Health IT vendors. We are proposing to modify the criteria for approval as a third party intermediary, and establish new requirements to promote continuity of service to clinicians and groups that use third party intermediaries for their MIPS submissions. With respect to QCDRs, we are also proposing requirements to: Engage in activities that will foster improvement in the quality of care; and enhance performance feedback requirements. These QCDR proposals would also affect the self-nomination process. We are also proposing to update considerations for QCDR measures. With respect to qualified registries, we are also proposing to require enhanced performance feedback requirements. Finally, we are clarifying the remedial action and termination provisions applicable to all third party intermediaries.

Because we believe that third party intermediaries, such as QCDRs, represent a useful path to fulfilling MIPS requirements while reducing the reporting burden for clinicians, we believe the proposals discussed in this section justify the collection of information and regulatory impact burden estimates discussed in sections IV. and VI. of this proposed rule, respectively, for additional information on the costs and benefits.

(1) Proposed Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

We refer readers to § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088) for our current policy regarding the types of MIPS data third-party intermediaries may submit. In sum, the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. Through education and outreach, we have become aware of stakeholders' desires to have a more cohesive participation experience across all performance categories under MIPS. Specifically, we have heard of instances where clinicians would like to use their QCDR or qualified registry for reporting the improvement activities and promoting interoperability performance categories, but their particular third party intermediary does not support all categories, only quality. Based on this feedback and additional data regarding QCDRs and qualified registries respectively, which are discussed further below, we believe it is reasonable to strengthen our policies at § 414.1400(a)(2), and require QCDRs and qualified registries to support three performance categories: Quality; improvement activities; and Promoting Interoperability. Accordingly, we propose to amend § 414.1400(a)(2) to state that beginning with the 2021 performance period and for all future years, for the MIPS performance categories identified in the regulation, QCDRs and qualified registries must be able to submit data for each category, and Health IT vendors must be able to submit data for at least one category. We solicit feedback on the benefits and burdens of this proposal, including whether the requirement to support all three identified categories of MIPS performance data should extend to health IT vendors.

However, we recognize the need to create an exception to allow QCDRs and qualified registries that only represent MIPS eligible clinicians that are eligible for reweighting under the Promoting Interoperability performance category. For example, as discussed in the CY 2019 PFS final rule (83 FR 59819 through 59820), physical therapists generally are eligible for reweighting of the Promoting Interoperability performance category to zero percent of the final score; therefore, under this exception, a QCDR or qualified registry that represents only physical therapists that reweighted the Promoting Interoperability performance category to zero percent of the final score, would not be required to support the Promoting Interoperability performance category. Therefore, we are proposing to revise § 414.1400(a)(2)(iii) to state that for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) or (5) or § 414.1380(c)(2)(i)(C)(1)–(7) or § 414.1380(c)(2)(i)(C)(9). We refer readers to section III.K.3.c.(4) of this proposed rule for additional information on the clinician types that are eligible for reweighting the Promoting Interoperability performance category. We anticipate using the self-nomination vetting process to assess whether the QCDR or qualified registry is subject to our proposed requirement to support reporting the Promoting Interoperability performance category. We solicit comments on this proposal, including the scope of the proposed exception from the Promoting Interoperability reporting requirement for certain types of QCDRs and qualified registries. Specifically, we solicit comment on whether we should more narrowly tailor, or conversely broaden, the proposed exceptions for when QCDRS and qualified registries must support the Promoting Interoperability performance category.

(2) Approval Criteria for Third Party Intermediaries

We refer readers to § 414.1400(a)(4) and the CY 2019 PFS final rule (83 FR 59894 through 59895; 60088) for previously finalized policies related to the approval criteria for third party intermediaries.

Based on experience with third party intermediaries thus far, in this proposed rule we are proposing to adopt two additional criteria for approval at § 414.1400(a)(4) to ensure continuity of services to MIPS eligible clinicians, groups, and virtual groups that utilize the services of third party intermediaries. Specifically, we have experienced instances where a third party intermediary withdraws mid-performance period, which impacts the clinician or group's ability to participate in the MIPS program, through no fault of their own. We are proposing two

changes to help prevent these disruptions. First, we are proposing at § 414.1400(a)(4) to add a new paragraph (v) to establish that a condition of approval for a third party intermediary is for the entity to agree to provide services for the entire performance period and applicable data submission period. In addition, we are proposing at § 414.1400(a)(4) to add a new paragraph (vi) to establish that a condition of approval is for third party intermediary to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third party intermediary according to a CMS approved a transition plan. We believe it is important to condition the approval of a third party intermediary on the entity agreeing to follow this process so that in the case a third-party intermediary fails to meet its obligation under the proposed new § 414.1400(a)(4)(v) to provide services for the entire performance period and corresponding data submission period, the third party intermediary and the clinicians, groups, and virtual groups it serves have common expectations of the support the third party intermediary will provide to its users in connection with its withdrawal. We believe these proposed conditions of approval will help ensure that entities seeking to become approved as third party intermediaries are aware of the expectations to provide continuous service for the duration of the entire performance period and corresponding data submission period, will help reduce the extent to which the clinicians, groups, and virtual groups are inadvertently impacted by a third party intermediary withdrawing from the program, and will help clinicians, groups, and virtual groups avoid additional reporting burden that may result from withdrawals mid-performance period. We note that under this proposal, if CMS determines that a third party intermediary has ceased to meet either of these proposed new criteria for approval, CMS may take remedial action or terminate the third party intermediary in accordance with § 414.1400(f). We also refer readers to sections III.K.3.g.(3) and III.K.3.g.(4) where we discuss these proposals for QCDRs and qualified registries specifically.

(3) Qualified Clinical Data Registries (QCDRs)

In this proposed rule, we propose to update: (a) QCDR approval criteria; and (b) various policies related to QCDR measures. These proposals would also affect the QCDR self-nomination process.

(a) QCDR Approval Criteria

We generally refer readers to section 1848(m)(3)(E) of the Act, as added by section 601(b)(1)(B) of the American Taxpayer Relief Act of 2012, which requires the Secretary to establish requirements for an entity to be considered a Qualified Clinical Data Registry (QCDR) and a process to determine whether or not an entity meets such requirements. We refer readers to section 1848(m)(3)(E)(i), (v) of the Act, the CY 2019 PFS final rule (83 FR 60088), and § 414.1400(a)(4) through (b) for previously finalized policies about third party intermediaries and QCDR approval criteria. In this proposed rule, we are proposing to add to those policies to require QCDRs to: (a) Support all three performance categories where data submission is required; (b) engage in activities that will foster improvement in the quality of care; and (c) enhance performance feedback requirements.

(i) Requirement for QCDRs To Support All Three Performance Categories Where Data Submission Is Required

We also refer readers to section III.K.3.g.(1) above, where we propose to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In this section, we discuss QCDRs specifically. As previously stated in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), section 1848(q)(1)(E) of the Act encourages the use of QCDRs in carrying out MIPS. Although section 1848(q)(5)(B)(ii)(I) of the Act specifically requires the Secretary to encourage MIPS eligible clinicians to use QCDRs to report on applicable measures for the quality performance category, and section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through QCDRs, the statute does not specifically address use of QCDRs for the other MIPS performance categories (81 FR 77363). Although we previously could have limited the use of QCDRs to assessing only the quality performance category under MIPS and providing performance feedback, we believed (and still believe) it would be less burdensome for MIPS eligible clinicians if we expand QCDRs' capabilities (81 FR 77363). By allowing QCDRs to report on quality measures, improvement activities, and Promoting Interoperability measures, we alleviate the need for individual MIPS eligible clinicians and groups to use a separate mechanism to report data for these performance categories (81 FR 77363). It is important to note that QCDRs do not need to submit data for the cost performance category since these measures are administrative claims-based measures (81 FR 77363).

As noted above, based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability.

Through education and outreach, we have become aware of stakeholders' desires to have a more cohesive participation experience across all performance categories under MIPS. Specifically, we have heard of instances where clinicians would like to use their QCDR for reporting the improvement activities and promoting interoperability performance categories, but their particular QCDR does not support all categories, only quality. This results in the clinician needing to enter into a business relationship with another third party to complete their MIPS reporting or leverage a different submitter type or submission type, which can create additional burden to the clinician. We believe that requiring QCDRs to be able to support these performance categories will be a step towards addressing stakeholders concerns on having a more cohesive participation experience across all performance categories under MIPS. In addition, we believe this proposal will help to reduce the reporting burden MIPS eligible clinicians and groups face when having to utilize multiple submission mechanisms to meet the reporting requirements of the various performance categories. Furthermore, as we move to a more cohesive participation experience under the MIPS Value Pathways (MVP), as discussed in section III.K.3.a., Transforming MIPS: MIPS Value Pathways Framework, we believe this proposal will assist clinicians in that transition.

Based on our review of existing 2019 QCDRs through the 2019 QCDR Qualified Posting, approximately 92

QCDRs, or about 72 percent of the QCDRs currently participating in the program are supporting all three performance categories. The 2019 QCDR qualified posting is available in the QPP Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/347/2019%20QCDR%20Qualified%20Posting_Final_v3.xlsx*. In addition, in our review of prior data through previous qualified postings for the 2017 and 2018 performance periods, we have observed that a majority of the QCDRs participating in the program supported the three performance categories that require data submission. In 2017, 73 percent (approximately 83 QCDRs) and in 2018, 73 percent (approximately 110 QCDRs) have supported all three performance categories. Based on this data, we believe it is reasonable to want to continue to strengthen our policies at § 414.1400(a)(2), to require that QCDRs have the capacity to support the reporting requirements of the quality, improvement activities, and promoting interoperability performance categories.

Therefore, beginning with the 2021 performance period and for future years, we propose to require QCDRs to support three performance categories: Quality, improvement activities, and Promoting Interoperability. Additionally, for reasons, as discussed above, we propose to amend § 414.1400(a)(2) to state beginning with the 2021 performance period and for all future years, for the following MIPS performance categories, QCDRs must be able to submit data for all categories, and Health IT vendors must be able to submit data for at least one category: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability with an exception. As discussed in section III.K.3.g.(1) of this proposed rule, we are proposing that based on the proposed amendment to § 414.1400(a)(2)(iii), for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4), (c)(2)(i)(A)(5), (c)(2)(i)(C)(1) through (c)(2)(i)(C)(7), or (c)(2)(i)(C)(9). As part of this proposal, we would require QCDRs to attest to the ability to submit data for these performance categories, as applicable, at time of self-nomination.

(ii) Requirement for QCDRs To Engage in Activities That Will Foster Improvement in the Quality of Care

We generally refer readers to section 1848(m)(3)(E)(i) and (v) of the Act, which requires the Secretary to establish requirements for an entity to be considered a qualified clinical data registry and a process to determine whether or not an entity meets such requirements. Section 1848(m)(3)(E)(ii)(IV) of the Act provides that in establishing such requirements, the Secretary must consider whether an entity, among other things, supports quality improvement initiatives for participants.

As detailed at § 414.1305(1) a QCDR means: For the 2019, 2020 and 2021 MIPS payment year, a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

Although ''improvement in the quality of care'' is broadly included under paragraph (2) of the definition of a QCDR at § 414.1305 in the 2019 PFS final rule (83 FR 59897), we want to further clarify how a QCDR can be successful in fostering improvement in the quality of care provided to patients by clinicians and groups. We understand putting parameters around exactly what improvement in the quality of care may be can be difficult due to the varying nature of QCDRs organizational structures. For example, we have QCDRs that are founded by both large and small specialty societies, and healthcare systems where the volumes of services, available resources, and volume of members may vary. However, we believe QCDRs should enhance education and outreach to clinicians and groups to improve patient care.

The definition of qualified clinical data registry (QCDR) at § 414.1305(2) currently states that beginning with the 2022 MIPS payment year, an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. In this proposed rule, we are proposing policies with regards to ''foster improvement in the quality of care.''

Therefore, we are proposing to add § 414.1400(b)(2)(iii) that beginning with the 2023 MIPS payment year, the QCDRs must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives. Quality improvement services may be broad, and do not necessarily have to be specific towards an individual clinical process. An example of a broad quality improvement service would be for the QCDR to provide reports and educating clinicians on areas of improvement for patient populations by clinical condition for specific clinical care criteria. Furthermore, an example of an individual clinical process specific quality improvement service would be if the QCDR supports a metric that measures blood pressure management, the QCDR could use that data to identify best practices used by high performers and broadly educate other clinicians and groups on how they can improve the quality of care they provide. We believe educational services in quality improvement for eligible clinicians and groups would encourage meaningful and actionable feedback for clinicians to make improvements in patient care. To be clear, these QCDR quality improvement services would be separate and apart from any activities that are reported on under the improvement activities performance category. We believe improvement activities can be distinguished from quality improvement services, because they are actions taken by MIPS eligible clinicians under the improvement activities performance category. Improvement activities means an activity that relevant MIPS eligible clinician, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes (§ 414.1305). Quality improvement services, on the other hand, would be actions taken by the QCDR. While these QCDR quality improvement services could potentially overlap with an improvement activity, requirements for the improvement activities performance category would still apply to MIPS eligible clinicians and groups.

We are proposing to require QCDRs to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. We intend on including the QCDR's approved quality improvement services in the qualified posting for each approved QCDR.

(iii) Enhanced Performance Feedback Requirement

Section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through QCDRs. In addition, in establishing the requirements, the Secretary must consider, among other things, whether an entity provides timely performance reports to participants at the individual participant level (section 1848(m)(3)(E)(ii)(III) of the Act). Currently, CMS requires QCDRs to provide timely performance feedback at least 4 times a year on all of the MIPS performance categories that the QCDR reports to CMS (82 FR 53812). Based on our experiences thus far under the Quality Payment Program, we agree that providing feedback at least 4 times a year is appropriate. However, in the future CMS would like to see, and therefore encourages QCDRs, to provide timely feedback on a more frequent basis more than 4 times a year. Receipt of more frequent feedback will help clinicians and groups make more timely changes to their practice to ensure the highest quality of care is being provided to patients. We see value in providing more timely feedback to meet the objectives [136] of the Quality Payment Program in improving the care received by Medicare beneficiaries, lowering the costs to the Medicare program through improvement of care and health, and advance the use of healthcare information between allied providers and patients. We also believe there is value in this performance feedback, and therefore, encourage QCDRs to work with their clinicians to get the data in earlier in the reporting period so the QCDR can give meaningful, timely feedback.

In the QCDR performance feedback currently being provided to clinicians and groups, we have heard from stakeholders that that not all QCDRs provide feedback the same way. We have heard through stakeholder comments that some QCDR feedback contains information needed to improve quality, whereas other QCDR feedback does not supply such information due to the data collection timeline. Additionally, we believe that clinicians would benefit from feedback on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure or QCDR measure) within the QCDR they are reporting through, so they can identify areas of measurement in which improvement is needed, and furthermore, they can see how they compare to their peers based within a QCDR, since the feedback provided by the QCDR would be limited to those who reported on a given measure using that specific QCDR.

Therefore, we are proposing a change so that QCDRs structure feedback in a similar manner. We propose a new paragraph at § 414.1400(b)(2)(iv), beginning with the 2023 MIPS payment year, to require that QCDRs provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period. We are also soliciting comment on other exceptions that may be necessary under this requirement.

We also understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. We believe QCDR internal comparisons can still help MIPS eligible clinicians identify areas where further improvement is needed. The ability for MIPS eligible clinicians to be able to know in real time how they are performing against their peers, within a QCDR, provides immediate actionable feedback. We believe this provides value gained for clinicians as the majority of QCDRs are specialty specific or regional based, therefore the clinician can gain peer comparisons that are specific to their peer cohort, which can be specialty specific or locality based.

Furthermore, we are also proposing to strengthen the QCDR self-nomination process at § 414.1400(b)(1) to add that beginning with the 2023 MIPS payment year, QCDRs are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(b)(2)(iv)).

In addition, the current performance period begins January 1 and ends on December 31st, and the corresponding data submission deadline is typically March 31st as described at § 414.1325(e)(1). As discussed above, we have heard from QCDR stakeholders that in some instances clinicians wait until the end of the performance period to submit data to the third party intermediary, who are then unable to provide meaningful feedback to their clinicians 4 times a year. Therefore, we are also seeking comment for future notice-and-comment rulemaking on whether we should require MIPS eligible clinicians, groups, and virtual groups who utilize a QCDR to submit data throughout the performance period, and prior to the close of the performance period (that is, December 31st). We are also seeking comment for future notice-and-comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the QCDR is providing feedback and the clinician or group during the performance period. This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.

(b) QCDR Measures

We refer readers to § 414.1400(b)(1), the CY 2018 Quality Payment Program final rule (82 FR 53814) and the CY 2019 PFS final rule (83 FR 59898 through 59900) for our previously established policies for the QCDR measure self-nomination process. In this proposed rule, we are proposing policies related to: (a) Considerations for QCDR measure approval; (b) requirements for QCDR measure approval; (c) considerations for QCDR measure rejections; (d) the approval process; and (e) QCDR measures that have failed to reach benchmarking thresholds. These are discussed in detail below.

(c) QCDR Measure Requirements

(i) QCDR Measure Considerations and Requirements for Approval or Rejection

Through education and outreach, we have heard stakeholders' concerns about the complexity of reporting when there is a large inventory of QCDR measures to choose from, and believe our proposals will help to ensure that the measures made available in MIPS are meaningful to a clinician's scope of practice. In this proposed rule, we are proposing to codify established QCDR measure considerations and propose, beginning with the CY 2021 performance period, a number of QCDR measure specific requirements, that would generally align with MIPS measure policies, which can be found in the CY 2018 Quality Payment Program final rule (82 FR 53636), and as described in section III.K.3.c.(1) of this proposed rule.

[136] Quality Payment Program Overview. *https://qpp.cms.gov/about/qpp-overview.*

(A) QCDR Measure Considerations

(aa) Previously Finalized QCDR Measure Considerations

We generally refer readers to the § 414.1400(b)(3), CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) and the CY 2019 PFS final rule (83 FR 59900 through 59902) for previously finalized standards and criteria used for selecting and approving QCDR measures. QCDR measures are reviewed for inclusion on an annual basis during the QCDR measure review process that occurs once the self-nomination period closes (82 FR 53810). All previously approved QCDR measures and new QCDR measures are currently reviewed on an annual basis to determine whether they are appropriate for the program (82 FR 53811). The QCDR measure review process occurs after the self-nomination period closes on September 1st. QCDR measures are not finalized or removed through notice and comment rulemaking; instead, they are currently approved or not approved through a subregulatory processes (82 FR 53639).

In the CY 2019 PFS final rule (83 FR 59902), we finalized our proposal to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

In this proposed rule, we propose to codify a number of those previously finalized QCDR measure considerations (83 FR 59902). We are proposing to amend § 414.1400 by adding § 414.1400(b)(3)(iv) to include the following previously finalized QCDR measure considerations for approval:

- Preference for measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.

More information on QCDR measure approval criteria can be found in the QCDR/Qualified Registry Self-Nomination Tool-Kit in the QPP Resource Library. We refer readers to section III.K.3.g.(3)(c)(i)(B) of this rule where we are proposing to change the following previously finalized considerations into requirements:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

(bb) New QCDR Measure Considerations for Approval

(AA) QCDR Measure Availability

In the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), we finalized a policy beginning with the 2018 performance period, that allowed QCDRs to seek permission from another QCDR to use an existing and approved QCDR measure. If a QCDR would like to report on an existing QCDR measure that is owned by another QCDR, they must have permission from the QCDR that owns the measure that they can use the measure for the performance period. Permission must be granted at the time of self-nomination, so that the QCDR that is using the QCDR measure can include written proof of permission for CMS review and approval. We also finalized in the CY 2018 Quality Payment Program final rule (82 FR 53814) that once QCDR measures are approved, we will assign QCDR measure IDs, and the same measure IDs must be used by the other QCDRs that have permission to also report on the measure.

We generally encourage QCDR measure owners to permit other QCDRs to report their measures on behalf of MIPS eligible clinicians for purposes of MIPS. To the extent that QCDR measure owners limit the availability of their measures, such limitations may adversely affect a QCDR's ability to benchmark the measure, the robustness of the benchmark, or the comparability of MIPS eligible clinicians' performance results on the measure. For these reasons, we propose to amend § 414.1400 to add paragraph (b)(3)(iv)(H) to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(BB) QCDR Measure Addresses a Measurement Gap

As a part of the QCDR measure development process, QCDRs should conduct an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy program, PQRS; and review the most recent CMS Quality Measure Development Plan Annual Report, which is currently available for 2019 at: *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2019-Quality-MDP-Annual-Report-and-Appendices.zip* and the Blueprint for the CMS Measures Management System: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* for guidance in areas where CMS has identified gaps in quality measurement to reduce the possibility of duplicative measure development. We propose to amend § 414.1400 to add § 414.1400(b)(3)(iv)(I) to state that we would give greater consideration to measures for which QCDRs: (a) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and (b) utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development.

(CC) QCDRs Measures Meeting Benchmarking Thresholds

Over the first 2 years of MIPS, we have observed instances where QCDR measures have been approved for continued use in the program, but have had low reporting volumes, below the case minimum and reporting volume thresholds required for a measure to be benchmarked within the program. As described in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77282), for benchmarks to be developed, a measure must have a minimum of 20 individual clinicians or groups who reported the measure to meet the data completeness requirement and the minimum case size criteria. QCDRs should be aware of which measures are considered low-reported, since measures that do not meet benchmarking thresholds result in a 3-point floor, as described in the CY 2017 Quality Payment Program final rule (81 FR 77282). QCDR measures are reviewed and approved on an annual

basis, and as a part of the review process, we review: The benchmarking file from the previous year (for example, the 2019 Quality Benchmark file, found on the QPP Resource Library, which is available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip*); production submission data submitted from the previous year's data submission period; and data provided to us by the QCDRs themselves.

As discussed in our QCDR measure rejection considerations proposal below, we propose a QCDR measure that does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance may not continue to be approved in the future if our proposal is finalized as proposed. We note that this factor is parallel to what is being proposed for MIPS quality measures in section III.K.3.c.(1) of this proposed rule, and is important when considering the volume of QCDR measures that are currently in the program that have had low reporting rates year-over-year. We propose to amend § 414.1400 to add paragraph (b)(3)(iv)(J) to state that beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved. We refer readers to section III.K.3.g.(3)(c)(ii) below in this proposed rule, for discussion on how QCDRs may create participation plans for existing approved QCDR measures that have failed to reach benchmarking thresholds, in order to be reconsidered for future use. We also refer readers to § 414.1330 for additional information.

(B) QCDR Measure Requirements

(aa) Previously Finalized Requirements Considerations Codified as Requirements

As mentioned above, in this proposed rule, we propose to change two previously finalized measure considerations into requirements and codify those requirements. We previously finalized that we would apply certain criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS (83 FR 59902). We refer readers to section III.K.3.g.(3)(c)(i)(A) where we are proposing to codify the majority as measure considerations. However, for two of those previously finalized consideration, we are proposing them as requirements:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

We believe the previously finalized consideration that measures are beyond the measure concept phase of development should be a requirement because measures that do not surpass the measure concept phase will not be able to complete another QCDR measure requirement, measure testing. In addition, we believe the previously finalized consideration that measures address significant variation in performance should be a requirement because QCDR measures that do not demonstrate performance variation will likely be identified as topped out and will not be approved.

Therefore, beginning with the 2020 performance period, we are proposing to change both of those considerations into requirements and are proposing to amend § 414.1400 by adding § 414.1400(b)(3)(v) to include the following:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

(bb) Linking QCDR Measures to Cost Measures, Improvement Activities, and MIPS Value Pathways (MVP)

To prepare QCDR measures for self-nomination, we believe there should be consideration of how these QCDR measures relate to similar topics covered through the other performance categories. We believe (as noted in the Transforming MIPS: MIPS Value Pathways Framework, *see* section III.K.3.a. of this proposed rule) that to transform the MIPS program to one of value, MIPS measures and QCDR measures, should have an associated cost measure, improvement activity, and eventually a corresponding MVP. This would strengthen the QCDR measure's relevance in the program. We believe that evaluating the strength of these linkages may decrease the frequency of receiving extraneous QCDR measures that are not relevant or meaningful within the framework of the MIPS program.

Therefore, beginning with the 2021 performance period and future years, we propose that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measure (as found in section III.K.3.c.(2) of this proposed rule); (b) Improvement Activity (as found in Appendix 2: Improvement Activities Tables); or (c) CMS developed MVPs (as described in Table C–B1 of section III.K.3.a. of this proposed rule). Under the pathway framework for example, a surgery specific QCDR should be able to correlate their surgery-related QCDR measure to an MVP, such as the Major Surgery pathway.

We understand that not all measures may have a direct link. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements defined above.

However, we believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities. Therefore, we also propose to amend § 414.1400 to add paragraph (b)(3)(iv)(G) to require, beginning with the 2021 performance period, that QCDRs link their QCDR measures to the following at the time of self-nomination: (a) Cost measure; (b) improvement activity; and (c) an MVP. If the potential QCDR measure otherwise meets the QCDR measure requirements but does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions for measures that otherwise meet the QCDR measure requirements and considerations as discussed above.

Therefore, we also propose to amend § 414.1400 to add paragraph (b)(3)(iv)(G) to require, beginning with the 2021 performance period, that QCDRs link their QCDR measures to the following at the time of self-nomination: (a) Cost measure; (b) improvement activity; and (c) an MVP. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements.

(cc) Completion of QCDR Measure Testing

We refer readers to the CY 2019 PFS final rule, where we gave notice to the public that we were considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking (83 FR 59901 through 59902). After consideration of the public comments received, and our priority to ensure that all measures available in MIPS are reliable and valid thereby reducing reporting burden on eligible clinicians and groups, we are moving forward with a proposal in this proposed rule.

Beginning with the 2021 performance period and future years, we propose,

that for a QCDR measure to be considered for use in the program, all QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), and as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. We believe that full development and testing with completed testing results at the clinician level helps to demonstrate whether the QCDR measure is ready for implementation at the time of self-nomination. We intend to include only measures that are valid, reliable, and feasible for use by clinicians and will be consistent with the criteria that is expected of MIPS quality measures. As a result, we are also proposing to amend § 414.1400 to add paragraph (b)(3)(v)(C) to reflect this proposal. At § 414.1400(b)(3)(v)(C), we propose beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

We note that the testing process for quality measures is dependent on the measure type (for example, a measure that is specified as an eCQM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards which further illustrate these differences based on measure type. Additionally, the costs associated with testing vary based on the complexity of the measure and the developing organization. The Journal of the American Medical Association states that the costs associated with quality measures are generally unknown or unreported.[137] While we understand the proposed policy will result in additional costs for QCDRs to develop measures, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, we are unable to determine the financial impact of this proposal on QCDRs beyond the likelihood of it being more than trivial. Likewise, we understand that some QCDRs already perform measure testing prior to submission for approval while others do not. This variability makes it difficult to estimate the incremental impact of this regulation. Please refer to section VI the Regulatory Impact Analysis of this rule for additional details.

(dd) Collection of Data on QCDR Measures

We have observed several instances in which QCDRs have attempted to use the MIPS Program to ''test'' out measure concepts without concrete evidence that there is a measurement performance gap. We want to discourage that and ensure QCDR measures used for the MIPS Program are valid and reliable. In addition, through reviews of QCDR measure submissions, where reporting data was provided by the QCDR or through submission data from the 2017 performance period, we have identified some current QCDR measures in the program that have continuously low reporting rates, which affects the ability to meet benchmarking criteria. The data submitted is insufficient in meeting the case minimum and volume thresholds required for benchmarking.

Therefore, we are proposing to require QCDRs to collect data on the potential QCDR measure. For a QCDR measure to be considered for use in the program, beginning with the 2021 performance period and future years, we are proposing to amend § 414.1400 to add paragraph (b)(3)(v)(D) that QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. The data collected must demonstrate whether the QCDR measure is valid and reflects an important clinical concept(s) that clinicians wish to be measured on. By collecting data on the QCDR measure prior to self-nomination, QCDRs would be able to demonstrate whether the measure is implementable and data collection on the metric is possible. In addition, the data collected on the QCDR measure prior to self-nomination, could be used to demonstrate that there is a performance gap and need for measurement. We suggest QCDRs to collect data on as many months as possible, but strongly encourage QCDRs to collect data for 12 months prior to submitting the QCDR measure for our consideration at the time of self-nomination, since quality reporting requires 12 months of data, as described in § 414.1335, as this will also likely increase the chance that the measure will be able to be benchmarked.

(ee) Duplicative QCDR Measures

As first discussed by commenters in the CY 2018 Quality Payment Program final rule (82 FR 53814), the topic of ''shared'' measures was discussed and how would CMS intend to harmonize. In the CY 2019 PFS proposed rule (83 FR 35983), and further discussed in CY 2019 PFS final rule (83 FR 59901), we shared that we believe duplicative measures are counterintuitive to the Meaningful Measures initiative that promotes more focused quality measure development towards outcomes that are meaningful to patients, families and their providers. Therefore, it is our intent to move toward measure harmonization, which supports our efforts to increase measure alignment and eliminate redundancy both within the MIPS measure set and across our programs (83 FR 59901). Taking the previous feedback into consideration, we are moving forward with a proposal in this rule.

Therefore, we propose, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. In other words, we would not approve duplicative QCDR measures (which will be identified as a part of our scan of previously approved measures, and new QCDR measure submissions) if QCDRs choose not to address the areas of duplication with other approved QCDR measures identified by us during the previous year's QCDR measure review period. We believe this policy would help to reduce the number of duplicative QCDR measures that are submitted as a part of the self-nomination process. Adding a structured timeframe provides

[137] Schuster, Onorato, and Meltzer. ''Measuring the Cost of Quality Measurement: A Missing Link in Quality Strategy'', Journal of the American Medical Association. 2017; 318(13):1219–1220. *https://jamanetwork.com/journals/jama/fullarticle/2653111?resultClick=1.*

transparency to QCDRs who will know what next steps to expect if they do not address the identified areas of duplication as requested. Therefore, we propose to amend § 414.1400 to add paragraph (b)(3)(v)(E) to state beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. If the QCDR measures are not harmonized, CMS may reject the duplicative QCDR measure(s) as discussed in section III.K.3.g.(3)(c)(i)(C) below.

(C) QCDR Measure Rejections

We are proposing QCDR measure rejection criteria that generally aligns with finalized removal criteria for MIPS quality measures in the CY 2019 PFS final rule (83 FR 59763 through 59765). Utilizing these considerations would help to ensure that QCDR measures available in the program are truly meaningful and measurable areas where quality improvement is sought. As part of this proposal, all previously approved QCDR measures and new QCDR measures would be reviewed on an annual basis (as a part of the QCDR measure review process that occurs after the self-nomination period closes on September 1st) to determine whether they are appropriate for the program.

We propose to amend § 414.1400 to add paragraph (b)(3)(vii) to state that beginning with the 2020 performance period, we propose to reject QCDR measures with consideration of, but not limited to, the following factors:

- QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.
- QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.
- QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.
- QCDR measures that meet the ''topped out'' definition as described at § 414.1305 and in the CY 2017 QPP final rule (81 FR 77282 through 77283). If a QCDR measure is topped out and rejected, it may be reconsidered for the program in future years if the QCDR can provide evidence through additional data and/or recent literature that a performance gap exists and show that the measure is no longer topped out during the next QCDR measure self-nomination process.
- QCDR measures that are process-based, with considerations to whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the QCDR measure has potential unintended consequences to a patient's care. For example, the measure disqualifies a patient from receiving oxygen therapy or other comfort measures.
- Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.
- Whether the previously identified areas of duplication have been addressed as requested. (We refer readers to our proposal discussed in section III.K.3.g.(3)(c)(i)(B) above.)
- QCDR measures that split a single clinical practice or action into several QCDR measures. For example, splitting a measure into multiple measures based on a particular body extremity: Improvement in toe pain—the 5th toe, and a separate measure for the 2nd toe.
- QCDR measures that are ''check-box'' with no actionable quality action. For example, a QCDR measure that measures that a survey has been distributed to patients.
- QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years (we also refer readers to our proposal in section III.K.3.g.(3)(c)(ii) below).
- Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality action, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.
- QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician (that is, the quality aspect being measured cannot be attributed to the clinician or is not under the direct control of the reporting clinician).
- QCDR measures that focus on rare events or ''never events'' in the measurement period. An example of a ''never event'' would be a fire in the operating room.

(ii) QCDR Measure Review Process

(A) Current QCDR Measure Approval Process

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), and the CY 2019 PFS final rule (83 FR 59900 through 59906), and § 414.1400(b)(3) for our previously established policies for the QCDR measure self-nomination process. QCDR measures are reviewed for inclusion on an annual basis during the QCDR measure review process that occurs once the self-nomination period closes (82 FR 53810). All previously approved QCDR measures and new QCDR measures are currently reviewed on an annual basis to determine whether they are appropriate for the program (82 FR 53811). The QCDR measure review process occurs after the self-nomination period closes on September 1st. QCDR measures are not finalized or removed through notice and comment rulemaking; instead, they are currently approved or not approved through a subregulatory processes (82 FR 53639). While we would continue to review measures on an annual basis, in this proposed rule, we are proposing the addition of a multi-year approval process.

(B) Multi-Year QCDR Measure Approval

Previously in the CY 2018 Quality Payment Program final rule (82 FR 53808), we discussed our concerns with multi-year approval for QCDR measures and sought comment from stakeholders as to how to mitigate our concerns. Based on the evolution of public comments in the CY 2019 PFS final rule (83 FR 59898 through 59901) and ongoing engagement with QCDRs, we are moving forward with a proposal in this rule.

Currently, our QCDR measure approvals are on a year-to-year basis (82 FR 53811), from September to December once self-nomination occurs. In addition to that process, to help reduce yearly self-nomination burden and address stakeholder feedback (83 FR 59898 through 59901), we are proposing to amend § 414.1400 to add paragraph (b)(3)(vi) to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described above.

However, as part of this proposal, upon annual review, we may revoke the second year's approval if a QCDR measure approved for 2 years is:

- Topped out (we refer readers to § 414.1305, in the CY 2017 QPP final rule (81 FR 77282 through 77283));
- Duplicative of a more robust measure (this proposal aligns with our

proposal at section III.K.3.g.(3)(c) above);

- Reflects an outdated clinical guideline;
- Requires measure harmonization (this proposal aligns with our proposal at section III.K.3.g.(3)(c)(i)(B) above); or
- The QCDR self-nominating the QCDR measure is no longer in good standing, as described in the CY 2018 Quality Payment Program final rule (82 FR 53808).

We believe that this policy should be an incentive for QCDRs who have remained in good standing in the program. Additionally, for QCDRs not in good standing, we want to make clear that we would not remove a measure mid-year; rather, the measure's 2-year approval would be revoked during annual review after 1 year and the QCDR's measures would no longer qualify for multi-year approval in the future. For example, if QCDR ABC is placed on probation in July, all of the QCDR's measures still would be available for reporting for that performance period (until December 31st); however, if any of QCDR ABC's QCDR measures were previously approved for 2 years, the approval would be revoked for the second year.

(iii) Participation Plan for Existing QCDR Measures That Have Failed To Reach Benchmarking Thresholds

We refer readers to section III.K.3.g.(3)(c)(i), above in this proposed rule for discussion of the consideration of QCDR measures that fail to meet benchmarking thresholds after being in the program for 2 consecutive CY performance may not continue to be approved in the future.

However, we understand that there are instances where measures that are low-reported may still be considered important to a respective specialty. Therefore, beginning with the 2020 performance period, we propose to amend § 414.1400 to add paragraph (b)(3)(iv)(J)(aa) to state in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program. As examples, a QCDR measure participation plan could include one or more of the following:

- Development of an education and communication plan.
- Update the QCDR measure's specification with changes to encourage broader participation, which would require review and approval by us.
- Require reporting on the QCDR measure as a condition of reporting through the QCDR.

To be clear, implementation of a participation plan would not guarantee that a QCDR measure would be approved for a future performance period, as we consider many factors in whether to approve QCDR measures. At the following annual review of QCDR measures, we would analyze the measure's data submissions to determine whether the QCDR measure participation plan was effective (meaning, reporting volume increased, thereby increasing the likelihood of the QCDR measure being benchmarked). If the data does not show an increase in reporting volume, we may not approve the QCDR measure for the subsequent year.

(4) Qualified Registries

We refer readers to §§ 414.1305 and 414.1400, the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818) and the CY 2019 PFS final rule proposed rule (83 FR 59906) for our previously finalized policies regarding qualified registries. In this proposed rule, we propose to update qualified registry required services. These proposals would also affect the qualified registry self-nomination process.

(a) Qualified Registry Required Services

(i) Requirement for Qualified Registries To Support All Three Performance Categories Where Data Submission Is Required

We refer readers to section 1848(k)(4) of Act for statutory authority. We also refer readers to section III.K.3.g.(3) above, where we propose to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In addition, we refer readers to section III.K.3.g.(3)(a)(i) where we discuss a parallel requirement for QCDRs. In this section, we discuss qualified registries specifically. Based on previously finalized policies the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at (83 FR 60088) and § 414.1400(a)(2), the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability.

We want to continue to strengthen our policies at § 414.1400(a)(2). Based on our review of existing 2019 qualified registries, approximately 95 qualified registries, or about 70 percent of the qualified registries currently participating in the program are supporting all three performance categories. The qualified posting of approved 2019 qualified registries can be found on the QPP resource library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/348/2019%20Qualified%20Registry%20Posting_Final_v1.0.xlsx*. We believe it is reasonable that all qualified registries have the capacity to support the improvement activities and promoting interoperability performance categories.

We believe that requiring qualified registries to be able to support these performance categories will be a step towards addressing stakeholders concerns on having a more cohesive participation experience across all performance categories under MIPS. In addition, we believe this proposal will help to reduce the reporting burden MIPS eligible clinicians and groups face when having to utilize multiple submission mechanisms to meet the reporting requirements of the various performance categories. Furthermore, as we move to a more cohesive participation experience under the MVPs, as discussed in section III.K.3.a. of this proposed rule, Transforming MIPS Path to Value, we believe this proposal will assist clinicians in that transition.

Therefore, as discussed above beginning with the 2021 performance period and for future years, we propose at § 414.1400(a)(2) to require qualified registries to support all three performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability with an exception. As discussed in section III.K.3.g.(1) of this rule, we are proposing that based on the proposed amendment to § 414.1400(a)(2)(iii), to state that for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4), (c)(2)(i)(A)(5), (c)(2)(i)(C)(1) through (c)(2)(i)(C)(7), or (c)(2)(i)(C)(9). As part of this proposal, we would require qualified registries to attest to the ability to submit data for

these performance categories, as applicable, at time of self-nomination. We are also proposing this same requirement for QCDRs in section III.K.3.g.(3) of this proposed rule.

(ii) Enhanced Performance Feedback Requirement

Section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through qualified registries. In addition, in establishing the requirements, the Secretary must consider, among other things, whether an entity ''provides timely performance reports to participants at the individual participant level''. Currently, CMS requires qualified registries to provide feedback on all of the MIPS performance categories at least 4 times per year (81 FR 77367 through 77386). While based on our experiences thus far during the initial years of the Quality Payment Program, we agree that providing feedback at least 4 times a year is appropriate. However, in the future CMS would like to see, and therefore encourages qualified registries, to provide timely feedback on a more frequent basis more than 4 times a year. Receipt of more frequent feedback will help clinicians and groups make more timely changes to their practice to ensure the highest quality of care is being provided to patients. We see value in providing more timely feedback to meet the objectives [138] of the Quality Payment Program in improving the care received by Medicare beneficiaries, lowering the costs to the Medicare program through improvement of care and health, and advance the use of healthcare information between allied providers and patients. We also believe there is value in this performance feedback and therefore encourage qualified registries to work with their clinicians to get the data in earlier in the reporting period so the qualified registry give that meaningful timely feedback.

Surrounding the qualified registry performance feedback provided to clinicians and groups, we have heard from stakeholders that not all qualified registries provide feedback the same way. We have heard through stakeholder comments some qualified registries feedback contains information needed to improve quality, whereas other qualified registries feedback does not supply such information due to the data collection timeline. Additionally, we believe that clinicians would benefit from feedback on how they compare to other clinicians who have submitted data on a given MIPS quality measure within the qualified registry they are reporting through, so they can identify areas of measurement in which improvement is needed, and furthermore they can see how they compare to their peers based within a qualified registry, since the feedback provided by the qualified registry would be limited to those who reported on a given measure using that specific qualified registry.

As a result, we are proposing to add a new paragraph at § 414.1400(c)(2) to require (i) and (ii). We are simply proposing to revise the current § 414.1400(c)(2) to reclassify at paragraph (c)(2)(i) that beginning with the 2022 MIPS payment year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period. Additionally, we are proposing to add a new paragraph, § 414.1400(c)(2)(ii), beginning with the 2023 MIPS payment year, to require that qualifed registries provide the following as a part of the performance feedback given at least 4 times a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registry. We understand that there would be instances in which the qualified registry cannot meet this requirement; and therefore, we are also proposing an exception to this requirement: If the qualified registry does not receive the data from their clinician until the end of the performance period, this will preclude the qualified registry from providing feedback 4 times a year, and the qualified registry could be excepted from this requirement. We are also soliciting comment on other exceptions that may be necessary under this requirement.

We also understand that qualified registries can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the qualified registry does not have access to. We believe qualified registry internal comparisons can still help MIPS eligible clinicians identify areas where further improvement is needed. The ability for MIPS eligible clinicians to be able to know in real time how they are performing against their peers, within a qualified registry, provides immediate actionable feedback.

Furthermore, we are also proposing to strengthen the qualified registry self-nomination process at § 414.1400(c)(1) to add that beginning with the 2023 MIPS payment year, qualified registries are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(c)(2)(ii)). We refer readers to section III.K.3.g.(3)(1) where we are proposing a parallel requirement for QCDRs; we intend to have the same requirements for both QCDRs and qualifies registries.

In addition, the current performance period begins January 1 and ends on December 31st, and the corresponding data submission deadline is typically March 31st as described at § 414.1325(e)(1). As discussed above, we have heard from qualified registry stakeholders that in some instances clinicians wait until the end of the performance period to submit data to the third party intermediary, who are then unable to provide meaningful feedback to their clinicians 4 times a year. Therefore, we are also seeking comment for future notice-and-comment rulemaking on whether we should require MIPS eligible clinicians, groups, and virtual groups who utilize a qualfied registry to submit data throughout the performance period, and prior to the close of the performance period (that is, December 31st). We are also seeking comment for future notice-and-comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the qualified registry is providing feedback and the clinician or group during the performance period. This would allow qualified registries some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.

(5) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548) and the CY 2019 PFS final rule (83 FR 59908 through 59910) for previously finalized policies for remedial action and termination of third party intermediaries.

Based on experience with third party intermediaries thus far, we have concerns that certain third party intermediaries may not fully appreciate their existing compliance obligations or the implications of non-compliance. Among other provisions, § 414.1400(a)(5) specifically obligates each third party intermediary to certify that all data it submits to CMS on behalf of a MIPS eligible clinician, group or virtual group is true, accurate and complete to the best of its knowledge.

[138] Quality Payment Program Overview. *https://qpp.cms.gov/about/qpp-overview.*

Section 414.1400(f)(1) states that, after providing written notice, CMS may take remedial action or terminate a third party intermediary if CMS determines that the third party intermediary has ceased to meet one or more of the applicable criteria for approval or has submitted data that is inaccurate, unusable or otherwise compromised. Moreover, § 414.1400(f)(3) identifies specific circumstances under which CMS may determine that data submitted by a third party intermediary meets the standard for inaccurate, unusable or otherwise compromised data.

Third parties intermediaries have an affirmative obligation to certify that the data they submit on behalf of a MIPS eligible clinician, group or virtual group are true, accurate and complete to the best of its knowledge. MIPS data that are inaccurate, incomplete, unusable or otherwise compromised can result in improper payment. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period, commonly referred to as ''cherry-picking,'' results in data submissions that are not true, accurate or complete. A third party intermediary cannot certify that data submitted to CMS by the third party intermediary are true, accurate and complete to the best of its knowledge if the third party intermediary knows the data submitted are not representative of the clinician's or group's performance. As described in section III.K.3.c.(1) of this proposed rule, we proposed to further amend § 414.1340(a)(3) to clarify that the submitted data should be reflective of a 70 percent random sample. We believe this clarification will emphasize to all parties that the data submitted on each measure is expected to be representative of the clinician's or group's performance. Accordingly, a third party intermediary that submits a certification under § 414.1400(a)(5) in connection with the submission of data it knows are cherry-picked has submitted a false certification in violation of existing regulatory requirements. If CMS believes cherry-picking of data may be occurring, we may subject the third party intermediary and its clients to auditing in accordance with § 414.1400(g).

Despite these existing obligations, we have received inquiries from third party intermediaries regarding perceived opportunities to selectively submit data that are unrepresentative of the MIPS performance of the clinician or group for which the third party intermediary is submitting data. These inquires suggest that certain third party intermediaries may not fully appreciate their current regulatory obligations or their implications.

The current regulations at § 414.1400(f) clearly establish that CMS enforcement authority includes the authority to pursue remedial actions or termination based on its determination that a third party intermediary was non-compliant with any applicable criteria for approval in § 414.1400(a) through (e) or if the third party intermediary submitted data that are inaccurate, unusable or otherwise compromised. Compliance within § 414.1400(a)(5) is a criteria for approval. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period results in data that are inaccurate, unusable and otherwise compromised. Accordingly, if CMS determined that third party intermediary knowingly submitted data that are not representative of the clinician's or group's performance and certified that the submitted data were true, accurate and complete, CMS would have multiple grounds to impose remedial action or termination under existing regulations.

In this proposed rule, we propose two changes to more expressly emphasize CMS enforcement authority. First, we propose to clarify in this proposed rule that remedial action and termination provisions at § 414.1400(f)(1) are triggered if we determine that a third party intermediary submits a false certification under paragraph (a)(5). Second, as discussed below, we propose to clarify in this proposed rule that CMS authority to bring remedial actions or terminate a third party intermediary for submitting data that is inaccurate, unusable or otherwise compromise extends beyond the specific examples set forth in § 414.1400(f)(3). With these revisions and a grammatical correction described below, the proposed § 414.1400(f)(1) would affirm existing CMS authority to purse remedial actions or termination if we determine that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, submits a false certification under paragraph (a)(5), or has submitted data that are inaccurate, incomplete, unusable, or otherwise compromised. We anticipate that these proposed revisions will emphasize to third party intermediaries the sanctions they may face from CMS if they submit improper data to CMS. In addition, we note that third party intermediaries may face liability under the federal False Claims Act if they submit or cause to submission of false MIPS data.

As noted above, we are proposing revisions to § 414.1400(f)(3) to clarify the intent of this provision. We refer readers to CY 2019 PFS final rule (83 FR 59908 through 59910) for the discussion of the evolution of policies regarding remedial actions and termination of a third party intermediary. The agency's enforcement authority as codified in § 414.1400(f) broadly extends to include instances of willful misconduct by the third party intermediary and well as other instances in which a third party intermediary inadvertently submits data with deficiencies and errors that render the data ''inaccurate, unusable or otherwise compromised.'' To facilitate a more fulsome understanding on when inadvertent conduct could trigger an enforcement action against a third party intermediary, the current regulatory text in § 414.1400(f)(3) provides that the threshold for ''inaccurate, unusable or otherwise compromised'' may be met if the submitted data includes TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies that affect more 3 percent of the total number of MIPS eligible clinicians or groups for which data was submitted by the third party intermediary. Through this proposed rule, we propose to add the phrase ''including but not limited to'' to the text of § 414.1400(f)(3) to emphasize that this provision is illustrative of circumstances that may result in enforcement action and should not be misinterpreted to limit the agency's ability to impose remedial actions or terminate a third party intermediary that knowingly submits inaccurate data.

Lastly, we propose grammatically corrections related to the use of the plural term ''data.''

h. Public Reporting on Physician Compare

(1) Background

For previous discussions on the background of Physician Compare, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), and the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*.

We are proposing to publicly report on Physician Compare: (1) Aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY

2019), as technically feasible; and (2) an indicator on the profile page or in the downloadable database that displays if a MIPS eligible clinicians is scored using facility-based measurement, as specified under § 414.1380(e)(6)(vi), as technically feasible. These proposals are discussed in more detail in this proposed rule.

(2) Regulation Text Changes

Section 1848(q)(9)(A) and (D) of the Act requires that we publicly report on Physician Compare in an easily understandable format:

- The final score for each MIPS eligible clinician;
- Performance of each MIPS eligible clinician for each performance category;
- Periodic aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category;
- The names of eligible clinicians in advanced APMs and, to the extent feasible, the names of such advanced APMs and the performance of such APMs.

Section 1848(q)(9)(B) of the Act requires that the information made available under section 1848(q)(9) of the Act must indicate, where appropriate, that publicized information may not be representative of the eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

To more completely and accurately reference the data available for public reporting on Physician Compare, we propose to amend § 414.1395(a) by adding paragraph (1) stating that CMS posts on Physician Compare, in an easily understandable format: (i) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and (ii) the names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs. As discussed in section III.K.3.h.(3) of this proposed rule, we are also proposing to amend § 414.1395(a) by adding paragraph (2) stating that CMS periodically posts on Physician Compare aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. Finally, we propose to amend § 414.1395(a) by adding paragraph (3) stating that the information made available under § 414.1395 will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

(3) Final Score, Performance Categories, and Aggregate Information

Section 1848(q)(9)(D) of the Act requires the Secretary to periodically post on Physician Compare aggregate information on the MIPS, including the range of composite scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53823), where we previously finalized policies to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years.

Although we previously finalized a policy to periodically post aggregate information on the MIPS, as technically feasible, for all future years, we have not proposed or finalized in rulemaking a specific timeframe for doing so. As part of our phased approach to public reporting, we wanted to first gain experience with the MIPS data prior to publicly reporting it in aggregate, since we had not publicly reported on Physician Compare aggregate data under legacy programs. For example, we publicly reported the Physician Quality Reporting System (PQRS) performance information only at an individual clinician and group practice level. Now that we have experience with the MIPS data, including the Year 1 performance information which was not available for analysis at the time of prior rulemaking, we can now propose a specific timeframe for publicly reporting aggregate MIPS data on Physician Compare.

Therefore, in accordance with section 1848(q)(9)(D) of the Act, we propose to publicly report on Physician Compare aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY 2019), as technically feasible, and to codify this proposed policy at § 414.1395(a). We wish to clarify that the aggregate data publicly reported would be inclusive of all MIPS eligible clinicians. We also note that some aggregate MIPS data is already publicly available in other places, such as via the Quality Payment Program Experience Report. We note that the 2017 Quality Payment Program Experience Report is available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/491/2017%20QPP%20Experience%20Report.pdf*. As noted in the CY 2018 Quality Payment Program final rule (82 FR 53823), we will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel, to determine how and where these data are best reported on Physician Compare (for example in the Physician Compare Downloadable Database or on the Physician Compare Initiative page). In addition to minimum and maximum MIPS performance category and final scores, we also seek comment on any other aggregate information that stakeholders would find useful for future public reporting on Physician Compare.

(4) Quality

For previous discussions on publicly reporting quality performance category information on the Physician Compare website, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53824) and the CY 2019 Quality Payment Program final rule (83 FR 59912).

Although we are not making any proposals regarding publicly reporting quality performance category information, we are seeking additional comments on adding patient narratives to the Physician Compare website in future rulemaking, to the extent consistent with our authority to collect such information under section 1848(q) of the Act and our authority to include an assessment of patient experience and patient, caregiver, and family engagement under section 10331(a)(2)(E) of the Affordable Care Act. Physician Compare website user testing has repeatedly shown that Medicare patients and caregivers greatly desire narrative reviews, quotes and testimonials by their peers, and a single overall ''value indicator,'' reflective for each MIPS eligible clinician and group, and would expect to find such information on the Physician Compare website already, based on their experiences with other consumer-oriented websites. We currently do not

display any narrative patient satisfaction information on Physician Compare or any single overall value indicator for MIPS eligible clinicians and groups (except MIPS performance category and final scores); currently all performance information on Physician Compare is publicly reported at the individual measure level. Therefore, we are seeking comment on the value of and considerations for publicly reporting such information to assist patients and caregivers with making healthcare decisions, building upon the feedback received in response to the CY 2018 Quality Payment Program proposed rule (82 FR 30166 through 30167), in which we specifically sought comment on publicly reporting responses to five open-ended questions that are part of the Agency for Healthcare Research and Quality (AHRQ)'s CAHPS Patient Narrative Elicitation Protocol (*https://www.ahrq.gov/cahps/surveys-guidance/item-sets/elicitation/index.html*). We refer readers to section III.K.3.c.(1)(c)(i) of this proposed rule for an additional solicitation for comments to add narrative reviews into the CAHPS for MIPS group survey in future rulemaking.

To be publicly reported on Physician Compare, patient narrative data would have to meet our public reporting standards, described at § 414.1395(b), and reviewed in consultation with the Physician Compare Technical Expert Panel, to determine how and where these data would be best reported on Physician Compare. We seek comment on the value of collecting and publicly reporting information from narrative questions and other PROMs, as well as publishing a single ''value indicator'' reflective of cost, quality and patient experience and satisfaction with care for each MIPS eligible clinician and group, on the Physician Compare website and will consider feedback from the patient, caregiver, and clinician communities before proposing any policies in future rulemaking. We also note that if we propose to publicly report patient narratives in future rulemaking, we will address all related patient privacy safeguards consistent with section 10331(c) of the Affordable Care Act, which requires that information on physician performance and patient experience is not disclosed in a manner that violates the Freedom of Information Act (5 U.S.C. 552) or the Privacy Act of 1974 (5 U.S.C. 552a) with regard to the privacy individually identifiable health information, and other applicable law.

(5) Promoting Interoperability

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53827) and the CY 2019 Quality Payment Program final rule (83 FR 59913) for previously finalized policies related to the Promoting Interoperability performance category and Physician Compare.

Although we are not making any proposals regarding publicly reporting Promoting Interoperability category information, we do want to refer readers to the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers'' proposed rule (referred to as the Interoperability and Patient Access proposed rule) published in the March 4, 2019 **Federal Register** (84 FR 7646 through 7647), where we proposed to include an indicator on Physician Compare for the eligible clinicians and groups that submit a ''no'' response to any of the three prevention of information blocking attestation statements in § 414.1375(b)(3)(ii)(A) through (C). To report successfully on the Promoting Interoperability performance category, in addition to satisfying other requirements, a MIPS eligible clinician must submit an attestation response of ''yes'' for each of these statements. These statements contain specific representations about a clinician's implementation and use of CEHRT and are intended to verify that a MIPS eligible clinician has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology. In the event that these statements are left blank, that is, a ''yes'' or a ''no'' response is not submitted, the attestations would be considered incomplete, and we would not include an indicator on Physician Compare. We also proposed to post this indicator on Physician Compare, either on the profile pages or the downloadable database, as feasible and appropriate, starting with the 2019 performance period data available for public reporting starting in late 2020. We refer readers to the CY 2017 Quality Payment Program final rule for additional information on these attestation statements (81 FR 77028 through 77035).

We note that addressing comments on this proposed policy is outside of the scope of this proposed rule and instead direct readers to review that proposed rule, available at *https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and*, for more information.

(6) Facility-Based Clinician Indicator

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53823), we finalized a policy to publicly report the MIPS performance category and final scores earned by each MIPS eligible clinician on Physician Compare, either on profile pages or in the downloadable database. We also finalized that we will make all measures under the MIPS quality performance category available for public reporting on Physician Compare, either on profile pages or in the downloadable database, as technically feasible (82 FR 53824). We will use statistical testing and user testing to determine how and where measures are reported on Physician Compare. We established at § 414.1380(e) a facility-based measurement scoring option under the MIPS quality and cost performance categories for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year. Section 414.1380(e)(1)(ii) provides that the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period.

With this in mind, we have considered how to best display facility-based MIPS eligible clinician quality and cost information on Physician Compare, appreciating our obligation to publicly report certain MIPS data for MIPS eligible clinicians and groups. As those clinicians and groups scored under the facility-based option are MIPS eligible, we will publicly report their performance category and MIPS final scores on Physician Compare and considered two options for publicly reporting their facility-based measure-level performance information on Physician Compare: (a) Displaying hospital-based measure-level performance information on Physician Compare profile pages, including scores for specific measures and the hospital overall rating; or (b) including an indicator showing that the clinician or group was scored using the facility-based scoring option with a link from the clinician's Physician Compare profile page to the relevant hospital's

measure-level performance information on Hospital Compare. We believe that a link from the clinician's Physician Compare profile page to the relevant hospital's performance information on Hospital Compare is preferable for several reasons including: Concerns about duplication with Hospital Compare, interpretability by Physician Compare website users expecting to find clinician-level, rather than hospital-level, information and operational feasibility. Additionally, we believe this approach is consistent with our consumer testing findings that Medicare patients and caregivers find value in information on the relationships clinicians and groups may have with facilities where they perform services. We note that the facility-based scoring indicator would be separate from the hospital affiliation information for admitting privileges currently posted on Physician Compare profile pages.

For these reasons, we are proposing to make available for public reporting an indicator on the Physician Compare profile page or downloadable database that displays if a MIPS eligible clinician is scored using facility-based measurement, as specified under § 414.1380(e)(6)(vi), as technically feasible. We are also proposing to provide a link to facility-based measure-level information, as specified under § 414.1380(e)(1)(i), for such MIPS eligible clinicians on Hospital Compare, as technically feasible. In addition, we are proposing to post this indicator on Physician Compare with the linkage to Hospital Compare beginning with CY 2019 performance period data available for public reporting starting in late CY 2020 and for all future years, as technically feasible. We request comment on this proposal.

4. Overview of the APM Incentive

a. Overview

Section 1833(z) of the Act requires that an incentive payment be made in years 2019 through 2024 (or, in years after 2025, a different PFS update) to Qualifying APM Participants (QPs) for achieving threshold levels of participation in Advanced APMs. In the CY 2017 Quality Payment Program final rule (81 FR 77399 through 77491), we finalized the following policies:

- Beginning in payment year 2019, if an eligible clinician participated sufficiently in an Advanced APM during the QP Performance Period, that eligible clinician may become a QP for the year. Eligible clinicians who are QPs are excluded from the MIPS reporting requirements for the performance year and payment adjustment for the payment year.
- For payment years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year's estimated aggregate payments for Part B covered professional services. Beginning in payment year 2026, QPs receive a higher update under the PFS for the year than non-QPs.
- For payment years 2019 and 2020, eligible clinicians may become QPs only through participation in Medicare Advanced APMs.
- For payment years 2021 and later, eligible clinicians may become QPs through a combination of participation in Medicare Advanced APMs and Other Payer Advanced APMs (which we refer to as the All-Payer Combination Option).

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to Advanced APMs, QP and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and Physician-Focused Payment Models (PFPMs).

In the CY 2019 PFS final rule (83 FR 59915 through 59940), we finalized clarifications, modifications, and additional details pertaining to use of Certified Electronic Health Record Technology (CEHRT), MIPS-comparable quality measures, bearing financial risk for monetary losses, the QP Performance Period, Partial QP election to report to MIPS, Other Payer Advanced APM criteria, determination of Other Payer Advanced APMs, calculation of All-Payer Combination Option Threshold Scores and QP determinations under the All-Payer Combination Option.

In this proposed rule, we discuss proposals pertaining to Advanced APMs and the All-Payer Combination Option.

b. Terms and Definitions

As we continue to develop the Quality Payment Program, we have identified the need to propose new definitions to go along with the previously defined terms. A list of the previously defined terms is available in the CY 2017 Quality Payment Program final rule (81 FR 77537 through 77540), the CY 2018 Quality Payment Program final rule (82 FR 53951 through 53952), and in the CY 2019 PFS final rule (83 FR 60075 through 60076), and reflected in our regulation at § 414.1305.

In the CY 2017 Quality Payment Program final rule, we defined the term ''Medical Home Model'' and ''Medicaid Medical Home Model.'' Since defining these terms in the CY 2017 Quality Payment Program final rule, we have sought comment on whether or not to establish a similar definition to describe payment arrangements similar to Medical Home Models and Medicaid Medical Home Models that are operated by other payers (82 FR 30180).

As discussed in section III.I.4.d.(2)(a) of this proposed rule, we propose to add the defined term ''Aligned Other Payer Medical Home Model'' to § 414.1305, to mean a payment arrangement (not including a Medicaid payment arrangement) operated by an other payer that formally partners with CMS in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU), and is determined by CMS to have the following characteristics:

- The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;
- Empanelment of each patient to a primary clinician; and
- At least four of the following: Planned coordination of chronic and preventive care; Patient access and continuity of care; Risk-stratified care management; Coordination of care across the medical neighborhood; Patient and caregiver engagement; Shared decision-making; and/or Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

c. Advanced APMs

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

• Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);

• Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and

• Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to the Advanced APM criteria, Qualifying APM Participant (QP) and Partial QP determinations, the Other Payer Advanced APM criteria, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and we discussed Physician-Focused Payment Models (PFPMs).

In the CY 2019 PFS final rule (83 FR 59915 through 59938), we finalized the following:

Use of CEHRT:

• We revised § 414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity, or, for APMs in which hospitals are the APM Entities, each hospital, use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

MIPS-Comparable Quality Measures:

• We revised § 414.1415(b)(2) to clarify, effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

• We revised § 414.1415(b)(3), effective January 1, 2020, to provide that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

Bearing Financial Risk for Monetary Losses:

• We revised § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

In this section of the proposed rule, we address policies regarding several aspects of the Advanced APM criterion on bearing financial risk for monetary losses—specifically our proposal to amend the definition of expected expenditures, and our request for comment on whether certain items and services should be excluded from the capitation rate for our definition of full capitation arrangements.

(2) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77418), we divided the discussion of this criterion into two main topics: (1) What it means for an APM Entity to bear financial risk for monetary losses under an APM (which we refer to as either the generally applicable financial risk standard or Medical Home Model financial risk standard); and (2) what levels of risk we would consider to be in excess of a nominal amount (which we refer to as either the generally applicable nominal amount standard or the Medical Home Model nominal amount standard).

(b) Expected Expenditures

In the CY 2017 Quality Payment Program final rule (81 FR 77550), we established a definition of expected expenditures at § 414.1415(c)(5) to mean the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, 'expected expenditures' means the episode target price. We established this definition of expected expenditures for the purpose of applying the Advanced APM financial risk criterion to determine whether an APM meets the generally applicable nominal amount standard.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28305 through 28309), we proposed to measure three dimensions of risk under our generally applicable nominal amount standards: (1) Marginal risk, which refers to the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under the APM; (2) minimum loss rate (MLR), which is a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk; and (3) total potential risk, which refers to the maximum potential payment for which an APM Entity could be liable under the APM.

However, based on commenters' concerns regarding technical complexity, we did not finalize the marginal risk and MLR components of the generally applicable nominal standard under the Advanced APM criteria (81 FR 77427), but did finalize those additional elements of risk under the Other Payer Advanced APM criteria. We stated in the CY 2017 Quality Payment Program final rule (81 FR 77426) that the marginal risk and MLR components were not necessary to explicitly include in the generally applicable nominal amount standard for Advanced APMs because we are committed to creating Advanced APMs with strong financial risk designs that incorporate risk adjustment, benchmark methodologies, sufficient stop-loss amounts, and sufficient marginal risk; and that all APMs involving financial risk that we operate now or in the future would meet or exceed the proposed marginal risk and MLR requirements. In the CY 2017 Quality Payment Program proposed rule (81 FR 28306), we explained that to determine whether an APM satisfies the marginal risk component of the generally applicable nominal amount standard, we would examine the payment required under the APM as a percentage of the amount by which actual expenditures exceeded expected expenditures. We proposed that we would require that this percentage exceed a required marginal risk percentage of 30 percent regardless of the amount by which actual expenditures exceeded expected expenditures. We believed that any marginal risk below 30 percent could create scenarios in which the total risk could be very high, but the average or likely risk for an APM Entity would actually be very low (81 FR 28306).

Our rationale for proposing the marginal risk requirement was that the inclusion of the marginal risk requirement would contribute to maintaining a more than nominal level of average or likely risk under an Advanced APM. We did not finalize the marginal risk requirement under the Advanced APM criteria because, as noted above, we believed that all Advanced APMs that we operate now or would potentially operate in the future would meet or exceed the previously proposed marginal risk and MLR requirements, and more importantly, we believed the total risk portion of the nominal amount standard alone was sufficient to ensure that the level of average or likely risk under an

Advanced APM would actually be more than nominal for participants.

However, based on our experience to date, we are concerned that the total risk portion of the benchmark-based nominal amount standard as currently constructed may not always be sufficient to ensure that the level of average or likely risk under an Advanced APM is actually more than nominal for participants. This is because the benchmark-based nominal amount standard at § 414.1415(c)(3)(i)(B) is dependent upon the definition of expected expenditures codified at § 414.1415(c)(5), where expected expenditures are defined as the beneficiary expenditures for which an APM Entity is responsible under an APM, and for episode payment models, the episode target price.

In our experience implementing the Quality Payment Program and considering the diversity of model designs, we now believe there is a need to amend the definition of expected expenditures to ensure there are more-than-nominal levels of average or likely risk under an Advanced APM that would meet the generally applicable benchmark-based nominal amount standard. For instance, an APM could have a sufficient total risk to meet the benchmark-based nominal amount standard and a sharing rate that results in adequate marginal risk if actual expenditures exceed expected expenditures. However, in that same APM, the level of expected expenditures reflected in the APM's benchmark or episode target price could be set in a manner that would substantially reduce the amount of loss the APM Entity would reasonably expect to incur.

For an APM to meet the generally applicable benchmark-based nominal amount standard, we believe there should be not only the potential for financial losses based on expenditures in excess of the benchmark as provided in § 415.1415(c)(3)(i)(B) of our regulations, but also a meaningful possibility that an APM Entity might exceed the benchmark. If the benchmark is set in such a way that it is extremely unlikely that participants would exceed it, then there is little potential for participants to incur financial losses, and the amount of risk is essentially illusory.

Therefore, in § 414.1415(c)(5), we are proposing to amend the definition of expected expenditures. Specifically, we are proposing to define expected expenditure as, for the purposes of this section, the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the expected Medicare Parts A and B expenditures for a participant in the absence of the APM. If expected expenditures under the APM exceed the Medicare Parts A and B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for Advanced APM determinations.

In general, expected expenditures are expressed as a dollar amount, and may be derived for a particular APM from national, regional, APM Entity-specific, and/or practice-specific historical expenditures during a baseline period, or other comparable expenditures. However, we recognize expected expenditures under an APM often are risk-adjusted and trended forward, and may be adjusted to account for expenditure changes that are expected to occur as a result of APM participation. For the purpose of this proposed definition of expected expenditures, we would not consider risk adjustments to be excess expenditures when comparing to the costs that an APM Entity would be expected to incur in the absence of the APM.

We believe that this proposed amendment would allow us to ensure that there are more-than-nominal amounts of average or likely risk under an APM that meets the generally applicable benchmark-based nominal amount standard. We believe that the proposed amended definition of expected expenditures, particularly by our not considering excess expenditures when determining whether an APM meets the benchmark-based nominal amount standard, would provide a more definite basis for us to assess whether an APM Entity would bear more than a nominal amount of financial risk for participants under the generally applicable benchmark-based nominal amount standard.

We are also proposing a similar amendment to the definition of expected expenditures applicable to the Other Payer Advanced APM criteria in section III.I.4.d.(2)(b)(i) of this proposed rule.

We seek comment on this proposal.

(c) Excluded Items and Services Under Full Capitation Arrangements

In the CY 2017 Quality Payment Program final rule (81 FR 74431), we finalized a capitation standard at § 414.1415(c)(6), which provides that a full capitation arrangement meets the Advanced APM financial risk criterion. We defined a capitation arrangement as a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. We clarified that arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program are not considered capitation arrangements for purposes of this definition.

In the CY 2019 PFS final rule (83 FR 59939), we made technical corrections to the Advanced APM financial risk capitation standard at § 414.1415(c)(6). These corrections clarified that our financial risk capitation standard applies only to full capitation arrangements where a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement or reconciliation is performed.

As we have begun to collect information on other payer payment arrangements for purposes of making Other Payer Advanced APM determinations, we have noticed that some payment arrangements that are submitted as capitation arrangements consistent with § 414.1420(d)(7) include a list of services that have been excluded from the capitation rate, such as hospice care, organ transplants, and out-of-network emergency services. In reviewing these exclusion lists, we believe that it may be appropriate for CMS to allow certain capitation arrangements to be considered ''full'' capitation arrangements even if they categorically exclude certain items or services from payment through the capitation rate.

As such, we are seeking comment on what categories of items and services might be excluded from a capitation arrangement that would still be considered a full capitation arrangement. Specifically, we seek comment on whether there are common industry practices to exclude certain categories of items and services from capitated payment rates and, if so, whether there are common principles or reasons for excluding those categories of services. We also seek comment on what percentage of the total cost of care such exclusions typically account for under what is intended to be a ''full'' global capitation arrangement. We also seek

comment on how non-Medicare payers define or prescribe certain categories of services that are excluded with regards to global capitation payment arrangements.

In addition, we are seeking comment on whether a capitation arrangement should be considered to be a full capitation arrangement even though it excludes certain categories of services from the capitation rate under the full capitation standard for Other Payer Advanced APMs as discussed in section III.I.4.d.(2)(c)(ii) of this proposed rule.

(3) Summary of Proposals

In this section, we are proposing the following policy:

- *Expected Expenditures:* We are proposing to amend the definition of expected expenditures codified at § 414.1415(c)(5) to state, for the purposes of this section, expected expenditures means the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures mean the episode target price. In addition, for purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the APM should not exceed the expected Medicare Parts A and B expenditures (including model-specific risk-adjustments and trend adjustments), for the APM Entity in the absence of the APM. If expected expenditures under the APM exceed the Medicare Parts A and B expenditures that the APM Entity would be expected to incur in the absence of the APM, such excess expenditures would not be considered when CMS assesses financial risk under the APM for Advanced APM determinations.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

We finalized policies relating to QP and Partial QP determinations in the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450). In the CY 2019 PFS final rule (83 FR 59923 through 59925), we finalized additional policies relating to QP determinations and Partial QP election to report to MIPS.

(2) Group Determination

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77440), we finalized that QP determinations would generally be made at the APM Entity level, but for two exceptions in which we make the QP determination at the individual level: (1) Individuals participating in multiple Advanced APM Entities, none of which meet the QP threshold as a group; and (2) eligible clinicians on an Affiliated Practitioner List when that list is used for the QP determination because there are no eligible clinicians on a Participation List for the APM Entity (81 FR 77439 through 77443). As a result, the QP determination for the APM Entity would apply to all the individual eligible clinicians who are identified as part of the APM Entity participating in an Advanced APM. If that APM Entity's Threshold Score meets the relevant QP threshold, all individual eligible clinicians in that APM Entity would receive the same QP determination, applied to their NPIs, for the relevant year. The QP determination calculations are aggregated using data for all eligible clinicians participating in the APM Entity on a determination date during the QP Performance Period.

(b) Application of Partial QP Status

In the CY 2017 Quality Payment Program final rule (81 FR 77440), we stated that we would apply QP status at the NPI level instead of at the TIN/NPI level. We noted that an individual clinician identified by an NPI may have reassigned billing rights to multiple TINs, resulting in multiple TIN/NPI combinations being associated with one individual clinician (NPI). We also stated that if QP status was only applied to one of an individual clinician's multiple TIN/NPI combinations, an eligible clinician who is a QP for only one TIN/NPI combination might still have to report under MIPS for another TIN/NPI combination. Under that approach, the APM Incentive Payment would be based on only a fraction of the clinician's covered professional services instead of, as we believe is the most logical reading of the statute, all those services furnished by the individual clinician, as represented by an NPI. Therefore, we expressed our concern with applying QP status only to a specific TIN/NPI combination as it would not effectuate the goals of the APM incentive path of the Quality Payment Program to reward individual clinicians for their commitment to Advanced APM participation.

For Partial QPs, we currently apply Partial QP status at the NPI level across all TIN/NPI combinations, as we have for QP status. However, upon further consideration, and based on our experience implementing the Quality Payment Program to date, we no longer believe we should apply Partial QP status at the individual clinician (NPI) level across all TIN/NPI combinations, as we have and do for QP status. Partial QPs are excluded from MIPS based on an election made at the APM Entity or individual eligible clinician level, and this exclusion is currently applied at the NPI level across all of their TIN/NPI combinations. When this MIPS exclusion is applied at the NPI level, it does not always provide a similar net positive outcome across an individual clinician's TIN/NPI combinations when compared to the APM Incentive Payment that QPs receive. The MIPS exclusion is different from QP status as Partial QPs do not receive an APM Incentive Payment, Partial QPs are only relieved of the MIPS reporting requirements and not subject to a MIPS payment adjustment. As such, while a Partial QP might wish to be excluded from the MIPS reporting requirements and payment adjustment with respect to the TIN/NPI combination that relates to an APM Entity in an Advanced APM, that same Partial QP might benefit from reporting to MIPS and receiving a MIPS payment adjustment with respect to some or all of their other TIN/NPI combinations because they anticipate receiving an upward MIPS payment adjustment.

So, while the current policy excludes Partial QPs from MIPS reporting requirements and allows Partial QPs to avoid any potential downward MIPS payment adjustment, we have heard from stakeholders, including some clinicians, that this policy has prevented eligible clinicians from receiving a positive MIPS payment adjustment earned through a different TIN/NPI combination not associated with the APM Entity through which they attained Partial QP status. Furthermore, in many circumstances, the election to be excluded from MIPS for an eligible clinician is made outside their control at the APM Entity level. In such scenarios, an eligible clinician may have reported to MIPS as part of a group or as an individual under a separate TIN/NPI combination, but would not receive any MIPS payment adjustment based on that reporting. If eligible clinicians who would have received a positive MIPS adjustment are excluded from MIPS because of their Partial QP status, it could potentially discourage eligible clinicians from participating in Advanced APMs. Additionally, in future years of the Quality Payment Program, we anticipate that it will become harder to attain QP and Partial QP status because the QP and Partial QP payment amount and patient count thresholds will rise, as set forth in § 414.1430. As a result, a greater number of Advanced APM participants may attain Partial QP status, which we

believe increases the importance of removing the potential disincentive for Advanced APM participation based on the way the MIPS exclusion for Partial QPs is applied.

Therefore, we are proposing that beginning with the 2020 QP Performance Period, Partial QP status would apply only to the TIN/NPI combination(s) through which an individual eligible clinician attains Partial QP status, and to amend our regulation by adding § 414.1425(d)(5) to reflect this change. This means that any MIPS election for a Partial QP would only apply to the TIN/NPI combination through which Partial QP status is attained, so that an eligible clinician who is a Partial QP for only one TIN/NPI combination may still be a MIPS eligible clinician and report under MIPS for other TIN/NPI combinations.

We seek comment on this proposal.

(3) QP Performance Period

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77446 through 77447), we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year. We finalized that during the QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which will be a final determination for the eligible clinicians who are determined to be QPs. The QP Performance Period and the three separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

(b) APM Entity Termination

In the CY 2017 Quality Payment Program final rule, we finalized at § 414.1425(c)(5) and § 414.1425(d)(3) that an eligible clinician is not a QP or Partial QP for a year if the APM Entity group voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period (81 FR 77446 through 77447). We also finalized at § 414.1425(c)(6) and § 414.1425(d)(4) that an eligible clinician is not a QP or Partial QP for a year if one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP or Partial QP payment amount threshold or QP or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities (81 FR 77446 through 77447). We finalized these policies in part to ensure that APM Entities and eligible clinicians who achieve QP or Partial QP status during a QP Performance Period actually assume a more than a nominal amount of financial risk, as is necessary for Advanced APMs, for at least the full QP performance period from January 1 through August 31, if not the entire performance year under the Advanced APM.

Currently, under the terms of some Advanced APMs, APM Entities can terminate their participation in the Advanced APM while bearing no financial risk after the end of the QP Performance Period for the year (August 31). Under our current regulation, an APM Entity's termination after that date would not affect the QP or Partial QP status of all eligible clinicians in the APM Entity. We acknowledge that it may be appropriate for an Advanced APM to allow participating APM Entities to terminate without bearing financial risk for that performance period under the terms of the Advanced APM itself, including allowing such terminations to occur after the end of the QP Performance Period (August 31). However, allowing those eligible clinicians to retain their QP or Partial QP status without having borne financial risk under the Advanced APM through which they attained QP or Partial QP status is not aligned with the structure and principles of the Quality Payment Program, which is designed to reward those APM Entities and eligible clinicians for meaningfully assuming more than a nominal amount of financial risk, as required by the Advanced APM criteria. A critical aspect of Advanced APMs is that participants must bear more than a nominal amount of financial risk under the model. If an APM Entity terminates participation in the Advanced APM without financial accountability, the APM Entity has not yet borne more than a nominal amount of financial risk. As such, we do not believe it is appropriate for eligible clinicians in an APM Entity that terminates after QP determinations are made, but before bearing more than a nominal amount of financial risk, to retain any status as QPs or Partial QPs.

Therefore, regarding QP status, we are proposing to revise § 414.1425(c)(5) and add §§ 414.1425(c)(5)(i) and 414.1425(c)(5)(ii) which states, beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if: (1) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; (2) or the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. In addition, we are proposing to revise § 414.1425(c)(6) and add §§ 414.1425(c)(6)(i) and § 414.1425(c)(6)(ii), which states, beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if: (1) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.

Regarding Partial QP status, we are also proposing to revise § 414.1425(d)(3) and add §§ 414.1425(d)(3)(i) and 414.1425(d)(3)(ii), which states, beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if: (1) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or (2) the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. We are also proposing to revise § 414.1425(d)(4) and add §§ 414.1425(d)(4)(i) and 414.1425(d)(4)(ii), which states, beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if: (1) One or more of the APM Entities in which the eligible clinician participates

voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities. We believe these additions account for the scenarios in which an APM Entity terminates from an Advanced APM at a date on which the APM Entity would not incur any financial accountability under the terms of the Advanced APM.

We seek comment on this proposal.

(4) Summary of Proposals

In this section, we are proposing the following policies:

- *Application of Partial QP Status:* We propose that beginning with the 2020 QP Performance Period, Partial QP status will apply only to the TIN/NPI combination(s) through which an individual eligible clinician attains Partial QP status. We propose to amend § 414.1425(d)(5) to reflect this change.
- *APM Entity Termination:* We propose to revise §§ 414.1425(c)(5), 414.1425(c)(6), 414.1425(d)(3), and 414.1425(d)(4) to state that an eligible clinician is not a QP or a Partial QP for the year when an APM Entity terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs.

e. All-Payer Combination Option

(1) Overview

Section 1833(z)(2)(B)(ii) of the Act requires that beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the Combination All-Payer and Medicare Payment Threshold Option, which we refer to as the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule (81 FR 77459), we finalized our overall approach to the All-Payer Combination Option. The Medicare Option focuses on participation in Advanced APMs, and we make QP determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an APM Entity. The All-Payer Combination Option does not replace or supersede the Medicare Option; instead, it will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through payment arrangements offered by payers other than Medicare that CMS has determined meet the criteria to be Other Payer Advanced APMs. We finalized that beginning in payment year 2021, we will conduct QP determinations sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77438). The All-Payer Combination Option encourages eligible clinicians to participate in payment arrangements that satisfy the Other Payer Advanced APM criteria with payers other than Medicare. It also encourages sustained participation in Advanced APMs across multiple payers.

We finalized that the QP determinations under the All-Payer Combination Option are based on payment amounts or patient counts as illustrated in Tables 36 and 37, and Figures 1 and 2 of the CY 2017 Quality Payment Program final rule (81 FR 77460 through 77461). We also finalized that, in making QP determinations with respect to an eligible clinician, we will use the Threshold Score (that is, based on payment amount or patient count) that is most advantageous to the eligible clinician toward achieving QP status, or if QP status is not achieved, Partial QP status, for the year (81 FR 77475).

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TABLE 56: QP Payment Amount Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	25%	25%	25%
Total			50%	50%	75%
Partial QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			40%	40%	50%

TABLE 57: QP Patient Count Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			35%	35%	50%
Partial QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	10%	10%	10%
Total			25%	25%	35%

FIGURE 2: QP Determination Tree, Payment Years 2021-2022

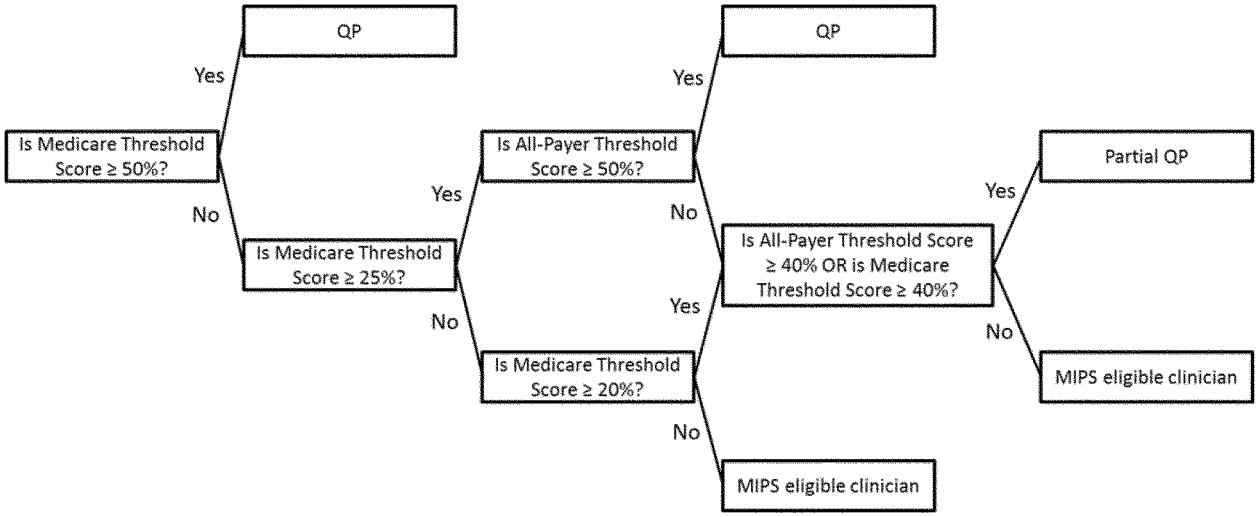
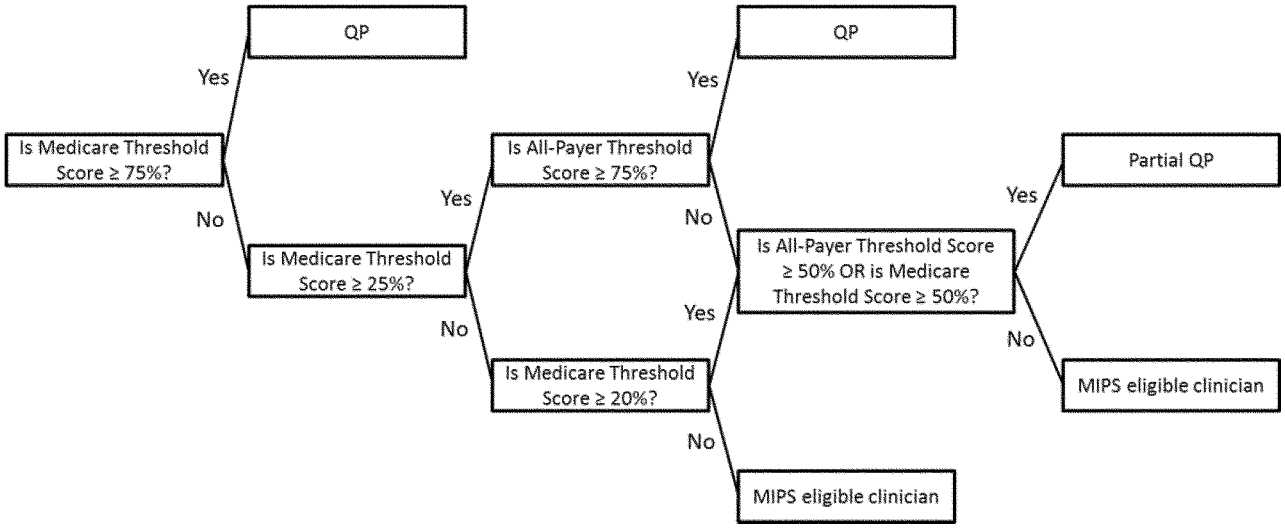


FIGURE 3: QP Determination Tree, Payment Years 2023 and Later



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Unlike the Medicare Option, where we have access to all of the information necessary to determine whether an APM meets the criteria to be an Advanced APM, we cannot determine whether payment arrangements offered by other payers meet the criteria to be an Other Payer Advanced APM without receiving information about the payment arrangements from an external source. Similarly, we do not have the necessary payment amount and patient count information to determine under the All-Payer Combination Option whether an eligible clinician meets the payment amount or patient count threshold to be a QP without receiving certain information from an external source.

In the CY 2018 Quality Payment Program final rule (82 FR 53844 through 53890), we established additional policies to implement the All-Payer Combination Option and finalized certain modifications to our previously finalized policies. A detailed summary of those policies can be found at 82 FR 53874 through 53876 and 53890 through 53891.

In the CY 2019 PFS final rule (83 FR 59926 through 59938), we finalized the following:

Other Payer Advanced APM Criteria:

- We changed the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each participating APM Entity group, or each hospital if hospitals are the APM Entities, use CEHRT to document and communicate clinical care.

• We allowed payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement.

• We clarified § 414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

• We revised § 414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, that to be an Other Payer Advanced APM, an other payer arrangement must use an outcome measure, that must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

• We also revised our regulation at § 414.1420(c)(3)(i) to provide that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year that did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as finalized in CY 2019 PFS final rule (83 FR 55931 through 55932), we would continue to apply the previous requirements for purposes of those determinations. This revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

• We revised § 414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

Determination of Other Payer Advanced APMs:

• We finalized details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we aligned the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

• We eliminated the Payer Initiated Process that is specifically for CMS Multi-Payer Models. These payers will be able to submit their arrangements through the Payer Initiated Process for Remaining Other Payers as finalized in the CY 2019 PFS final rule (82 FR 59933 through 59935), or through the Medicaid or Medicare Health Plan payment arrangement submission processes, and no longer need a special pathway.

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations:

• We added a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We modified our regulation at § 414.1440(d) by adding a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.

• We clarified that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We codified this clarification by amending § 414.1440(d)(1).

• We extended the weighting methodology that is used to ensure that an eligible clinician does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level in order to apply a similar policy to the proposed TIN level Medicare Threshold Scores.

In this section of the proposed rule, we address our proposal to define the term Aligned Other Payer Medical Home Model, and our proposals regarding bearing financial risk for monetary losses, specifically the Medicaid Medical Home Model financial risk standard and the definition of expected expenditures. We also discuss our request for comment on whether certain items and services should be excluded from the capitation rate for our definition of full capitation arrangements.

(2) Aligned Other Payer Medical Home Models

(a) Definition

As we explained when finalizing the definitions of Medical Home Model and Medicaid Medical Home Model in the CY 2017 Quality Payment Program final rule, MACRA does not define 'medical homes,' but sections 1848(q)(5)(C)(i), 1833(z)(2)(B)(iii)(II)(cc)(BB), 1833(z)(2)(C)(iii)(II)(cc)(BB), and 1833(z)(3)(D)(ii)(II) of the Act make medical homes an instrumental piece of the law (81 FR 77403). The terms Medical Home Model and Medicaid Medical Home Model are limited to Medicare and Medicaid payment arrangements, respectively, and do not include other payer payment arrangements.

As we discuss in section III.I.4.b. of this proposed rule, we are proposing to add the defined term ''Aligned Other Payer Medical Home Model'' to § 414.1305, which would mean an aligned other payer payment arrangement (not including a Medicaid payment arrangement) operated by an other payer formally partnering in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation with CMS, such as a memorandum of understanding (MOU), and is determined by CMS to have the following characteristics:

• The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

• Empanelment of each patient to a primary clinician; and

• At least four of the following: Planned coordination of chronic and preventive care; Patient access and continuity of care; risk-stratified care management; coordination of care across the medical neighborhood; patient and caregiver engagement; shared decision-making; and/or

payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

The proposed definition of Aligned Other Payer Medical Home Model includes the same characteristics as the definitions of Medical Home Model and Medicaid Medical Home Model, but it applies to other payer payment arrangements. We believe that structuring this proposed definition in this manner is appropriate because we recognize that there may be medical homes that are operated by other payers that may be appropriately considered medical home models under the All-Payer Combination Option.

We are proposing to exclude Medicaid payment arrangements from this proposed definition of Aligned Other Payer Medical Home Model because we have previously defined the term Medicaid Medical Home Model at § 414.1305 and we believe it is important to distinguish Medicaid payment arrangements from other payment arrangements, given the requirements in sections 1833(z)(2)(B)(ii)(I)(bb) and 1833(z)(3)(B)(ii)(I)(bb) of the Act requiring us to consider whether there is a medical home or alternative payment model under the Title XIX state plan in each state when making QP determinations using the All-Payer Combination Option.

For purposes of the Aligned Other Payer Medical Home Model definition, for an arrangement to be aligned, we mean through a written expression of alignment and cooperation with CMS, such as an MOU. CMS Multi-Payer Models require alignment across the different payers and a written expression reflects the fact that each arrangement has been reviewed by CMS and CMS has determined that the other payer payment arrangement is aligned with a CMS Multi-Payer Model that is a Medical Home Model. We are proposing to limit this Aligned Other Payer Medical Home Model definition to other payer payment arrangements that are aligned with CMS Multi-Payer Models that are Medical Home Models because we can be assured that the structure of these arrangements is similar to the Medical Home Models and Medicaid Medical Home Models for which we have already made a similar determination. Based on our experience to date, we anticipate that participants in these arrangements may generally be more limited in their ability to bear financial risk than other entities because they may be smaller and predominantly include primary care practitioners, whose revenues are a smaller fraction of the patients' total cost of care than those of other eligible clinicians. At the same time, we do not believe that participants in all medical homes, regardless of payer, face the same limitations on their ability to bear financial risk. We believe that some participants may have different organizational or financial circumstances that allow them to bear greater such risk. We believe that applying the proposed Aligned Other Payer Medical Home Model definition to all other payer payment arrangements would create potential new opportunities for gaming in commercial settings where we do not have control over the design of such models. However, we believe that payment arrangements that have been aligned and are similar to a Medicaid Home Model, where we have already put in place policies to control against gaming, would be similarly constrained.

In addition, we have acquired additional understanding of some other payer payment arrangements after one year of experience with the Payer Initiated Process, which included some arrangements that are aligned with CMS Multi-Payer Models that are Medical Home Models.

We seek comment on this proposal.

(b) Other Payer Advanced APM Criteria for Aligned Other Payer Medical Home Models

As defined in § 414.1305, an Other Payer Advanced APM is an other payer arrangement that meets the Other Payer Advanced APM criteria set forth in § 414.1420. Accordingly, we propose that the CEHRT criterion codified in § 414.1420(b) and the use of quality measures criterion codified in § 414.1420(c) would apply to any Aligned Other Payer Medical Home Model for which we would make an Other Payer Advanced APM determination. Further, we propose to revise § 414.1420(d)(8) to require Aligned Other Payer Medical Home Models to comply with the 50 eligible clinician limit to align with the requirements that apply to Medical Home Models and Medicaid Medical Home Models.

Regarding the applicable financial risk and nominal amount standards, consistent with the financial risk and nominal amount standards applicable to Medical Home Models and Medicaid Medical Home Models, we propose that the Aligned Other Payer Medical Home Model financial risk and nominal amount standards would be the same as the Medicaid Medical Home Model financial risk and nominal amount standards. We are proposing corresponding amendments to § 414.1420(d)(2) and (4) so that those sections note, Medicaid Medical Home Model and Aligned Other Payer Medical Home Model financial risk standard and Medicaid Medical Home Model and Aligned Other Payer Medical Home Model nominal amount standard, respectively. We believe that this proposal, as described in section III.I.3.b. of this proposed rule, is appropriate because the same expectation of ability to bear a more than nominal amount of financial risk applies to participants in these models as Medical Home Models and Medicaid Medical Home Models because the arrangements are already aligned and the participants are the same.

(c) Determination of Aligned Other Payer Medical Home Model and Other Payer Advanced APM Status

We propose that payers may submit other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Payer Initiated Process. This proposal would be effective January 1, 2020 for the 2021 performance year. In the CY 2019 PFS final rule, we finalized a process for Remaining Other Payers to submit other payer arrangements for CMS determination of Other Payer Advanced APM status (83 FR 59934 through 59935). Other payers would be required to submit their other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, using this Remaining Other Payer process.

We propose that APM Entities and eligible clinicians can submit other payer arrangements for CMS to determine whether they are Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Eligible Clinician Initiated Process.

We seek comment on these proposals.

(3) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77466), we divided the discussion of this criterion into two main topics: (1) What it means for an APM Entity to bear financial risk if actual aggregate expenditures exceed expected aggregate expenditures under a payment arrangement (which we refer to as either the generally applicable financial risk standard or Medicaid Medical Home Model financial risk standard); and (2) what levels of risk we would consider to be in excess of a

nominal amount (which we refer to as either the generally applicable nominal amount standard or the Medicaid Medical Home Model nominal amount standard).

In the CY 2017 Quality Payment Program final rule, we finalized that for a Medicaid Medical Home Model to be an Other Payer Advanced APM, if the APM Entity's actual aggregate expenditures exceed expected aggregate expenditures, the Medicaid Medical Home Model must:

- Withhold payment for services in the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians;
- Require direct payment by the APM Entity to the Medicaid program; or
- Require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

We based this standard on our belief that Medicaid Medical Home Models are unique types of Medicaid APMs because they are identified and treated differently under the statute. We believe it is appropriate to establish a unique standard for bearing financial risk that reflects these statutory differences and remains consistent with the statutory scheme, which is to provide incentives for participation by eligible clinicians in Advanced APMs (81 FR 77467 through 77468).

In addition, to be an Other Payer Advanced APM, a Medicaid Medical Home Model must require that the total annual amount that an APM Entity potentially owes or foregoes under the Medicaid Medical Home Model must be at least:

- For QP Performance Period 2019, 3 percent of the APM Entity's total revenue under the payer.
- For QP Performance Period 2020, 4 percent of the APM Entity's total revenue under the payer.
- For QP Performance Period 2021 and later, 5 percent of the APM Entity's total revenue under the payer.

(b) Aligned Other Payer Medical Home Model Financial Risk and Nominal Amount Standards

Neither the current Medical Home Model financial risk and nominal amount standards nor the Medicaid Medical Home Model financial risk and nominal amount standards do not apply to similar arrangements with other payers for purposes of Other Payer Advanced APM determinations. Consistent with our proposal to define the term Aligned Other Payer Medical Home Model, we are proposing to amend § 414.1420(d)(2) and (d)(4) of our regulations to also include that conform the financial risk and nominal amount standards for Aligned Other Payer Medical Home Models with the existing Medicaid Medical Home Model financial risk and nominal amount standards for Medicaid Medical Home Models. Consistent with recognizing the similar characteristics of these payment arrangements and the same participants, we believe that the same financial risk and nominal amount standards should be applied to Aligned Other Payer Medical Home Models.

Further, we are proposing a corresponding amendment to § 414.1420(d)(2)(ii) to state that an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model require the direct payment by the APM Entity to the payer, which meaning either the other payer or the Medicaid agency.

We believe that if we applied the Medicaid Medical Home Model financial risk and nominal amount standards to all other payer arrangements that would meet the Aligned Other Payer Medical Home Model definition but for not being aligned with a CMS Multi-Payer Model that is a Medical Home Model, we might create gaming opportunities amongst other payers where medical homes are developed solely to take advantage of the unique nominal amount standard, particularly because we would have less insight into the nature of arrangements not aligned with CMS Multi-Payer Models.

In addition, as the 50 eligible clinician limit as codified in §§ 414.1415(c)(7) and 414.1420(d)(8) currently applies to Medical Home Models and Medicaid Medical Home Models, respectively, we correspondingly propose that the 50 eligible clinician limit apply to Aligned Other Payer Medical Home Models by amending § 414.1420(d)(8).

We seek comment on these proposals.

(b) Generally Applicable Other Payer Advanced APM Nominal Amount Standard

(i) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77471), we finalized at § 414.1420(d)(3)(ii) that except for risk arrangements described under the Medicaid Medical Home Model Standard, for a payment arrangement to meet the nominal amount standard the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and total potential risk must be at least 4 percent of the expected expenditures. Furthermore, we finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement. Section 414.1420(d)(6) provides for the purposes of this section, expected expenditures is defined as the Other Payer Advanced APM benchmark, except for episode payment models, for which it is defined as the episode target price.

(ii) Marginal Risk

As we stated in the 2017 Quality Payment Program final rule (81 FR 77470), to determine that a payment arrangement satisfies the marginal risk portion of the nominal amount standard, we would examine the payment required under the payment arrangement as a percentage of the amount by which actual expenditures exceeded expected expenditures. Specifically for marginal risk, we finalized that for a payment arrangement to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures. We also stated that the rate of marginal risk could vary with the amount of losses.

To date, we have applied the marginal risk requirement as requiring that a payment arrangement must exceed the marginal risk rate of 30 percent at all levels of total losses even as the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, consistent with § 414.1420(d)(5)(i). For example, certain other payer arrangements where the marginal risk met or exceeded 30 percent at lower levels of losses in excess of expected expenditures, but fell below 30 percent at higher levels of losses, would not meet the marginal risk requirement of the generally applicable nominal amount standard.

In general, this approach has worked well and served its intended purpose of ensuring only other payer arrangements with strong financial risk components are determined to be Other Payer Advanced APMs. At the same time, this policy has necessitated that we determine that certain other payer arrangements are not Other Payer Advanced APMs even though they include strong financial risk components and well exceed the 30 percent marginal risk requirement at the most common levels of losses in excess of expected expenditures, and employ marginal risk rates below 30 percent only at much higher levels of losses. We

do not believe these other payer arrangements include marginal risk rates below 30 percent to avoid subjecting participants to more than nominal amounts of risk. Rather, we believe that these other payer arrangements employ the lower marginal risk rates at higher levels of losses in order to protect participants from potentially catastrophic losses and undue financial burden that might arise because of market factors likely outside their control.

Therefore, we propose to amend § 414.1420(d)(5) by amending paragraph (d)(5)(i) to provide that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, with exceptions for large losses and small losses as described in paragraphs (d)(5)(ii) and (d)(5)(iii) of this section.

We would calculate the average marginal risk rate in two steps. An example of such a calculation is presented in Table 58. This example uses a model relying on a Total Cost of Care (TCOC) benchmark. This methodology can also be applied to other types of other payer payment arrangements. In this example, first, take the sum of the marginal risk for each percent above the Total Cost of Care (TCOC) benchmark to determine the participant losses. For example, at 3 percent add 50 percent (amount for 1 percent above benchmark) plus 50 percent (amount for 2 percent above benchmark) plus 50 percent (amount for 3 percent above benchmark) equals 1.50 percent. Second, divide the participant losses by the percentage above the benchmark (in our example, 1.50 percent divided by 3) to get average marginal risk. The average marginal risk rate remains above 30 percent at all levels of potential losses up to point where the participant would be responsible for losses equal to the total potential risk requirement of 3 percent. We note that this example presents the calculation only up to the point where the total potential risk requirement is met.

TABLE 58—EXAMPLE AVERAGE MARGINAL RISK CALCULATION

Performance (% above TCOC benchmark)	Marginal risk (%)	Participant losses (%)	Average marginal risk (%)
1	50	0.50	50
2	50	1.00	50
3	50	1.50	50
4	25	1.75	44
5	25	2.00	40
6	25	2.25	38
7	25	2.50	36
8	25	2.75	34
9	25	3.00	33

Through this amendment, significant and meaningful financial risk would continue to be required for Other Payer Advanced APMs because the average marginal risk rate would need to be or exceed 30 percent, while recognizing that such risk can be demonstrated with some variation in the application of marginal risk rates, allowing for continued innovation in the marketplace. This proposed policy ensures that all Other Payer Advanced APMs have 30 percent of marginal risk up until the participant owes 3 percent of losses, which is the intended effect of the standard without excluding certain payment arrangement that have strong financial risk designs. When considering average marginal risk in the context of total risk, as we do for Other Payer Advanced APM determinations, certain risk arrangements can create meaningful and significant risk-based incentives for performance and at the same time ensure that the payment arrangement has strong financial risk components.

We believe this proposed change is consistent with the statute and the use of guardrails to maintain financially strong models, and note that in making this change we are not lowering the standard for the applicable marginal risk rate but rather allowing for a new demonstration of how it can be met. We clarify that the proposed amendment would also continue to maintain the allowance for large losses provision as described in paragraph (d)(5)(ii) of § 414.1420, so that when calculating the average marginal risk rate we may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the payment arrangement greater than or equal to the total risk requirements. We also clarify that the exception for small losses described in paragraph (d)(5)(iii) would also be maintained.

We seek comment on this proposal.

(iii) Expected Expenditures

In the CY 2017 Quality Payment Program final rule (81 FR 77551), we established the definition of ''expected expenditures'' at § 414.1420(d)(6) to mean the Other Payer APM benchmark, except for episode payment models, for which it is defined as the episode target price. We also finalized at § 414.1420(d)(3)(ii) that, except for arrangements assessed under the Medicaid Medical Home Model financial risk and nominal amount standards, in order to meet the Other Payer Advanced APM nominal amount standard, a payment arrangement's level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and the total potential risk must be at least 4 percent (81 FR 77471).

In the CY 2017 Quality Payment Program proposed rule (81 FR 28332), we proposed to measure three dimensions of risk under our generally applicable nominal amount standards: (1) Marginal risk, which refers to the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under the APM; (2) minimum loss rate (MLR), which is a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk; and (3) total potential risk, which refers to the maximum potential payment for which an APM Entity could be liable under the APM. However, based on commenters' concerns regarding technical complexity, we finalized only the marginal risk and MLR requirements.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28333), we explained that to determine whether an APM satisfies the marginal risk portion of the nominal risk standard, we would examine the payment required under the APM as a percentage of the amount by which actual expenditures exceeded expected expenditures. We proposed that we would require that this percentage exceed a required marginal risk percentage of 30 percent regardless of the amount by which actual expenditures exceeded expected expenditures.

Our rationale for proposing the marginal risk requirement was that the inclusion of a marginal risk requirement would be intended to focus on maintaining a more than nominal level of likely risk under an Advanced APM or an Other Payer Advanced APM. However, even with a marginal risk requirement, as there is under the Other Payer Advanced APM criteria, we believe there is a need to amend the definition of expected expenditures to ensure there are more than nominal levels of average or likely risk under Other Payer Advanced APMs that meets the generally applicable benchmark-based nominal amount standard. Even with the current marginal risk requirement, a more rigorous definition of expected expenditures is needed to avoid situations where the level of expected expenditures would be set in a manner that reduces the losses a participant might incur. We also believe it is important that our definition of expected expenditures is consistent across both the Advanced APM and Other Payer Advanced APM criteria. We generally try to align the Advanced APM and Other Payer Advanced APM criteria to the extent feasible and appropriate.

As discussed in section III.I.4.c.(2)(c) of this proposed rule, this proposal is intended to account for scenarios where a payment arrangement could have a sufficient total risk potential to meet our standard and a sharing rate that results in adequate marginal risk if actual expenditures exceed expected expenditures; however, the level of expected expenditures reflected in the payment arrangements benchmark or episode target price could be set in a manner which substantially reduces the amount of loss a participant in the payment arrangement would reasonably expect to incur.

For a payment arrangement to meet the generally applicable benchmark-based nominal amount standard, we believe there should be not only the potential for financial losses based on expenditures in excess of the benchmark as provided in § 414.1420(d)(6), but also some meaningful likelihood that a participant might exceed the benchmark. If the benchmark is set in such a way that it is extremely unlikely that participants would exceed it, then there is little potential for participants to incur financial losses, and the amount of risk is essentially illusory.

Therefore, in § 414.1420(d)(6), we are proposing to amend the definition of expected expenditures. Specifically, we would define expected expenditures as, for the purposes of this section, as the Other Payer APM benchmark. For episode payment models, expected expenditures mean the episode target price. For purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement. If expected expenditures (that is, benchmarks) under the payment arrangement exceed the expenditures that the participant would be expected to incur in the absence of the payment arrangement such excess expenditures are not considered when CMS assesses financial risk under the payment arrangement for Other Payer Advanced APM determinations.

We believe that this proposed change would prevent the expected expenditures under the other payer payment arrangement being set in a manner which substantially reduces the amount of losses a participant may face while otherwise satisfying this Other Payer Advanced APM criterion.

We clarify that, in general, expected expenditures are expressed as a dollar amount, and may be derived from national, regional, APM Entity-specific, and/or practice-specific historical expenditures during a baseline period, or other comparable expenditures. However, we recognize expected expenditures under a payment arrangement are often risk-adjusted and trended forward, and may be adjusted to account for expenditure changes that are expected to occur as a result of payment arrangement participation. For the purpose of this proposed definition of expected expenditures, we would not consider risk adjustments to be excess expenditures when comparing to the costs that an APM Entity would be expected to incur in the absence of the payment arrangement.

We believe that this proposed amendment would allow us to ensure that there are more-than-nominal amounts of average or likely risk under an other payer payment arrangement that meets the generally applicable benchmark-based nominal amount standard. We believe that the proposed amended definition of expected expenditures, particularly by our not considering excess expenditures, would provide a more definite basis for us to assess whether an APM Entity would bear more than a nominal amount of financial risk for participants under the generally applicable benchmark-based nominal amount standard.

We seek comment on this proposal.

(iv) Excluded Items and Services Under Full Capitation Arrangements

In the CY 2017 Quality Payment Program final rule (81 FR 77551), we finalized a capitation standard at § 414.1420(d)(7) which provides a capitation arrangement meets the Other Payer Advanced APM financial risk criterion. For purposes of § 414.1420(d)(3), we defined a capitation arrangement as a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the APM Entity. We clarified that arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program are not considered capitation arrangements for purposes of § 414.1420(d)(7).

In the CY 2019 PFS final rule (83 FR 59939), we made technical corrections to the Advanced APM financial risk capitation standard at § 414.1420(d)(7). These corrections clarified that our financial risk capitation standard applies only to full capitation arrangements where a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement or reconciliation is performed.

As we have begun to collect information on other payer payment arrangements for purposes of making Other Payer Advanced APM determinations, we have noticed that some payment arrangements that are submitted for CMS to determine as capitation arrangements consistent with § 414.1420(d)(7) include a list of services that have been excluded from the capitation rate, such as hospice care, organ transplants, or out-of-network emergency room services. In reviewing

these exclusion lists, we believe that it may be appropriate for CMS to allow certain capitation arrangement to be considered ''full'' capitation arrangements even if they categorically exclude certain services from payment through the capitation rate. Therefore, we are seeking comment on how other payers define or determine what, if any, exclusions are reasonable in a given capitation arrangement. Specifically, we seek comment on whether there are common industry practices to exclude certain categories of items and services from capitated payment rates and, if so, whether there are common principles or reasons for excluding those categories of services. In addition, we seek comment on why such items or services are excluded.

We also seek comment on how non-Medicare payers define or prescribe certain categories of services that are excluded with regards to global capitation payment arrangements. We also seek comment on whether a capitation arrangement should be considered to be a full capitation arrangement even though it excludes certain categories of services from the capitation rate under a full capitation arrangement.

(4) Summary of Proposals

In this section, we are proposing the following policies:

- *Aligned Other Payer Medical Home Model:* We proposed to define the term Aligned Other Payer Medical Home Model. We also propose to apply the existing Medicaid Medical Home Model financial risk and nominal amount standards, including the 50 eligible clinician limit, to Aligned Other Payer Medical Home Models.
- *Marginal Risk:* We propose that when that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate requirement, with exceptions for large losses and small losses as provided in § 414.1420(d)(5).
- *Expected Expenditures:* We are proposing to amend the definition of expected expenditures codified at § 414.1420(d)(6) to define expected expenditures as the Other Payer Advanced APM benchmark, and, for episode payment models, expected expenditures means the episode target price.

5. Quality Payment Program Technical Revisions

We are proposing certain technical revisions to our regulations to correct several technical errors and to reconcile the text of several of our regulations with the final policies we adopted through notice and comment rulemaking.

We are proposing a technical revision to § 414.1405(f) of our regulations to specify that the exception for the application of the MIPS payment adjustment factors to model-specific payments is applicable starting in the 2019 MIPS payment year, not just for the 2019 MIPS payment year. This proposed revision would align the regulation text with our final policy as stated in the preamble of the CY 2019 PFS final rule with comment period (83 FR 59887 through 59888) which makes clear that the exception begins with the 2019 MIPS payment year and continues in subsequent years.

We are also proposing technical revisions to Table 59 of the CY 2019 PFS final rule with comment period (83 FR 59935) to correct two dates. Specifically we propose to change the date for Medicare Health Plans: Guidance made available to ECs, then Submission Period Opens; it is currently listed as September 2020, and we propose to change that date to August 2020. Similarly, we propose to change the date for Remaining Other Payers: Guidance made available to ECs, then Submission Period Opens; it is currently listed as September 2020, and we propose to change that to August 2020. These changes align with what was originally finalized in the CY 2018 QPP final rule with comment period (82 FR 53864) which stated that the dates were to be August 2020, and which we did not intend to change in the CY 2019 PFS final rule. Table 59 is included as the corrected Table 59 from the CY 2019 PFS final rule.

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TABLE 59: Proposed Other Payer Advanced APM Determination Process for Medicaid, Medicare Health Plans, and Remaining Other Payers for QP Performance Period 2020

	Payer Initiated Process	Date	Eligible Clinician (EC) Initiated Process*	Date
Medicaid	Guidance sent to states, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2019
	Submission Period Closes	April 2019	Submission Period Closes	November 2019
	CMS contacts states and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and states and posts Other Payer Advanced APM List	December 2019
Medicare Health Plans	Guidance made available to Medicare Health Plans, then Submission Period Opens	April 2019	Guidance made available to ECs, then Submission Period Opens	August 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Medicare Health Plans and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Medicare Health Plans and posts Other Payer Advanced APM List	December 2020
Remaining Other Payers	Guidance made available to Remaining Other Payers, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	August 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Remaining Other Payers and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Remaining Other Payers and posts Other Payer Advanced APM List	December 2020

*Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

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We are also proposing technical revisions to §§ 414.1415(c)(6) and 414.1420(d)(7) to correct the internal citation. The current citation, 42 U.S.C. 422, is incorrect. It should instead be 42 CFR part 422. We also are proposing technical revisions to § 414.1420(d)(5). We clarify that ''APM'' in § 414.1420(d)(5) should be ''other payer payment arrangement.'' In the CY 2019 PFS final rule, we finalized deleting § 414.1420(d)(3)(ii)(B) and consolidating § 414.1420(d)(3)(ii)(A) into § 414.1420(d)(3)(ii), but that change was not applied to the regulation. We are proposing to revise the regulation accordingly in this proposed rule. Relatedly, we propose to amend § 414.1420(d)(i), (ii), and (iii) to state in ''paragraph (d)(3)(ii)'' of this section instead of ''paragraph (d)(3)(ii)(A)'' of this section. We are also proposing to clarify that ''Other Payer Advanced APM'' in § 414.1420(d)(5)(ii) should be ''other payer payment arrangement,'' as the marginal risk rate requirements are applied to any other payer payment arrangement that CMS assesses against the Other Payer Advanced APM criteria. These proposed revisions are technical in nature and do not change any substantive policies for the Quality Payment Program.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (ICRs).

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/*

oes/current/oes_nat.htm). In this regard, Table 60 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 60—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43–3021	19.00	19.00	38.00
Bookkeeping, Accounting, and Auditing Clerks	43–3031	22.46	22.46	44.92
Chief Executive	11–1011	96.22	96.22	192.44
Compliance Officer	13–1041	41.85	41.85	83.70
Computer Systems Analysts	15–1121	45.01	45.01	90.02
Health Diagnosing and Treating Practitioners	29–1000	49.02	49.02	98.04
Licensed Practical Nurse (LPN)	29–2061	22.62	22.62	45.24
Medical Secretary	43–6013	17.83	17.83	35.66
Physicians	29–1060	101.43	101.43	202.86
Practice Administrator (Medical and Health Services Managers)	11–9111	54.68	54.68	109.36

As indicated, we adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs) (§§ 414.800 Through 414.806)

As described in section II.G. of this rule, section 2005 of the SUPPORT for Patients and Communities Act establishes a new Medicare Part B benefit for OUD treatment services furnished by OTPs for episodes of care beginning on or after January 1, 2020. In this rule, CMS proposes to use the payment methodology in section 1847A of the Act, which is based on Average Sales Price (ASP), to set the payment rates for the ''incident to'' drugs and ASP-based payment to set the payment rates for the oral product categories when we receive manufacturers' voluntarily-submitted ASP data for these drugs.

The proposed burden consists of the time/cost for manufacturers of oral opioid agonist or antagonist treatment medications (that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for use in the treatment of OUD) to voluntarily prepare and submit their ASP data to CMS.

The burden for such reporting is currently approved by OMB under control number 0938–0921 (CMS–10110) and would remain unchanged (13 hours per response, 4 responses per year, 180 respondents, and 9,360 total hours) since our currently approved burden already accounts for the voluntary reporting of ASP data. We estimate that there are approximately 15 manufacturers of oral drugs used for treatment of opioid use disorder (OUD). We believe that approximately 10 of the 15 manufacturers already report ASP data to CMS for other drugs, and thus up to 5 manufacturers may newly report ASP data to CMS. However, we note that some of these new respondents may have subsidiary or similar relationships with manufacturers that already report ASP data and may be able to submit their data with a current respondent. While this rule's proposed requirements may slightly increase the number of respondents, our 180 respondent per quarter estimate historically fluctuates over time as new Part B drug manufacturers are added while others leave or consolidate. The annual fluctuation in respondents in the past has typically been +/− 5 to 10 manufacturers per year; over the past few years, the annual fluctuation has sometimes been greater, ranging from −13 to +11, but over that several year period the overall average of the annual fluctuation is near 0. As a result, the potential slight increase in respondents associated with voluntary reporting from oral OUD drug manufacturers is well within the range of recent fluctuations in the number or respondents, and the net figure, taking into account voluntary OTP reporting, remains unchanged from the currently approved burden estimate at 180 respondents. In addition, we believe that additional voluntary reporting for oral drugs used for treatment of OUD for those manufacturers that currently report ASP data to CMS would impose minimal additional burden. Consequently, we are not making any changes under the aforementioned control number. However, we will continue to monitor the number of respondents to account for various factors such as a change in the number of voluntary submissions from oral OUD drug manufacturers, as well as other issues that may not be related to the voluntary reporting for oral drugs used in OTPs, such as manufacturer consolidations, and new Part B drug and biological manufacturers. We will revise the burden estimate as needed.

2. ICRs Regarding the Ground Ambulance Data Collection System

Section 1834(l)(17)(A) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, we are not setting out the burden of the proposed collection of information under the data collection system. Please refer to section VI.F.2. of this proposed rule for a discussion of the estimated impacts associated with the ground ambulance data collection system.

3. ICRs Regarding Intensive Cardiac Rehabilitation (§ 410.49)

Section 410.49(b)(1)(vii) and (viii) of this proposed rule would expand the covered conditions to chronic heart failure and add other cardiac conditions as specified through the national coverage determination (NCD) process. The proposed rule would expand covered conditions, but, due to the breadth of the proposed and existing covered conditions, we do not anticipate the need to use the NCD process to add additional covered conditions in the near future. In the unlikely event an NCD request was submitted, it would be covered by OMB control number 0938–0776 (CMS–R–290), which will not expire until February 29, 2020. We are not proposing any changes under that control number since we are not proposing any changes to the submission process or burden.

4. ICRs Regarding the Medicare Shared Savings Program (42 CFR part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to section VI.E.6. of this proposed rule for a discussion of the impacts associated with the proposed changes to the Shared Savings Program quality reporting requirements included in this proposed rule.

5. ICRs Regarding the Open Payments Program

As described in section III.F. of this rule, we propose to: (1) Expand the definition of ''covered recipient,'' (2) modify ''nature of payment'' categories, and (3) standardize data on reported covered drugs, devices, biologicals, or medical supplies.

Expanding the Definition of ''Covered Recipient'' (§§ 403.902, 403.904, and 403.908): In this rule we propose to expand the definition of a ''covered recipient'' in accordance with the SUPPORT Act to include physician assistants, nurse practitioners, clinical nurse specialists, nurse anesthetists, and certified nurse midwifes. The definition currently includes certain physicians and teaching hospitals. Section 6111(c) of the SUPPORT Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the changes to the definition of a covered recipient included in the SUPPORT Act. In this regard we are not setting out burden under the authority of the PRA. . We do, however, provide a brief estimate in section V.8 of this proposed rule.

Modification of the ''Nature of Payment'' Categories (§§ 403.902 and 403.904): The following proposed changes will be submitted to OMB for approval under control number 0938–1237 (CMS–10495). Subject to renewal, the control number is currently set to expire on March 31, 2021. It was last approved on March 21, 2018, and remains active.

The proposed changes would modify the ''nature of payment'' categories and provide more options for applicable manufacturers and GPOs to capture the nature of the payment made to the covered recipient. To accommodate this change, we project that reporting entities would need to update their system to incorporate the proposed categories. We estimate, based on the trends in the number of entities that report every year, that there are 1,600 reporting entities and estimate, using the number of records that these entities report as a proxy for size of the entity. While the total number of entities that report fluctuates year to year, but has been close to 1,600 for the last two program years. We also estimate that 38 percent (or 611 entities) are small, 29 percent (or 457 entities) are medium, and 33 percent (or 532 entities) are large. We also estimate that 25 percent of reporting entities (400) would need to make minor, one-time updates to their data collection processes because they expect to report a transaction with one of the new categories. Among the 400 entities, we estimate it would take between 5 and 30 hours per entity depending on the size of the entity (with large companies requiring more time) at $44.92/hr for support staff. For all of these entities, we estimate a subtotal of 5,895 hours [(30 hrs for a large entity × 133 entities) + (10 hrs for a medium entity × 114 entities) + (5 hrs for a small entity × 153 entities)] at a cost of $264,804 (5,895 hrs × $44.92/hr).

We also expect that all entities would need to make minor, one-time adjustments to their submission processes. For each entity we estimate that this would take 2 to 5 hours at $44.92/hr (with larger entities requiring more time) for support staff and 1 hour at $83.70/hr for compliance officers. For all entities, we estimate a subtotal of 7,767 hours [(5 hrs for support staff at a large entity × 532 entities) + (5 hrs for support staff at a medium entity × 457 entities) + (2 hrs for support staff at a small entity × 611 entities) + (1 hr for compliance officer at each entity regardless of size × 1600 entities)] at a cost of $410,941 [(2,660 hrs for support staff at large entities × $44.92/hr) + (2,285 hrs for support staff at medium entities × $44.92/hr) + (1,222 hrs for support staff at small entities × $44.92/hr) + (1,600 hrs for compliance officers across all entities × $83.70/hr)].

In aggregate, we estimate a one-time burden of 13,662 hours (5,895 hrs + 7,767 hrs) at a cost of $675,745 ($264,804 + $410,941) to implement. After these adjustments are made, we do not anticipate any ongoing added burden beyond what is currently approved under the aforementioned control number.

TABLE 61—BURDEN TO MODIFY NATURE OF PAYMENT CATEGORIES

Description	Hours	Cost
Burden to update collection processes for entities that expect to report a transaction with a new Nature of Payment category	5,895	$264,804
Burden to update submission processes and systems to account for the new Nature of Payment categories	7,767	410,941
Total	13,662	675,745

Standardizing Data Reporting for Covered Drugs, Devices, Biologicals, or Medical Supplies (§§ 403.902 and 403.904): The following proposed changes will be submitted to OMB for approval under control number 0938–1237 (CMS–10495). Subject to renewal, the control number is currently set to expire on March 31, 2021. It was last approved on March 21, 2018, and remains active.

Applicable manufacturers and GPOs will need to accommodate the reporting of device identifiers. We have made some estimates below, but we recognize that these estimates may vary because the information collection system

changes that are needed will vary since some entities may already be capturing this information in their systems while others may not. Nevertheless, we have made some assumptions below, but we welcome feedback from stakeholders regarding the potential burden associated with this proposal and the extent to which device identifiers are already tracked by reporting entities.

We estimate, based on an analysis of currently available data, that approximately 850 entities (approximately 53 percent of an assumed 1,600) would need to report at least one record with a device identifier and that 450 of those entities do not already collect the device identifier. For this analysis we assumed that 38 percent of the entities would be small, 29 percent would be medium, and 33 percent would be large. We differentiate because we assume that larger companies would incur more burden to make the changes needed to begin reporting device identifiers because they have more complex systems and potentially more records to report. The number of records submissions would not change, but this rule would add a new data element that may need to be reported along with some or all of an entity's records. The precise tasks would vary by entity, but may include developing processes for gathering device identifier information or systems for collecting the data.

For the 450 entities that would be required to start collecting device identifiers, we estimate that this task would take between 20 and 100 hours for support staff depending on the size of the company (with larger companies requiring more time) at $44.92/hr. For all entities, we estimate a subtotal of 24,840 hours [(100 hrs for a large entity × 150 entities) + (50 hrs for a medium entity × 128 entities) + (20 hrs for a small entity × 172 entities)] at a cost of $1,115,813 [(15,000 hrs for support staff at a large entity × $44.92/hr) + (6,400 hrs for support staff at a medium entity × $44.92/hr) + (3,440 hrs for support staff at a small entity × $44.92/hr)].

For the 850 entities that we expect would be required to begin reporting a device identifier, we estimate that this would take support staff between 10 and 40 hours per entity (with larger companies requiring more time) at $44.92/hr and 2 hours at $83.70/hr for compliance officers. For all entities, we estimate a subtotal of 21,100 hours [(40 hrs for support staff at a large entity × 282 entities) + (20 hrs for support staff at a medium entity × 244 entities) + (10 hrs for support staff at a small entity × 324 entities) + (2 hrs for compliance officers at every entity regardless of size × 850 entities)] at a cost of $1,013,740 [(11,280 hrs for support staff at large entities × $44.92/hr) + (4,880 for support staff at medium entities × $44.92/hr) + (3,240 for support staff at small entities × $44.92/hr) + (1,700 hrs for compliance officers across all entities regardless of size × $83.70/hr)].

We also assume that the remaining 750 entities not planning to submit a device identifier would have a small amount of burden associated with updating their submission processes. We estimate that this would take support staff between 2 and 10 hours per entity (with larger entities requiring more time) at $44.92/hr and 2 hours for compliance officers at $83.70/hr. For all entities, we estimate a subtotal of 5,637 hours [(10 hrs for support staff at a large entity × 249 entities) + (5 hrs for support staff at a medium entity × 215 entities) + (2 hrs for support staff at a small entity × 286 entities) + (750 hrs for compliance officers at all entities regardless of size × 2 hrs)] at a cost of $311,384 [(2,490 hrs for support staff at large entities × $44.92/hr) + (1,075 hrs for support staff at medium entities × $44.92/hr) + (572 hrs for support staff at small entities × $44.92/hr) + (1,500 hrs for compliance officers at all entities regardless of size × $83.70/hr)].

In aggregate, we estimate a one-time burden of 51,577 hours (24,840 hrs + 21,100 hrs + 5,637 hrs) at a cost of $2,440,937 ($1,115,813 + $1,013,740 + $311,384) to implement. After these adjustments are made, we do not anticipate there being any ongoing added burden beyond what is currently approved under the aforementioned control number.

TABLE 62—BURDEN FOR CHANGES TO STANDARDIZE DATA ON REPORTED COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES

Description	Hours	Cost
First year data collection burden for entities that do not currently collect a device identifier	24,840	$1,115,813
First year submission burden for all entities that would be required to report a device identifier	21,100	1,013,740
One time submission process and system updates for entities not reporting a device identifier	5,637	311,384
Total	51,577	2,440,937

6. ICRs Regarding Medicare Enrollment of Opioid Treatment Programs

Except as noted otherwise, the following proposed changes will be submitted to OMB for approval under control number 0938–0685 (CMS–855B; ''Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers'').

As discussed previously in this rule, we propose that OTP providers be required to enroll in Medicare via the paper or internet-based version of the Form CMS–855B (or its successor application) and any applicable supplement, pay the application fee, submit fingerprints, and complete a provider agreement.

Based on SAMHSA statistics and our internal data, we generally estimate that: (1) There are about 1,700 certified and accredited OTPs eligible for Medicare enrollment; and (2) 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year), bringing the total amount of OTPs eligible to enroll to approximately 1,900 over the next 3 years.

Form Completion: We estimate that it would take each OTP an average of 3 hours to obtain and furnish the information on the Form CMS–855B and a new supplement thereto designed to capture information unique to OTPs. Per our experience, we believe that the OTP's medical secretary would be responsible for securing and reporting data on the Form CMS–855B and new accompanying OTP supplement. We estimate that this task would take approximately 2.5 hours; of this amount, roughly 30 minutes would involve completion of the data on the supplement, though this timeframe could be higher or lower depending upon the number of individuals whom the OTP must list. Additionally, the form would be reviewed and signed by a health diagnosing and treating practitioner of the OTP, a process we estimate would take 0.5 hours. We thus project a first-year burden of 5,301 hours (1,767 entities × 3 hr) at a cost of $732,439 (5,301 hr × ((2.5 hr × $35.66/

hr) + (0.5 hr × $98.04/hr)), a second-year burden of 201 hours (67 entities × 3 hr) at a cost of $27,772 (201 hr × ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)), and a third-year burden of 198 hours (66 entities × 3 hr) at a cost of $27,358 (198 hr x((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)). In aggregate, we estimate a burden of 5,700 hours (5,301 hr + 201 hr + 198 hr) at a cost of $787,569 ($732,439 + $27,772 + $27,358). When annualized over the 3-year period, we estimate an annual burden of 1,900 hours (5,700 hours/3) at a cost of $262,523 ($787,569/3).

A copy of the draft OTP supplement will be available on-line, and we welcome public comment on: (1) Its contents; (2) the usefulness of the data to be captured thereon; and (3) the anticipated burden of completion.

Fingerprinting: As we are proposing that OTPs be subject to high categorical risk level screening under § 424.518, we would require the submission of a set of fingerprints for a national background check (via FBI Applicant Fingerprint Card FD–258) from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the OTP. The burden is currently approved by OMB under control number 1110–0046. An analysis of the impact of this proposed requirement can be found in the RIA section of this rule.

Application Fee: As already discussed in this rule, each OTP would be required to pay an application fee at the time of enrollment. The application fee does not meet the definition of a ''collection of information'' and, as such, is not subject to the requirements of the PRA. Although we are not setting out such burden under this section of the preamble, the cost is scored under the RIA section.

Provider Agreement: As mentioned in the preamble of this proposed rule, OTPs would have to complete a provider agreement in order to enroll in Medicare. The burden for reporting and completing the Provider Agreement—CMS Form 1561 and 1561A (OMB control number 0938–0832) are based on SAMHSA statistics. We generally estimate that there are about 1,700 already certified and accredited OTPs eligible for Medicare enrollment initially; and approximately 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year). We anticipate would take the OPT 5 minutes at $192.44/hr for a Chief Executive to review and sign the CMS 1561 or CMS 1561A, and an additional 5 minutes at $35.66/hr for a Medical Secretary to file the document when fully executed.

In aggregate, we estimate a burden of 317 hours ([1,767 OPTs for year 1 + 67 OTPs for year 2 + 67 OTPs for year 3] × 10 min/60) at a cost of $36,154 ([317 hr/2 respondents × $192.44/hr] + [317 hr/2 respondents × $35.66/hr]). This results, roughly, in a Year 1 burden of 295 hours at $33,623, a Year 2 burden of 11 hours at $1,272, and a Year 3 burden of 11 hours at a cost of $1,254. Annually, over the course of OMB's typical 3-year approval period, we estimate a burden of 106 hours 317 hr/3 years) at a cost of $12,051 ($36,154/3 years).

Total: Table 63 summarizes our foregoing burden estimates.

TABLE 63—COMBINED BURDEN RELATED TO ENROLLMENT OF OTPS

[Completion of CMS–855B and provider agreement]

	Year 1	Year 2	Year 3	Total	Annualized average over 3-year period
Time (Hours)	5,596	212	209	6,017	2,006
Cost ($)	766,062	29,044	28,612	823,718	274,572

7. The Quality Payment Program (Part 414 and Section III.K. of This Proposed Rule)

a. Background

(1) Information Collection Requirements Associated With MIPS and Advanced APMs

The Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs.

The ICRs reflect this proposed rule's policies, as well as policies in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), and the CY 2019 PFS final rule (83 FR 59452).

(2) Summary of Quality Payment Program Changes: MIPS

As discussed in more detail in section IV.B.7, the MIPS ICRs consist of: Registration for virtual groups; qualified registry self-nomination applications; and QCDR self-nomination applications; CAHPS survey vendor applications; Quality Payment Program Identity Management Application Process; quality performance category data submission by Medicare Part B claims collection type, QCDR and MIPS CQM collection type, eCQM collection type, and CMS web interface submission type; CAHPS for MIPS survey beneficiary participation; group registration for CMS web interface; group registration for CAHPS for MIPS survey; call for quality measures; reweighting applications for Promoting Interoperability and other performance categories; Promoting Interoperability performance category data submission; call for Promoting Interoperability measures; improvement activities performance category data submission; nomination of improvement activities; and opt-out of Physician Compare for voluntary participants.

Two MIPS ICRs show an increase in burden due to proposed changes in policies: QCDR self-nomination applications and Call for Quality Measures. For the QCDR self-nomination applications ICR, we have increased our estimate of the time required to submit a QCDR measure by 1.5 hour due to the proposal to require QCDRs to identify a linkage between their QCDR measures to related cost measures, Improvement Activities, and MIPS Value Pathways starting with the 2021 self-nomination period (+1 hour); and the proposal to require QCDR measure stewards to submit measure testing data as part of the self-nomination process for each QCDR measure (+0.5 hours). For this same ICR, we have increased our estimate of the time required for a QCDR to submit their self-nomination by 0.25 due to the proposal to require QCDRs to include a description of the quality improvement services they intend to support. For the Call for Quality Measures, we have increased our estimate of the time required to nominate a quality measure for consideration by 1 hour due to the proposal to require that MIPS quality measure stewards link their MIPS quality measures to existing and related cost measures and improvement

activities and provide rationale for the linkage. The remaining changes to currently approved burden estimates are adjustments to reflect better understanding of the impacts of policies finalized in previous rules, as well as the use of updated data sources available at the time of publication of this proposed rule. We are not proposing any changes to the following ICRs: Registration for virtual groups, CAHPS survey vendor applications, Quality Payment Program Identity Management Application Process, CAHPS for MIPS survey beneficiary participation, and group registration for CAHPS for MIPS survey. See section IV.B.7.(n) of this proposed rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The revised requirements and burden estimates for all Quality Payment Program ICRs (except for CAHPS for MIPS and virtual groups election) will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). The CAHPS for MIPS Survey is approved under OMB control number 0938–1222 (CMS–10450). The Virtual Groups Election is approved under OMB control number 0938–1343 (CMS–10652).

Respondent estimates for the quality, Promoting Interoperability, and improvement activities performance categories are modeled using data from the 2017 MIPS performance period with the sole exception of 104 CMS Web Interface respondents, which is based on the number of groups who submitted data for the quality performance category via the CMS Web Interface for the 2018 MIPS performance period. Although we are using data from the 2017 MIPS performance period as we did in the CY 2019 PFS final rule, our respondent estimates have been updated to reflect revised assumptions regarding QPs and APM participants. Respondent data from the 2018 MIPS performance period was unavailable in time for publication for this proposed rule as was the number of groups and virtual groups registering to submit quality performance category data using the CMS Web Interface. Assuming updated information is available, we intend to update these estimates in the final rule.

Our participation estimates are reflected in Tables 69, 70, and 71 for the quality performance category, Table 87 for the Promoting Interoperability performance category, and Table 92 for the improvement activities performance category.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted due to two primary reasons. First, we anticipate the number of QPs to increase because of total expected growth in Advanced APM participation as new models that are Advanced APMs for which we do not yet have enrollment data become available for participation. The additional QPs will be excluded from MIPS and likely not report. Second, it is difficult to predict what eligible clinicians who may report voluntarily will do in the 2020 MIPS performance period compared to the 2017 MIPS performance period, and therefore, the actual number of participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data.

(3) Summary of Quality Payment Program Changes: Advanced APMs

As discussed in more detail in sections IV.B.7. of this rule, ICRs for Advanced APMs consist of: Partial Qualifying APM participant (QP) election; Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of data for All-Payer QP determinations under the All-Payer Combination Option.

For these ICRs, the proposed changes to currently approved burden estimates are adjustments based on updated projections for the 2020 MIPS performance period. We are not proposing any changes to our per-respondent burden estimates. We are also not proposing any changes to the Other Payer Advanced APM identification: Eligible Clinician Initiated Process ICR.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 64 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 64, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 64.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. For the 2020 MIPS performance period, the quality data submitted by MIPS APM participants reporting through the CMS Web Interface on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category. For other MIPS APMs, the quality data submitted by APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category if that data is available to be scored. However, as proposed in section III.K.3.c.(5)(c)(i)(A) of this rule, beginning in the 2020 MIPS performance period, MIPS eligible clinicians participating in MIPS APMs whose APM quality data is not available for MIPS may elect to report MIPS quality measures at either the APM entity, individual, or TIN-level in a manner similar to our established policy for the Promoting Interoperability performance category under the APM scoring standard for purposes of the MIPS quality performance category. If we determine there are not sufficient measures applicable and available, we will assign performance category weights as specified in § 414.1370(h)(5).

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum

improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844), but other than the election to participate in MIPS, we do not have data to estimate that burden.

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TABLE 64: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**Promoting Interoperability Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
MIPS Eligible Clinicians (not in MIPS APMs) and Other Eligible Clinicians Voluntarily Submitting MIPS Data [a]	As virtual group, group, or individual clinicians	As virtual group, group, or individual clinicians. Clinicians who are hospital-based, ambulatory surgical center-based, non-patient facing, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting.	As virtual group, group, or individual clinicians	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email.
MIPS Eligible Clinicians Participating in MIPS APMs that report via Web Interface	ACOs submit to the CMS Web Interface and CAHPS for ACOs on behalf of their participating MIPS eligible clinicians. If the ACO does not submit quality	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [Burden estimates for	CMS will assign the improvement activities performance category score to each APM Entity group based on the activities involved in participation in the MIPS APM.[d]	APM Entities will make Partial QP election for participating MIPS eligible clinicians.

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**Promoting Interoperability Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
	data, MIPS eligible clinicians participating in MIPS APMs may elect to report individually or at the TIN-level.[e] [Submissions by the ACO are not included in burden estimates for this proposed rule because quality data submission to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO Model are not subject to the PRA].[b]	this proposed rule assume group TIN-level reporting].[c]	[The burden estimates for this proposed rule assume no improvement activity reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity performance category score.]	
MIPS Eligible Clinicians Participating in Other MIPS APMs	APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians; however if the quality data is not available to MIPS in time for scoring, MIPS eligible clinicians participating in MIPS APMs may elect to report individually or at the TIN-level.[e] [Submissions made by APM Entities to MIPS on behalf of their participating MIPS eligible clinicians are not	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this proposed rule assume group TIN-level reporting].	CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates for this proposed rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement	APM Entities will make Partial QP election for participating eligible clinicians.

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
	included in burden estimates for this proposed rule because quality data submission for purposes of testing and evaluating Innovation Center models tested under Section 1115A of the Social Security Act (or Section 3021 of the Affordable Care Act) are not subject to the PRA.]		activity score.]	

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

a Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

b Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

c Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

d APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent.(42 CFR 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

e Both group TIN and individual clinician quality data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. We would then use the highest individual or TIN-level score attributable to each MIPS eligible clinician in an APM Entity in order to determine the APM Entity score based on the average of the highest scores for each MIPS eligible clinician in the APM Entity.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 PFS final rule and continued in this proposed rule create some additional data collection requirements not listed in Table 64. These additional data collections, some of which were previously approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional Approved ICRs Related to MIPS Third-Party Intermediaries

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).

Additional ICRs Related to the Data Submission and the Quality Performance Category

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs Related to the Promoting Interoperability Performance Category

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs Related To Call for New MIPS Measures and Activities

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for new quality measures (83 FR 60010 through 60011) (OMB 0938–1314).

Additional ICRs Related to MIPS

- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs Related to APMs

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule does not propose any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not making any virtual group election changes under that control number.

c. ICRs Regarding Third-Party Intermediaries (§ 414.1400)

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as one quality performance category measure, or can be used for completion of an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nominate process annually. The processes for self-nomination for entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to submit QCDR measures for the quality performance category. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

The burden associated with qualified registry self-nomination, QCDR self-nomination and measure submission, and the CAHPS for MIPS survey vendor applications follow: [139]

(2) Qualified Registry Self-Nomination Applications

The proposed requirements and burden associated with qualified registries and their self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As explained below, this rule would both adjust the number of self-nomination applications based on current data and revise the number of self-nomination applications due to policies promulgated in the CY 2019 final rule regarding the definition of a QCDR (83 FR 59895) and minimum participation requirements (83 FR 59897) which are effective beginning in the 2020 MIPS performance period. The adjustment would increase our total burden estimates while keeping our burden per response estimates unchanged. We are not proposing changes to the self-nomination process.

We refer readers to § 414.1400(a)(2) and (c)(1) which state that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so.

In the CY 2018 Quality Payment Program final rule and as stated in § 414.1400(c)(1), previously approved qualified registries in good standing (that is, that are not on probation or disqualified) may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period (82 FR 53815). In the same rule, we stated that qualified registries in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved qualified registry application for CMS review during the self-nomination period (82 FR 53815). The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period beginning with the 2020 MIPS performance period (83 FR 59906).

For this proposed rule, we have adjusted the number of self-nominating applicants from 150 to 290 based on more recent data and the assumption that any entity which self-nominated for approval as a QCDR in previous years and that no longer qualifies as a result of policies finalized in the CY 2019 PFS final rule, effective beginning with the 2020 MIPS performance period could elect to self-nominate for approval as a qualified registry. The policies revised both the definition of a QCDR (83 FR 59895) and minimum participation requirements for entities seeking approval as a QCDR (83 FR 59897). Entities which no longer meet the criteria for approval as QCDRs may seek other options such as collaborating with another entity to meet the new requirements or to end their participation in the Quality Payment Program, however, we believe the assumption that these entities will instead elect to self-nominate as a qualified registry is both appropriate and conservative. We were unable to change our estimates in the CY 2019 PFS final rule to reflect these policies because we had neither the data to support a change nor any notifications of intent by previously approved QCDRs indicating they would no longer self-nominate as a QCDR (83 FR 59999). As a result, we are making the necessary adjustments to our respondents' estimates in this proposed rule.

For the 2019 MIPS performance period, we received 198 applications for nomination to be a qualified registry, 135 of which were approved to submit data, a reduction of 6 from the currently approved estimate of 141 (83 FR 59997 through 59998). Based on the number of self-nominations received for the 2019 MIPS performance period, we estimate 200 entities will self-nominate as a qualified registry for the 2020 MIPS performance period, not considering

[139] As stated in the CY 2019 PFS final rule (83 FR 53998), health IT vendors are not included in the burden estimates for MIPS.

nominations from entities which previously qualified as QCDRs. Based on our analysis of the QCDRs approved for the CY 2019 performance period, 63 of the 127 approved QCDRs (49.6 percent) would not meet the criteria for approval for the CY 2020 performance period. For the 2019 MIPS performance period, 181 entities self-nominated for approval as QCDRs, therefore we assume that 90 (49.6 percent) of these entities will self-nominate for approval as qualified registries for the 2020 MIPS performance period. In total, we estimate 290 nomination applications (200 entities + 90 entities) will be received from entities seeking approval to report MIPS data as qualified registries, an increase of 140 from the currently approved estimate of 150 (83 FR 59997 through 59998). As previously stated, this increase is comprised of both an adjustment to due updated data (+50 self-nominations) and a revision due to policies promulgated in the CY 2019 PFS final rule (+90 self-nominations). Assuming updated data is available, we will update our estimates in the final rule to reflect the actual number of nomination applications received for the 2020 MIPS performance period.

The burden associated with the qualified registry self-nomination process varies depending on the number of existing qualified registries that elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53815). The QPP Self-Nomination Form is submitted electronically using a web-based tool. We will be submitting a revised version of the form for approval under OMB control number 0938–1314 (CMS–10621).

As described in the CY 2017 Quality Payment Program final rule, the full self-nomination process requires the submission of basic information, a description of the process the qualified registry will use for completion of a randomized audit of a subset of data prior to submission, and the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). As shown in Table 66, we estimate that the staff involved in the qualified registry self-nomination process will be mainly computer systems analysts or their equivalent, who have an adjusted labor rate of $90.02/hr. Consistent with the CY 2019 PFS final rule (83 FR 59998), we estimate that the time associated with the self-nomination process ranges from a minimum of 0.5 hours (for the simplified self-nomination process) to 3 hours (for the full self-nomination process) per qualified registry. When considering this rule's adjusted number of nomination applications (290) we estimate that the annual burden will range from 532.5 hours ([135 simplified self-nominations × 0.5 hr] + [155 full self-nominations × 3 hr]) to 870 hours (290 qualified registries × 3 hr) at a cost ranging from $47,936 (532.5 hr × $90.02/hr) to $78,317 (870 hr × $90.02/hr), respectively (*see* Table 66).

As shown in Table 65, compared to the currently approved minimum estimates of 97.5 hours and $8,777 and the maximum estimates of 450 hours and $40,509, the increase in the number of respondents would adjust our total burden estimates by 435 hours and $39,159 [(−6 registries × 0.5 hr × $90.02/hr) + (146 registries × 3 hr × $90.02/hr)] and 420 hours and $37,808 (140 registries × 3 hr × $90.02/hr). While we are proposing to adjust our total burden estimates based on more current data, the burden per response would remain unchanged.

TABLE 65—CHANGE IN ESTIMATED BURDEN FOR QUALIFIED REGISTRY SELF-NOMINATION

	Minimum burden	Maximum burden
Total Annual Hours for Qualified Registries in CY 2019 Final Rule (a)	97.5	450
Total Annual Hours for Qualified Registries in CY 2020 Proposed Rule (b)	532.5	870
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	435	870
Total Annual Cost for Qualified Registries in CY 2019 Final Rule (d)	$8,777	$40,509
Total Annual Cost for Qualified Registries in CY 2020 Proposed Rule (e)	$47,936	$78,317
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$39,159	$37,808

As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at (83 FR 60088) and in § 414.1400(a)(2), qualified registries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. In section III.K.3.g.(4)(a)(i) of this rule, beginning with the 2021 performance period and for future years, we propose to require that qualified registries support the reporting of improvement activities and Promoting Interoperability measures in addition to the quality performance category. As finalized in the CY 2017 Quality Payment Program final rule, qualified registries are required to provide feedback on all of the MIPS performance categories at least 4 times a year (81 FR 77367 through 77386). In section III.K.3.g.(4)(a)(ii), we propose, beginning with the 2023 MIPS payment period, to require qualified registries to provide the following as a part of the performance feedback given at least 4 times (to the extent feasible) a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registry. Further, qualified registries will be required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year, and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Because we are not requiring qualified registries to provide performance feedback to their clinicians and groups at a greater frequency than what has previously been required combined with qualified registries only being required to provide feedback using data they are already collecting, we do not believe the proposal creates enough additional burden for qualified registries to elect to discontinue participation in the Quality Payment Program. Therefore, we are not adjusting our estimates for the number of qualified registries that will self-nominate in the 2021 performance

period or future years as a result of this proposal; if reliable information becomes available indicating this assumption is incorrect, we will adjust our assumptions and respondent estimates at that time. As part of the current self-nomination process, qualified registries are already required to attest to the MIPS quality measures, performance categories, improvement activities, and/or Promoting Interoperability measures and objectives supported. In section III.K.3.g.(4)(a)(i) of this proposed rule, beginning with the 2021 performance period, we are proposing to require qualified registries to support all three performance categories: Quality, improvement activities, and Promoting Interoperability with the proviso that based on the proposed amendment to § 414.1400(a)(2)(iii) the requirement to support submission of Promoting Interoperability data would be inapplicable to the third party intermediary if the clinician, group or virtual group is exempt from this reporting requirement. As part of this proposal, we would require qualified registries to attest to the ability to submit data for all three of these performance categories at time of self-nomination. Because qualified registries will only be required to provide performance feedback to clinicians and not to CMS, and because qualified registries are already required to attest to the performance categories they support, we anticipate minimal changes to the self-nomination process as a result of these proposals and assume there will be minimal impact on the time required to complete either the simplified or full self-nomination process.

Qualified registries must comply with requirements on the submission of MIPS data to CMS. The burden associated with qualified registry submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. We expect that the time needed for a qualified registry to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry and the number of applicable measures. However, we believe that qualified registries already perform many of these activities for their participants. Therefore, we believe the estimates discussed earlier and shown in Table 66 represents the upper bound for qualified registry burden, with the potential for less additional MIPS burden if the qualified registry already provides similar data submission services.

Based on these assumptions, we estimate the total annual burden associated with a qualified registry self-nominating to be considered for approval.

TABLE 66—ESTIMATED BURDEN FOR QUALIFIED REGISTRY SELF-NOMINATION

	Minimum burden	Maximum burden
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	135	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	155	290
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours for Qualified Registries (e) = (a) * (c) + (b) * (d)	532.5	870
Cost Per Simplified Process Per Registry (@computer systems analyst's labor rate of $90.02/hr.) (f)	$45.01	$45.01
Cost Per Full Process Per Registry (@computer systems analyst's labor rate of $90.02/hr.) (g)	$270.06	$270.06
Total Annual Cost for Qualified Registries (h) = (a) * (f) + (b) * (g)	$47,936	$78,317

Both the minimum and maximum burdens shown in Table 66 reflect adjustments to the number of respondents (from 150 to 290) due to availability of more recent data (+50 respondents) and revisions due to policies finalized in the CY 2019 PFS final rule regarding the definition and minimum participation requirements for entities seeking approval as QCDRs which will be effective beginning with the 2020 MIPS performance period (+90 respondents). For purposes of calculating total burden associated with this proposed rule as shown in Table 90, only the maximum burden is being submitted to OMB for their review and approval.

(3) QCDR Self-Nomination Applications

(a) Self-Nomination Process

The proposed requirements and burden associated with QCDRs and the self-nomination process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As explained below, this rule would both adjust the number of self-nomination applications based on current data and revise the number of self-nomination applications due to policies promulgated in the CY 2019 final rule regarding the definition of a QCDR (83 FR 59895) and minimum participation requirements (83 FR 59897) which are effective beginning in the 2020 MIPS performance period. These changes result in a decrease from 200 to 91 self-nomination applications in the 2020 MIPS performance period. This rule would also adjust the number of QCDR measures submitted for consideration by each QCDR seeking to self-nominate (from 9 to 11.5), as well as the time required to submit information (from 1 hour to 2.5 hours) for each QCDR measure. These changes would increase our minimum total burden estimate (from 2,025 hours to 2,729.25 hours) and increase our maximum total burden estimate (from 2,400 hours to 2,889.25 hours). In addition, our per response estimates for the simplified and full self-nomination processes would increase from 9.5 hours to 29.25 hours and from 12 hours to 31.75 hours, respectively.

We refer readers to § 414.1400(a)(2) and (b)(1) which states that QCDRs interested in submitting MIPS data to us on behalf of a MIPS eligible clinician, group, or virtual group will need to complete a self-nomination process to be considered for approval to do so.

In the CY 2018 Quality Payment Program final rule and § 414.1400(b)(1), previously approved QCDRs in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously

approved form is still accurate and applicable (82 FR 53808). Existing QCDRs in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved QCDR application, for CMS review during the current self-nomination period, from September 1 to November 1 (82 FR 53808). The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period beginning in the 2020 MIPS performance period (83 FR 59898).

The burden associated with QCDR self-nomination will vary depending on the number of existing QCDRs that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813). The OPP Self-Nomination Form is submitted electronically using a web-based tool. We will be submitting a revised version of the form for approval under OMB control number 0938–1314 (CMS–10621).

For the 2019 MIPS performance period, we received 181 self-nomination applications from entities seeking approval as QCDRs, 127 of which were approved to submit data. Based on our analysis of the QCDRs approved for the CY 2019 performance period, 63 of the 127 approved QCDRs (49.6 percent) would not meet the criteria for approval for the CY 2020 performance period. We project that 90 (49.6 percent) of the 181 entities will not self-nominate for approval as QCDRs for the 2020 MIPS performance period but will instead self-nominate to be qualified registries. Entities which no longer meet criteria for approval as QCDRs may seek other options as well, including collaborating with another entity to meet the new requirements or to end their participation in the Quality Payment Program; however, we believe the assumption that these entities will instead elect self-nomination as a qualified registry is both appropriate and conservative. We also project the remaining 91 entities will submit nomination applications for approval to report MIPS data as QCDRs for the MIPS 2020 performance period, a decrease of 109 from the currently approved estimate of 200. This decrease of 109 is a result of both an adjustment due to use of more recent data accounts (decrease of 19 self-nominations) and a change due to previously finalized policies regarding the definition of a QCDR (83 FR 59895) and minimum participation requirements (83 FR 59897) (decrease of 90 self-nominations). We were unable to change our estimates in the CY 2019 PFS final rule to reflect these policies because we had neither the data to support a change nor any notifications of intent by previously approved QCDRs indicating they would no longer self-nominate as a QCDR (83 FR 59999). As a result, we are making the necessary adjustments to our respondent estimates in this proposed rule. We further estimate that the 64 QCDRs approved to submit data in the 2019 MIPS performance period that would also qualify as QCDRs for the 2020 MIPS performance period will use the simplified self-nomination process. Assuming updated data is available, we will update our estimates in the final rule to reflect the actual number of nomination applications received for the 2020 MIPS performance period.

Based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that all third party intermediaries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. In section III.K.3.g.(3)(a)(i) of this rule, we are proposing, beginning with the 2021 performance period and future years, to require that QCDRs support three performance categories: Quality, improvement activities, and Promoting Interoperability. We are also proposing in section III.K.3.g.(3)(a)(ii), beginning with the 2023 MIPS payment year and future years, QCDRs would be required to provide services to clinicians and groups to foster improvement in the quality of care provided to patients, by providing educational services in quality improvement and leading quality improvement initiatives and to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. As finalized in the CY 2018 Quality Payment Program final rule, QCDRs are required to provide feedback on all of the MIPS performance categories that the QCDR reports at least 4 times a year (82 FR 53812). In section III.K.3.g.(3)(a)(iii) we propose, beginning with the 2023 MIPS payment year, to require that QCDRs provide the following as a part of the performance feedback given at least 4 times a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure and/or QCDR measure) within the QCDR. We also understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. Further, we are also proposing, beginning with the 2023 MIPS payment year, to require QCDRs to attest during the self-nomination process that they can provide performance feedback at least 4 times a year, and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. We do not believe these proposals create enough additional burden for QCDRs to elect to discontinue participation in the Quality Payment Program for multiple reasons: We are not requiring QCDRs to provide performance feedback to their clinicians and groups at a greater frequency than what has previously been required, QCDRs will only being required to provide feedback using data they are already collecting, and we are giving QCDRs significant flexibility to provide broad quality improvement services that are tailorable to the specific QCDR and the clinicians they support. Therefore, we are not adjusting our estimates for the number of QCDRs that will self-nominate in the 2021 performance period or future years as a result of this proposal; if reliable information becomes available indicating this assumption is incorrect, we will adjust our assumptions and respondent estimates at that time. As part of the self-nomination process, QCDRs are already required to attest to the MIPS quality measures, performance categories, improvement activities, and Promoting Interoperability measures and objectives supported and will not be required to provide performance feedback to CMS. Therefore, we anticipate no additional steps being added to the self-nomination process as a result of these proposals and assume there will be no impact on the time required to complete either the simplified or full self-nomination process. With regard to the proposal to require QCDRs to describe the quality improvement services they will provide as part of their self-nomination, we estimate this will require approximately 15 minutes to complete.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3.25 hours per QCDR to submit information

required at the time of self-nomination as described in the CY 2017 Quality Payment Program final rule including basic information about the QCDR, describing the process it will use for completion of a randomized audit of a subset of data prior to submission, providing a data validation plan, and providing results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). However, for the simplified self-nomination process, we estimate 0.5 hours per QCDR to submit this information.

(b) QCDR Measure Requirements

As promulgated in the CY 2017 and CY 2018 Quality Payment Plan final rules (81 FR 77366 through 77374 and 82 FR 53812 through 53813), QCDRs calculate their measure results and also must possess benchmarking capabilities (for QCDR measures) that compare the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For QCDR measures, the QCDR must provide to us, if available, data from years prior (for example, 2017 data for the 2019 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their website prior to the start of the performance period, to the extent permitted by applicable privacy laws. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a QCDR will spend an additional 1 hour performing these activities per measure.

As discussed in section III.K.3.g.(3)(c)(i)(B)(cc), we are proposing that in order for a QCDR measure to be considered for use in the program beginning with the 2021 performance period and future years, all QCDR measures submitted for self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. Beginning with the 2021 performance period and future years, we are proposing in section III.K.3.g.(3)(c)(i)(B)(dd) to also require QCDRs to collect data on the potential QCDR measure, appropriate to the measure type, as defined in the CMS Blueprint for the CMS Measures Management System, prior to self-nomination. We estimate the time necessary to submit measure testing data as part of the self-nomination process will average approximately 0.5 hours per measure, understanding that this estimate may be either high or low depending on the type of measure and the quantity of data being submitted. We discuss additional impacts of this proposal in section VI.C.10.(f) of this rule's Regulatory Impact Analysis.

In section III.K.3.g.(3)(c)(i)(A)(bb) of this rule, we are proposing to amend § 414.1400 to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. Because the choice to license a QCDR measure is an elective business decision made by individual QCDRs and we lack insight into both the specific terms and frequency of agreements made between entities, we are not accounting for QCDR measure licensing costs as part of our burden estimate. However, if information regarding the number of licensing agreements and the approximate cost per agreement becomes available, we may adjust our assumptions and burden estimates at that time.

In section III.K.3.g.(3)(c)(i)(B)(cc) of this rule, we propose, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. We are unable to account for measure harmonization costs as part of our burden estimate, as the process and outcomes of measure harmonization will likely vary substantially depending on a number of factors, including: Extent of duplication with other measures, number of QCDRs involved in harmonizing toward a single measure, and number of measures being harmonized among the same QCDRs. We intend to identify only those QCDR measures which are duplicative to such an extent as to assume harmonization will not be overly burdensome, however, because the harmonization process will occur between QCDRs without our involvement, we are unable to predict or quantify the associated effort.

As discussed in section III.K.3.g.(3)(c)(i)(B)(bb) of this proposed rule, beginning with the 2021 performance period and future years, we are proposing that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measures (as found in section III.K.3.c.(2) of this proposed rule); (b) Improvement Activities (as found in Appendix 2: Improvement Activities Tables); or (c) CMS developed MIPS Value Pathways (as described in section III.K.3.a. of this proposed rule). We estimate that a QCDR will spend an additional 1 hour performing these activities per measure, on average.

We are also proposing to formalize factors we would take into consideration for approving and rejecting QCDR measures for the MIPS program beginning with the 2020 performance period and future years. With regard to approving QCDR measures, we are proposing the following: (a) 2-year QCDR measure approval process, and (b) participation plan for existing QCDR measures that have failed to reach benchmarking thresholds. As discussed in section III.K.3.g.(3)(c)(ii)(B) of this rule, we are proposing to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described in section III.K.3.g.(3)(c). The 2-year approvals would be subject to the following conditions whereby the multi-year approval will no longer apply if the QCDR measure is identified as: Topped out; duplicative of a new, more robust measure; reflects an outdated clinical guideline; requires measure harmonization, or if the QCDR self-nominating the measure is no longer in good standing. We believe this could result in reduced burden for QCDRs as they would not necessarily be required to submit every measure for approval annually. However, because we are

unable to predict which previously approved QCDR measures will be removed or retained in future years, we are likewise unable to predict the total number of measures that will be submitted for approval and the resulting impact on future burden. If this policy is finalized, the number of QCDR measures submitted in the 2021 performance period will reflect the impact of this policy; at that time we will update our assumptions and burden estimates accordingly.

We estimate that on average, each QCDR will submit information for 11.5 QCDR measures, for a total burden of 11.5 hours per QCDR (1 hr per measure × 11.5 measures). The estimated average of 11.5 measures per QCDR is based on an analysis of the QCDR measures submitted for consideration and QCDR measures approved for the 2019 MIPS performance period, as well as the measures for QCDRs approved for the CY 2019 performance period that would not meet criteria for approval for the CY 2020 performance period. For the 2019 MIPS performance period, 1,123 QCDR measures were submitted for consideration and 762 were approved; an approval rate of 68 percent. Of these approved measures, 264 are for the 63 QCDRs which would not meet criteria for approval for the 2020 MIPS performance period. Averaging the remaining 498 approved QCDR measures by the 64 QCDRs that would meet the criteria for approval for the 2020 MIPS performance period results in approximately 7.8 approved measures per QCDR (498 approved measures / 64 QCDRs). Assuming an identical 68 percent QCDR measure approval rate for measures submitted for consideration for the 2020 MIPS performance period, this results in approximately 11.5 measures submitted for consideration for each QCDR (7.8 approved measures / 0.68 approval rate). We believe the proposals to change requirements for QCDR measure submission and to require QCDRs to harmonize measures we identify as duplicative discussed earlier in this section will result in a reduction in the number of QCDR measures submitted for approval in future years. However, we are unable to quantify the impact these proposed changes will have on the number of measures QCDRs will submit for approval. As information becomes available in future years, we will revisit our assumptions to better reflect the impact of these proposals on QCDRs and the quantity of measures being submitted for consideration annually. When combined with our previously stated assumption regarding our inability to predict which QCDR measures will maintain approval in future years, we believe the estimate of 11.5 measures per QCDR to be both conservative and appropriate, as well as an overall decrease of 76 QCDR measures compared to the 1,123 QCDR measures submitted for consideration in the CY2019 performance period (1,123 QCDR measures − [91 QCDRs × 11.5 measures per QCDR]).

Beginning with the 2021 performance period, we are proposing in section III.K.3.g.(3)(c)(iii) of this proposed rule that in instances where an existing QCDR measure has been in MIPS for 2 years, and has failed to reach benchmarking thresholds due to low adoption, where a QCDR believes the low-reported QCDR measure is still important and relevant to a specialist's practice, that the QCDR may develop and submit to a QCDR measure participation plan, to be submitted as part of their self-nomination. Because we are unable to predict the frequency with which existing QCDR measures will meet the proposed criteria for allowing QCDRs to submit a measure participation plan or the likelihood of QCDRs electing to submit a plan, we are unable to estimate the total burden associated with this proposal. However, we anticipate the time involved in developing a measure participation plan is likely to average between 1 and 2 hours, depending on the QCDR and the level of detail they choose to include. In future performance periods we may reassess availability of the number of QCDR measure participation plans submitted by QCDRs and estimate the associated burden, if possible. In aggregate, we estimate a QCDR will require 2.5 hours per QCDR measure, an increase of 1.5 hours from the currently approved estimate of 1 hour (83 FR 59999). As discussed earlier in this section, we estimate each QCDR will submit 11.5 QCDR measures for approval, on average. Therefore, we estimate each QCDR will require 28.75 hours (11.5 measures × 2.5 hr per measure) to submit QCDR measures for approval, independent of the selection of the simplified or full self-nomination process.

In the CY 2019 PFS final rule, the burden associated with self-nomination of a QCDR was estimated to range from a minimum of 9.5 hours (0.5 hours to submit information for simplified self-nomination process and 9 hours for submission of QCDR measures) to a maximum of 12 hours (3 hours for the full self-nomination process and 9 hours for the submission of QCDR measures) (83 FR 59999). For this rule, we propose to increase the burden associated with self-nomination to a minimum of 29.25 hours (0.5 hours to submit information for the simplified self-nomination process and 28.75 hours for the submission of QCDR measures) to a maximum of 32 hours (3.25 hours to submit information for the full self-nomination process and 28.75 hours for the submission of QCDR measures) to account for our revised estimate of the average number of QCDR measures submitted for consideration per QCDR, as well as the revised estimate of burden per QCDR measure.

We assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $90.02/hr. Considering that the time per QCDR associated with the self-nomination process ranges from a minimum of 29.25 hours to a maximum of 32 hours, we estimate that the annual burden will range from 2,736 hours ([64 QCDRs × 29.25 hr] + [27 QCDRs × 32 hr]) to 2,912 hours (91 QCDRs × 32 hr) at a cost ranging from $246,295 (2,736 hr × $90.02/hr) and $262,138 (2,912 hr × $90.02/hr), respectively (*see* Table 67).

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 67—ESTIMATED BURDEN FOR QCDR SELF-NOMINATION AND QCDR MEASURE SUBMISSION

	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	64	0
# of QCDR Full Self-Nomination Applications submitted (b)	27	91
Total Annual Hours Per QCDR for Simplified Process (c)	29.25	29.25
Total Annual Hours Per QCDR for Full Process (d)	32.00	32.00

TABLE 67—ESTIMATED BURDEN FOR QCDR SELF-NOMINATION AND QCDR MEASURE SUBMISSION—Continued

	Minimum	Maximum
Total Annual Hours for QCDRs (e) = (a) *(c) + (b) * (d)	2,736	2,912
Cost Per Simplified Process Per QCDR (@computer systems analyst's labor rate of $90.02/hr) (f)	$2,633.09	$2,633.09
Cost Per Full Process Per QCDR (@computer systems analyst's labor rate of $90.02/hr) (g)	$2,880.64	$2,880.64
Total Annual Cost for QCDRs (h) = (a) * (f) + (b) * (g)	$246,295	$262,138

Both the minimum and maximum burden shown in Table 67 reflect adjustments to the number of respondents due to availability of more recent data, as well as changes resulting from policies finalized in the CY 2019 PFS final rule regarding the definition and minimum participation requirements for entities seeking approval as QCDRs which will be effective beginning with the 2020 MIPS performance period. For purposes of calculating total burden associated with the proposed rule as shown in Table 90, only the maximum burden is used.

Independent of the change to our per response time estimate, the decrease in the number of respondents (from 200 to 91) results in an adjustment of between −1,093 hours [(−86 QCDRs × 9.5 hr) + (−23 QCDRs × 12 hr)] at a cost of −$98,392 (−1,093 hr × $90.02) and −1,308 hours (−109 QCDRs × 12 hr) at a cost of −$117,746 (−1,308 hr × $90.02/hr). Accounting for the change in the number of QCDRs, the change in time per QCDR to self-nominate results in an adjustment of 1,820 hours (91 QCDRs × 20 hr) at a cost of $163,836 (1,820 hr × $90.02/hr). As shown in Table 68, when these two adjustments are combined, the net impact ranges between 727 hours (−1,093 hr + 1,820 hr) hours at a cost of $65,444 (−$98,392 + $163,836) and 512 hours (−1,308 hr + 1,820 hr) hours at a cost of $46,090 (−$117,746 + $163,836).

TABLE 68—CHANGE IN ESTIMATED BURDEN FOR QCDR SELF-NOMINATION AND QCDR MEASURE SUBMISSION

	Minimum burden	Maximum burden
Total Annual Hours for QCDRs in CY 2019 Final Rule (a)	2,025	2,400
Total Annual Hours for QCDRs in CY 2020 Proposed Rule (b)	2,736	2,912
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	711	512
Total Annual Cost for QCDRs in CY 2019 Final Rule (d)	$182,291	$216,048
Total Annual Cost for QCDRs in CY 2020 Proposed Rule (e)	$246,295	$262,138
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$64,004	$46,090

QCDRs must comply with requirements on the submission of MIPS data to CMS. The burden associated with the QCDR submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. We expect that the time needed for a QCDR to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the QCDR and the number of applicable measures. However, we believe that QCDRs already perform many of these activities for their participants. As stated in section III.K.3.g.(3)(a)(i), based on our review of existing 2019 QCDRs through the 2019 QCDR Qualified Posting, approximately 92 QCDRs, or about 72 percent of the QCDRs currently participating in the program are supporting these three performance categories. In addition, through our review of previous qualified postings for the 2018 and 2017 MIPS performance periods, we have observed that in 2018, 73 percent (approximately 110 QCDRs) and in 2017, 73 percent (approximately 83 QCDRs) have supported all three of the quality, Promoting Interoperability, and improvement activity performance categories. Given this, we believe it is reasonable that all QCDRs have the capacity to support the improvement activities and Promoting Interoperability performance categories and are not making any further changes to our burden estimates. Therefore, we believe the 2,912-hour estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

(4) CAHPS for MIPS Survey Vendor

This rule does not propose any new or revised collection of information requirements or burden related to CMS-approved CAHPS for MIPS survey vendors. The requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

d. ICRs Regarding Quality Data Submission (§§ 414.1325 and 414.1335)

(1) Background

As explained below, this rule would adjust the number of respondents based on current data. The adjustment would increase our total burden estimates while keeping our ''per response'' estimates unchanged. We are not revising any requirements regarding the number of measures to be submitted or the manner in which they may be submitted.

Under our current policies, two groups of clinicians must submit quality data under MIPS: Those who submit as MIPS eligible clinicians and those who opt to submit data voluntarily but are not be subject to MIPS payment adjustments.

Clinicians are ineligible for MIPS if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

To determine which QPs should be excluded from MIPS, we used the QP List for the 2019 predictive file that contains current participation in Advanced APMs as of January 15, 2019, that could be connected into our respondent data and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2020 QP performance period. We assumed that all partial QPs would participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future 2020 Medicare QP Performance Period (and therefore would no longer need to submit data to MIPS); hence, our model may under estimate or overestimate the number of respondents.

Using participation data from the 2017 MIPS performance period combined with the estimate of QPs for the 2020 performance period, we estimate a total of 833,243 clinicians will submit quality data as individuals or groups in the 2020 MIPS performance period, a decrease of 131,003 clinicians when compared to our estimate of 964,246 clinicians in the CY 2019 PFS final rule (83 FR 60002). As previously stated in section IV.B.7.(a.(2), respondent data from the 2018 MIPS performance period was unavailable at the time of publication of this proposed rule. Assuming that updated respondent data becomes available before the publication of the CMS–1715–F final rule, we will revise our burden estimates in that rule.

In the CY 2017 Quality Payment Program final rule, we assumed that any clinician that submits quality data codes to us for the Medicare Part B claims collection type is intending to do so for the Quality Payment Program to ensure that we fully accounted for any burden that may have resulted from our policies (81 FR 77501 through 77504); we continued using this assumption in both the CY 2018 Quality Payment Program final rule and the CY 2019 PFS final rule. In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). However, we also elected to continue using the assumption that all clinicians (except QPs) who submitted data via the Medicare Part B claims collection type in the 2017 MIPS performance period would continue to do so for MIPS to avoid overstating the impact of the change as we lacked the data to accurately estimate both the number of clinicians who would be impacted by the finalized policies and the potential behavioral response of those clinicians who would be required to switch to another collection type (83 FR 60001). For this proposed rule, beginning with the 2020 MIPS performance period, we assume only clinicians in small practices who submitted quality data via Medicare Part B claims in the 2017 MIPS performance period will continue to do so for the 2020 MIPS performance period. Further, we assume that clinicians in other practices (not small practices) who meet at least one of the following criteria will not need to find an alternate collection type for submitting quality performance category data for the Quality Payment Program for the 2020 MIPS performance period: (1) Facility-based; (2) submitted quality data via Medicare Part B claims and at least one other collection type; or (3) were previously scored as part of a group. Finally, we assume clinicians in other practices (not small practices) who meet all of the following criteria will submit via the MIPS CQM collection type for the 2020 MIPS performance period because the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data: (1) Scored as individuals; (2) not facility-based; and (3) submitted quality data only via the Medicare Part B claims collection type in the 2017 MIPS performance period. Because we do not have data to accurately predict what collection type each affected clinician would use to collect and report quality data, we assume that the affected clinicians will select the MIPS CQM collection type because, when compared to Medicare Part B claims, we believe this is the next most accessible and least burdensome alternative. Our assumptions result in a 121,858 decrease in the estimated number of clinicians who will submit quality data via Medicare Part B claims and a 15,556 increase in the number of clinicians who will submit via the QCDR/MIPS CQM collection type, as shown in Table 69.

We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models. Consistent with assumptions used in the CY 2019 PFS final rule (83 FR 60000 through 60001), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. Therefore, we are not making any adjustments to our respondent estimates as a result of the proposal discussed in section III.K.3.c.(5)(c)(i)(A) of this proposed rule, which allows MIPS eligible clinicians participating in MIPS APMs to elect to report MIPS quality measures at either the individual or TIN-level under the APM scoring standard beginning in the 2020 MIPS performance period. To estimate who will be a MIPS APM participant in the 2020 MIPS performance period, we used the latest 2019 predictive file that contains current participation in MIPS APMs as of January 15, 2019, using all available data. This file was selected to better reflect the expected increase in the number of MIPS APMs in future years compared to previous APM eligibility files. If a MIPS eligible clinician is determined to not be scored as a MIPS APM, then their reporting assumption is based on their reporting for the CY 2017 MIPS performance period. For clinicians who participated in an APM in 2017, were not in an APM in 2019, and did not report MIPS quality data in 2017, we assume they will elect to report to MIPS via the MIPS CQM collection type, similar to our previously stated assumption regarding clinicians who are required to use an alternate reporting option. In addition, we assume that the 80 TINs that elect to form 16 virtual groups will continue to collect and submit MIPS data using the same collection and submission types as they did during the 2017 MIPS performance period, but the submission will be at the virtual group, rather than group level.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[140] Tables 69, 70, and 71 explain our

[140] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 69 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2020 MIPS performance period based on data from the 2017 MIPS performance period.

For the 2020 MIPS performance period, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and CMS Web Interface. We estimate the burden for collecting data via collection type: Claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintain consistency with previous rulemaking.

For an individual, group, or third-party to submit MIPS quality, improvement activities, or Promoting Interoperability performance category data using either the log in and upload or the log in and attest submission type or to access feedback reports, the submitter must have a CMS Enterprise Portal user account. Once the user account is created using the Identity Management Application Process, registration is not required again for future years.

Table 69 shows that in the 2020 MIPS performance period, an estimated 109,951 clinicians will submit data as individuals for the Medicare Part B claims collection type; 359,621 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 247,329 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 116,342 clinicians will submit as part of groups via the CMS Web Interface.

Table 69 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

TABLE 69—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of clinicians to collect data by collection type (as individual clinicians or groups) in 2020 MIPS performance period (excludes QPs) (a)	109,951	359,621	247,329	116,342	833,243
* Number of clinicians to collect data by collection type (as individual clinicians or groups) in 2019 MIPS performance period (excludes QPs) (b)	257,260	324,693	243,062	139,231	964,246
Difference between 2020 MIPS performance period (CY 2020 Proposed Rule) and 2019 MIPS performance period (CY 2019 Final Rule) (c) = (a) − (b)	−147,309	34,928	4,267	−22,889	−131,003

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule (82 FR 53625 through 53626), beginning with the 2019 MIPS performance period, we allowed MIPS eligible clinicians to submit data for multiple collection types for a single performance category. Therefore, with the exception of clinicians not in small practices who previously submitted quality data via Medicare Part B claims, we captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types. Hence, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the 2017 MIPS performance period.

Table 70 uses methods similar to those described to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the 2020 MIPS performance period. We estimate that approximately 109,951 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 106,039 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 47,455 clinicians will submit data as individuals using eCQMs collection type.

TABLE 70—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS BY COLLECTION TYPE

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of Clinicians to submit data as individuals in 2020 MIPS Performance Period (excludes QPs) (a)	109,951	106,039	47,455	0	263,445
* Number of Clinicians to submit data as individuals in 2019 MIPS Performance Period (excludes QPs) (b)	257,260	71,439	47,557	0	376,256

TABLE 70—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS BY COLLECTION TYPE—Continued

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Difference between 2020 MIPS Performance Period (CY 2020 proposed rule) and 2019 MIPS performance period (CY 2019 final rule) (c) = (a) − (b)	−147,309	+34,600	−102	0	−112,811

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 70 are not mutually exclusive.

Table 71 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2020 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. With the previously discussed exceptions regarding groups who experienced a change in APM participation status between the 2017 and 2019 MIPS performance periods, we assume that groups that submitted quality data as groups in the 2017 MIPS performance period will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the 2020 MIPS performance period. First, we estimated the number of groups or virtual groups that will collect data via each collection type during the 2020 MIPS performance period using data from the 2017 MIPS performance period. The second and third steps in Table 71 reflect our currently approved assumption that virtual groups will reduce the burden for quality data submission by reducing the number of organizations that will submit quality data on behalf of clinicians. We assume that 40 groups that previously collected on behalf of clinicians via QCDR or MIPS CQM collection types will elect to form 8 virtual groups that will collect via QCDR and MIPS CQM collection types. We assume that another 40 groups that previously collected on behalf of clinicians via eCQM collection types will elect to form another 8 virtual groups that will collect via eCQM collection types. Hence, the second step in Table 71 is to subtract out the estimated number of groups under each collection type that will elect to form virtual groups, and the third step in Table 71 is to add in the estimated number of virtual groups that will submit on behalf of clinicians for each collection type.

Specifically, we assume that 10,552 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 253,582 clinicians; 4,332 groups and virtual groups will submit for eCQM collection types on behalf of 199,874 eligible clinicians; and 104 groups will submit data via the CMS Web Interface on behalf of 116,342 clinicians.

TABLE 71—ESTIMATED NUMBER OF GROUPS AND VIRTUAL GROUPS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE ON BEHALF OF CLINICIANS

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of groups to collect data by collection type (on behalf of clinicians) in 2020 MIPS performance period (excludes QPs) (a)	0	10,584	4,364	104	15,052
Subtract out: Number of groups to collect data by collection type on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (b)	0	40	40	0	80
Add in: Number of virtual groups to collect data by collection type on behalf of clinicians in 2020 MIPS performance period (c)	0	8	8	0	16
Number of groups to collect data by collection type on behalf of clinicians in 2020 MIPS performance period (d) = (a) − (b) + (c)	0	10,552	4,332	104	14,988
* Number of groups to collect data by collection type on behalf of clinicians in 2019 MIPS performance period (e)	0	10,542	4,304	286	15,132
Difference between 2020 MIPS performance period (CY 2020 proposed rule) and 2019 MIPS performance period (CY 2019 final rule) (f) = (d) − (e)	0	10	28	−182	−144

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

The burden associated with the submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary

along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. In terms of the quality measures available for clinicians and groups to report for the 2020 MIPS performance period, the total number of quality measures will be 206. The new MIPS quality measures proposed for inclusion in MIPS for the 2020 MIPS performance period and future years are found in Table Group A of Appendix 1; MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 72, as well as counts of new, removed, and substantively changed measures.

TABLE 72—SUMMARY OF QUALITY MEASURES FOR THE 2020 MIPS PERFORMANCE PERIOD

Collection type	Number measures proposed as new	Number measures proposed for removal	Number measures proposed with a substantive change *	Number measures remaining for CY 2020
Medicare Part B Claims Specifications	0	17	22	47
MIPS CQMs Specifications	3	52	77	184
eCQM Specifications	1	6	33	45
Survey—CSV	0	0	0	1
CMS Web Interface Measure Specifications	1	1	9	10
Administrative Claims	0	0	0	1
Total **	4	55	95	206

* This column includes all measures that have a requested substantive change from the measure stewards. The total of 95 substantive changes reflects both measures that will continue and a subset of measures that have been proposed for removal for PY2020. There are 73 substantive changes that are proposed in Appendix 1 for measures not being proposed for removal.

** A measure may be specified under multiple collection types but will only be counted once in the total.

For the 2020 MIPS performance period, there is a net reduction of 51 quality measures across all collection types compared to the 257 measures finalized for the 2019 MIPS performance period (83 FR 60003). We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups as respondents are still required to submit quality data for 6 measures. Likewise, we do not anticipate a change in reporting burden as a result of the one proposed administrative claims measure (The All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure) which is being proposed for the 2021 MIPS performance period as discussed in section III.K.3.c.(1)(d)(ii) of this rule.

As discussed in section III.K.3.c.(1)(c)(ii) of this rule, we are proposing to adopt a higher data completeness threshold (the percentage of eligible patients the clinician must check to see whether the measure applies to) for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMs must submit data on at least 70 percent of the MIPS eligible clinician or group's patients that meet the denominator criteria, regardless of payer for the 2020 MIPS performance period. We believe this proposal may increase administrative burden for some clinicians as it affects the amount of data they have to collect, but will have no impact on regulatory burden as it affects neither the number of quality measures they are required to report nor the amount of data they must report for each quality measure once results have been aggregated.

(2) Quality Payment Program Identity Management Application Process

This rule does not propose any new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any identity management application process changes under that control number.

(3) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule does not propose any new or revised collection of information requirements related to the submission of Medicare Part B claims data for the quality performance category. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Table 69, based on 2017 MIPS performance period data, we assume that 109,951 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. This rule proposes to adjust the number of Medicare Part B claims respondents from 257,260 to 109,951 (a decrease of 147,309) based on more recent data and our updated methodology of accounting only for clinicians in small practices who submitted such claims data in the 2017 MIPS performance period rather than all clinicians who submitted quality data codes to us for the Medicare Part B claims collection type. We continue to anticipate that the Medicare Part B claims submission process for MIPS is operationally similar to the way the claims submission process functioned under the PQRS. Specifically, clinicians will need to

gather the required information, select the appropriate QDCs, and include the appropriate QDCs on the Medicare Part B claims they submit for payment. Clinicians will collect QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved by OMB under control number 0938–1197. This proposed rule's provisions do not necessitate the revision of either form and we are making no changes to the associated estimate of reporting burden.

As shown in Table 73, consistent with our currently approved per respondent burden estimates, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours at a cost of $13.50 (0.15 hr × $90.02/hr) to 7.2 hours at a cost of $648.14 (7.2 hr × $90.02/hr) per respondent. The burden will involve becoming familiar with MIPS data submission requirements. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $109.36/hr for a practice administrator, 1 hour at $202.86/hr for a clinician, 1 hour at $45.24/hr for an LPN/medical assistant, 1 hour at $90.02/hr for a computer systems analyst, and 1 hour at $38.00/hr for a billing clerk. We are not proposing revisions to our currently approved per response burden estimates.

The estimate for reviewing and incorporating measure specifications for the claims collection type is higher than that of QCDRs/Registries or eCQM collection types due to the more manual, and therefore, more burdensome nature of Medicare Part B claims measures.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual time ranges from 786,150 hours (7.15 hr × 109,951 clinicians) to 1,561,304 hours (14.2 hr × 109,951 clinicians). The estimated annual cost (per clinician) ranges from $717.70 [(0.15 hr × $90.02/hr) + (3 hr × $109.36/hr) + (1 hr × $90.02/hr) + (1 hr × $45.24/hr) + (1 hr × $38.00/hr + (1 hr × $202.86/hr)] to a maximum of $1,352.34 [(7.2 hr × $90.02/hr) + (3 hr × $109.36/hr) + (1 hr × $90.02/hr) + (1 hr × $45.24/hr) + (1 hr × $38.00/hr + (1 hr × $202.86/hr)]. The total annual cost ranges from a minimum of $78,912,163 (109,951 clinicians × $717.70) to a maximum of $148,691,575 (109,951 clinicians × $1,352.34).

Table 73 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

TABLE 73—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE MEDICARE PART B CLAIMS COLLECTION TYPE

	Minimum burden	Median burden	Maximum burden
# of Clinicians (a)	109,951	109,951	109,951
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Practice Administrator Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Clinician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	786,150	885,106	1,561,304
Cost to Submit Quality Data (@computer systems analyst's labor rate of $90.02/hr) (j)	$13.50	$94.52	$648.14
Cost to Review Measure Specifications (@practice administrator's labor rate of $109.36/hr) (k)	$328.08	$328.08	$328.08
Cost to Review Measure Specifications (@computer systems analyst's labor rate of $90.02/hr) (l)	$90.02	$90.02	$90.02
Cost to Review Measure Specifications (@LPN's labor rate of $45.24/hr) (m)	$45.24	$45.24	$45.24
Cost to Review Measure Specifications (@billing clerk's labor rate of $38.00/hr) (n)	$38.00	$38.00	$38.00
Cost to Review Measure Specifications (@physician's labor rate of $202.86/hr) (o)	$202.86	$202.86	$202.86
Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$717.70	$798.72	$1,352.34
Total Annual Cost (q) = (a) * (p)	$78,912,163	$87,820,173	$148,691,575

As shown in Table 74, using the unchanged currently approved per respondent burden estimates which range from $717.70 to $1,352.34, the decrease in number of respondents from 257,260 to 109,951 results in a total adjustment of between −1,053,259 hours (−147,309 respondents × 7.15 hr/respondent) at a cost of −$105,724,111 (−147,309 respondents × $717.70/respondent) and −2,091,788 hours (−147,309 respondents × 14.2 hr/respondent) at a cost of −$199,212,442 (−147,309 respondents × $1,352.34/respondent).

TABLE 74—CHANGE IN ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE MEDICARE PART B CLAIMS COLLECTION TYPE

	Minimum burden	Median burden	Maximum burden
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,839,409	2,070,943	3,653,092
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	786,150	885,106	1,561,304

TABLE 74—CHANGE IN ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE MEDICARE PART B CLAIMS COLLECTION TYPE—Continued

	Minimum burden	Median burden	Maximum burden
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−1,053,259	−1,185,837	−2,091,788
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$184,636,274	$205,478,964	$347,904,017
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$78,912,163	$87,820,173	$148,691,575
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$105,724,111	−$117,658,791	−$199,212,442

(4) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

This rule does not propose any new or revised collection of information requirements related to the MIPS CQM or QCDR collection types. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 69, 70, and 71, and based on 2017 MIPS performance period data, we assume that 359,621 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. Of these, we expect 106,039 clinicians, as shown in Table 70, will submit as individuals and 10,552 groups and virtual groups, as shown in Table 71, are expected to submit on behalf of the remaining 253,582 clinicians. As previously stated, we assume clinicians in other practices (not small practices) who meet all of the following criteria will submit via the MIPS CQM collection type for the 2020 MIPS performance period because the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data: (1) Scored as individuals; (2) not facility-based; and (3) submitted quality data only via the Medicare Part B claims collection type in the 2017 MIPS performance period. As a result of this assumption and our use of more recent data, this rule proposes to adjust the number of QCDR and MIPS CQM respondents from 81,981 to 116,591 (an increase of 34,610). Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS collection requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at $872.37 per individual clinician or group. This consists of 3 hours at $90.02/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $109.36/hr for a practice administrator, 1 hour at $90.02/hr for a computer systems analyst, 1 hour at $45.24/hr for a LPN/medical assistant, 1 hour at $38.00/hr for a billing clerk, and 1 hour at $202.86/hr for a clinician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a cost of $7.50 (0.083 hr × $90.02/hr for a computer systems analyst).

In aggregate, we estimate an annual burden of 1,058,996 hours (9.083 hr/response × 116,591 groups plus clinicians submitting as individuals) at a cost of $101,710,684 (116,591 responses × $872.37/response). The increase in number of respondents from 81,981 to 116,591 results in a total adjustment of 314,363 hours (34,610 respondents × 9.083 hr/respondent) at a cost of $30,192,783 (34,610 respondents × $872.37/respondent). Based on these assumptions, we have estimated in Table 75 the burden for these submissions.

TABLE 75—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE

	Burden estimate
# of clinicians submitting as individuals (a)	106,039
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	10,552
# of Respondents (groups plus clinicians submitting as individuals) (c) = (a) + (b)	116,591
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Practice Administrator Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Clinician Review Measure Specifications (i)	1

TABLE 75—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE—Continued

	Burden estimate
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k) = (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c) * (k)	1,058,996
Cost Per Respondent to Submit Quality Data (@computer systems analyst's labor rate of $90.02/hr) (m)	$270.06
Cost to Review Measure Specifications (@practice administrator's labor rate of $109.36/hr) (n)	$218.72
Cost Computer System's Analyst Review Measure Specifications (@computer systems analyst's labor rate of $90.02/hr) (o)	$90.02
Cost LPN Review Measure Specifications (@LPN's labor rate of $45.24/hr) (p)	$45.24
Cost Billing Clerk Review Measure Specifications (@clerk's labor rate of $38.00/hr) (q)	$38.00
Cost Clinician Review Measure Specifications (@physician's labor rate of $202.86/hr) (r)	$202.86
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@computer systems analyst's labor rate of $90.02/hr) (s)	$7.50
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$872.37
Total Annual Cost (u) = (c) * (t)	$101,710,684

As shown in Table 76, using the unchanged currently approved per respondent burden estimate, the increase in number of respondents from 81,981 to 116,591 results in a total difference of 314,363 hours (34,610 respondents × 9.083 hr/respondent) at a cost of $30,192,783 (34,610 respondents × $872.37/respondent).

TABLE 76—CHANGE IN ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	744,633
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	1,058,996
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	314,363
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$71,517,901
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$101,710,684
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$30,192,783

(5) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

This rule does not propose any new or revised collection of information requirements related to the eCQM collection type. However, we are proposing to adjust our currently approved burden estimates based on more recent data. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 69, 70, and 71, based on 2017 MIPS performance period data, we assume that 247,329 clinicians will elect to use the eCQM collection type; 47,455 clinicians are expected to submit eCQMs as individuals; and 4,332 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 199,874 clinicians. This rule proposes to adjust the number of eCQM respondents from 51,861 to 51,787 (a decrease of 74) based on more recent data. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to the CMS-designated clinical data warehouse.

We estimate that it will take no more than 2 hours at $90.02/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS submission. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $109.36/hr for a practice administrator, 1 hour at $202.86/hr for a clinician, 1 hour at $90.02/hr for a computer systems analyst, 1 hour at $45.24/hr for

a LPN/medical assistant, and 1 hour at $38.00/hr for a billing clerk.

In aggregate we estimate an annual burden of 414,296 hours (8 hr × 51,787 groups and clinicians submitting as individuals) at a cost of $40,128,711 (51,787 responses × $774.88/response). Based on these assumptions, we have estimated in Table 77 the burden for these submissions.

TABLE 77—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (SUBMITTING INDIVIDUALLY OR AS PART OF A GROUP) USING THE eCQM COLLECTION TYPE

	Burden estimate
# of clinicians submitting as individuals (a)	47,455
# of Groups submitting via EHR on behalf of individual clinicians (b)	4,332
# of Respondents (groups and clinicians submitting as individuals) (c) = (a) + (b)	51,787
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Practice Administrator Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Clinicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	414,296
Cost Per Respondent to Submit Quality Data (@computer systems analyst's labor rate of $90.02/hr) (l)	$180.04
Cost to Review Measure Specifications (@practice administrator's labor rate of $109.36/hr) (m)	$218.72
Cost to Review Measure Specifications (@computer systems analyst's labor rate of $90.02/hr) (n)	$90.02
Cost to Review Measure Specifications (@LPN's labor rate of $45.24/hr) (o)	$45.24
Cost to Review Measure Specifications (@clerk's labor rate of $38.00/hr) (p)	$38.00
Cost to D21Review Measure Specifications (@physician's labor rate of $202.86/hr) (q)	$202.86
Total Cost Per Respondent (r) = (l) + (m) + (n) + (o) + (p) + (q)	$774.88
Total Annual Cost (s) = (c) * (r)	$40,128,711

As shown in Table 78, using the unchanged currently approved per respondent burden estimate, the decrease in number of respondents from 51,861 to 51,787 results in a total difference of −592 hours (−74 respondents × 8 hr/respondent) at a cost of −$57,341 (−74 respondents × $774.88/respondent).

TABLE 78—CHANGE IN ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE eCQM COLLECTION TYPE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	414,888
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	414,296
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−592
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$40,186,052
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$40,128,711
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$57,341

(6) Quality Data Submission via CMS Web Interface

This rule does not propose any new or revised collection of information requirements related to submission of quality data via the CMS Web Interface. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We assume that 104 groups will submit quality data via the CMS Web Interface based on the number of groups who completed 100 percent of reporting quality data via the Web Interface in the 2018 MIPS performance period. This is a decrease of 182 groups from the currently approved number of 286 groups provided in the CY 2019 PFS final rule (83 FR 60007) due to receipt of more current data. We estimate that 116,342 clinicians will submit as part of groups via this method, a decrease of 22,889 from our currently approved estimate of 139,231 clinicians.

The burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. Our burden estimate for submission includes the time (61.67 hours) needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into

the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate an annual burden of 6,414 hours (104 groups × 61.67 hr) at a cost of $577,359 (6,414 hr × $90.02/hr). Based on the assumptions discussed in this section, Table 79 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 79—ESTIMATED BURDEN FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE

	Burden estimate
# of Eligible Group Practices (a)	104
Total Annual Hours Per Group to Submit (b)	61.67
Total Annual Hours (c) = (a) * (b)	6,414
Cost Per Group to Report (@computer systems analyst's labor rate of $90.02/hr.) (d)	$5,551.53
Total Annual Cost (e) = (a) * (d)	$577,359

As shown in Table 80, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of −11,224 hours (−182 respondents × 61.67 hr) at −$1,010,379 (−11,224 hr × $90.02/hr).

TABLE 80—CHANGE IN ESTIMATED BURDEN FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	17,637
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	6,413
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−11,224
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,587,739
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$577,359
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$1,010,379

(7) Beneficiary Responses to CAHPS for MIPS Survey

This rule does not propose any new or revised collection of information requirements or burden related to the CAHPS for MIPS survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

(8) Group Registration for CMS Web Interface

This rule does not propose any new or revised collection of information requirements related to the group registration for CMS Web Interface. However, we propose to adjust our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an on-line registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 81, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $90.02/hr for a computer systems analyst (or their equivalent) to register the group.

In this rule, we propose to adjust the number of respondents from 67 to 51 based on more recent data. We assume that approximately 51 groups will elect to use the CMS Web Interface for the first time during the 2020 MIPS performance period based on the number of new registrations received during the CY 2018 registration period; a decrease of 16 compared to the number of groups currently approved by OMB. The registration period for the CY 2019 MIPS performance period ends on June 30, 2019; assuming updated information is available, we will update our respondent estimates in the final rule. As shown in Table 81, we estimate a burden of 12.75 hours (51 new registrations × 0.25 hr/registration) at a cost of $1,148 (12.75 hr × $90.02/hr).

TABLE 81—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CMS WEB INTERFACE

	Burden estimate
Number of New Groups Registering for CMS Web Interface (a)	51
Annual Hours Per Group (b)	0.25

TABLE 81—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CMS WEB INTERFACE—Continued

	Burden estimate
Total Annual Hours (c) = (a) * (b)	12.75
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost for CMS Web Interface Group Registration (e) = (a) * (d)	$1,148

As shown in Table 82 using our unchanged currently approved per respondent burden estimates, the decrease in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of 4 hours at a cost of $360 (−16 groups × 0.25 hr × $90.02/hr).

TABLE 82—CHANGE IN ESTIMATED BURDEN FOR GROUP REGISTRATIONS FOR THE CMS WEB INTERFACE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	16.75
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	12.75
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−4
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,508
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$1,148
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$360

(9) Group Registration for CAHPS for MIPS Survey

This rule does not propose any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, are not making any MIPS survey vendor changes under that control number.

e. ICRs Regarding the Nomination of Quality Measures

The proposed requirements and burden associated with this data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Quality measures are selected annually through a call for quality measures under consideration, with a final list of quality measures being published in the **Federal Register** by November 1 of each year. Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a ''Call for Quality Measures'' each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of MIPS quality measures, as well as updates to the measures. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards.

As we described in the CY 2017 Quality Payment Program final rule (81 FR 77137), we will accept quality measures submissions at any time, but only measures submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual call for measures, which are further described at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html.*

To identify and submit a quality measure, eligible clinician organizations and other relevant stakeholders use a one-page online form that requests information on background, a gap analysis which includes evidence for the measure, reliability, validity, endorsement and a summary which includes how the proposed measure relates to the Quality Payment Program and the rationale for the measure. In addition, proposed measures must be accompanied by a completed Peer Review Journal Article form. As discussed in section III.K.3.c.(1)(d)(i) of this rule, we are proposing that beginning with the 2020 Call for Measures process, MIPS quality measure stewards would be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards would also be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities. We believe this would require approximately 0.6 hours at $109.36/hr for a practice administrator and 0.4 hours at $202.86 for a clinician to research existing measures or activities and provide a rationale for the linkage to the new measure. We also estimate it would require 0.3 hours at $109.36/hr for a practice administrator to make a strategic decision to nominate and submit a measure and 0.2 hours at $202.86/hr for clinician review time. We recognize there is additional burden on respondents associated with development of a new quality measure beyond the 1.5 hour estimate (0.6 hr + 0.4 hr + 0.3 hr + 0.2 hr) which only accounts for the time required for recordkeeping, reporting, and third-party disclosures associated with the policy; but we believe this estimate to be reasonable to nominate and submit a measure. The 1.5 hour estimate also assumes that submitters will have the necessary information to complete the nomination form readily available,

which we believe is a reasonable assumption. Additionally, some submitters familiar with the process or who are submitting multiple measures may require significantly less time, while other submitters may require more if the opposite is true. Representing an average across all respondents based on our review of the nomination process, the information required to complete the nomination form, and the criteria required to nominate the measure, we believe the total estimate of 1.5 hours per measure to be reasonable and appropriate.

As shown in Table 83, we estimate that 26 submissions will be received during the 2019 Call for Quality Measures based on the number of submissions received during the 2018 Call for Quality Measures process; a decrease of 114 compared to the number of submissions currently approved by OMB (140 submissions). The 2019 Call for Quality Measures process ends on June 3, 2019; assuming updated information is available, we will update our estimate in the final rule. In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using practice administrators and clinician time for our burden estimates.

Consistent with the CY 2017 Quality Payment Program final rule, we also estimate it will take 4 hours at $202.86/hr for a clinician (or equivalent) to complete the Peer Review Journal Article Form (81 FR 77153 through 77155). This assumes that measure information is available and testing is complete in order to have the necessary information to complete the form, which we believe is a reasonable assumption.

As shown in Table 83, in aggregate we estimate an annual burden of 143 hours (26 submissions × 5.5 hr/submission) at a cost of $26,821 {26 submissions × [(0.9 hr × $109.36/hr) + (4.6 hr × $202.86/hr}.

TABLE 83—ESTIMATED BURDEN FOR CALL FOR QUALITY MEASURES

	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	26
# of Hours Per Practice Administrator to Identify, Propose, and Link Measure (b)	0.9
# of Hours Per Clinician to Identify and Link Measure (c)	0.6
# of Hours Per Clinician to Complete Peer Review Article Form (d)	4.00
Annual Hours Per Response (e) = (b) + (c) + (d)	5.50
Total Annual Hours (f) = (a) * (e)	143
Cost to Identify and Submit Measure (@practice administrator's labor rate of $109.36/hr.) (g)	$98.42
Cost to Identify Quality Measure and Complete Peer Review Article Form (@physician's labor rate of $202.86/hr.) (h)	$933.16
Total Annual Cost Per Respondent (i) = (g) + (h)	$1,031.58
Total Annual Cost (j) = (a) * (i)	$26,821

Independent of the decrease in the number of new quality measures submitted for consideration, the increase in burden per nominated measure results in a difference of 140 hours at a cost of $20,546 {140 submissions × [(0.6 hr × $109.36/hr) + (0.4 hr × $202.86/hr)]}. The decrease in the number of new quality measures submitted results in an adjustment of −627 hours at −$117,600 (−114 submissions × [(0.9 hr × $109.36/hr) + (4.6 hr × $202.86/hr)]). As shown in Table 84, in aggregate, the combine impact of these changes is −487 hours (140 − 627) at a cost of −$97,054 ($20,546 − $117,600).

TABLE 84—CHANGE IN ESTIMATED BURDEN FOR CALL FOR QUALITY MEASURES

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	630
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	143
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−487
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$123,875
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$26,821
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$97,054

f. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the 2020 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. We have worked to further align the Promoting Interoperability performance category with other MIPS performance categories. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting

the quality data submission will also support the Promoting Interoperability data submission process. In the 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category via a qualified registry or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type. The proposals discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) requiring qualified registries and QCDRs to support the reporting of quality, improvement activities, and Promoting Interoperability performance categories would alleviate this issue. Hence, the following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

This rule does not propose any new or revised collection of information requirements related to the submission of reweighting applications for Promoting Interoperability and other performance categories. However, we propose to adjust our currently approved burden estimates based on an updated analysis of individuals and groups who submitted reweighting applications for the 2017 MIPS performance period but likely would not submit such applications for the 2019 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability performance category in the following circumstances: Insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, clinicians who are in a small practice, and decertified EHR technology (81 FR 77240 through 77243 and 82 FR 53680 through 53686, respectively). In addition, in the CY 2018 Quality Payment Program final rule, we established that MIPS eligible clinicians and groups citing extreme and uncontrollable circumstances may also apply for a reweighting of the quality, cost, and/or improvement activities performance categories (82 FR 53783 through 53785). As discussed in section III.K.3.d.(2)(b)(ii)(A), we are proposing, beginning with the 2018 MIPS performance period and 2020 MIPS payment year, to reweight the performance categories for a MIPS eligible clinician who we determine has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents if we learn the relevant information prior to the beginning of the associated MIPS payment year. Because this is a new policy and we believe these occurrences are rare based on our experience, we are unable to estimate the number of clinicians, groups, or third party intermediaries that may contact us regarding a potential data issue. Similarly, the extent and source of documentation provided to us for each event may vary considerably. Therefore, we are not proposing any changes to our currently approved burden estimates as a result of this proposal. Respondents who apply for a reweighting for any of these performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications. Data on the number of reweighting applications submitted for the 2018 MIPS performance period is unavailable for this proposed rule. Assuming updated information is available for the final rule, we will assess the utility of using this information to estimate burden for future performance periods and will make a determination at that time as to the most appropriate data to use in estimating future burden.

Table 85 summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Based on the number of reweighting applications received for the 2017 MIPS performance period, we assume 6,025 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including clinicians in small practices) or EHR decertification. Of that amount we estimate that 3,365 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 2,660 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship.

The application to request a reweighting to zero percent only for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances impair the clinician or group's ability to submit Promoting Interoperability data, as well as some proof of circumstances beyond the clinician's control. The application for reweighting of the quality, cost, Promoting Interoperability, and/or improvement activities performance categories due to extreme and uncontrollable circumstances requires the same information with the exception of there being only one option for the type of hardship experienced. We estimate it would take 0.25 hours at $90.02/hr for a computer system analyst to complete and submit the application. As shown in Table 85, we estimate an annual burden of 1,506.25 hours (6,025 applications × 0.25 hr/application) at a cost of $135,593 (1,506.25 hr × $90.02/hr).

TABLE 85—ESTIMATED BURDEN FOR REWEIGHTING APPLICATIONS FOR PROMOTING INTEROPERABILITY AND OTHER PERFORMANCE CATEGORIES

	Burden estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions (a)	3,365
# of Eligible Clinicians or Groups Applying Due to Significant Hardship for Small Practice (b)	2,660
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	6,025
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	1,506.25
Labor Rate for a computer systems analyst (f)	$90.02/hr
Total Annual Cost (g) = (a) * (f)	$135,593

As shown in Table 86, using our unchanged currently approved per respondent burden estimate, the decreased number of respondents results in a total adjustment of −4 hours (−16 respondents × 0.25 hr/respondent) and −$360 (−16 respondents × $22.50/respondent).

TABLE 86—CHANGE IN ESTIMATED BURDEN FOR REWEIGHTING APPLICATIONS FOR PROMOTING INTEROPERABILITY AND OTHER PERFORMANCE CATEGORIES

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,510
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	1,506
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−4
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$135,953
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$135,593
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$360

(3) Submitting Promoting Interoperability Data

This rule does not propose any new or revised collection of information requirements related to the submission of Promoting Interoperability data. However, we propose to adjust our currently approved burden estimates based on updated estimates of QPs and MIPS APMs for 2019 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264) and CY 2019 PFS final rule (83 FR 59822–59823), we established that eligible clinicians in MIPS APMs (including the Shared Savings Program) may report for the Promoting Interoperability performance category as an APM Entity group, individuals, or a group.

As shown in Table 87, based on data from the 2017 MIPS performance period, we estimate that a total of 93,863 respondents consisting of 81,358 individual MIPS eligible clinicians and 12,505 groups and virtual groups will submit Promoting Interoperability data. Similar to the process shown in Table 71 for groups reporting via QCDR/MIPS CQM and eCQM collection types, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period.

Because our respondent estimates are based on the number of actual submissions received for the Promoting Interoperability performance category, it is not necessary to account for policies adopted in the CY 2017 Quality Payment Program final rule regarding reweighting, which state that if a clinician submits Promoting Interoperability data, they will be scored and the performance category will not be reweighted (81 FR 77238–77245). This approach is identical to the approach we used in the CY 2019 PFS final rule (83 FR 60013 through 60014), however we failed to state the distinction in that final rule that we no longer need to make modifications to our estimates due to the use of actual MIPS submission data. As established in the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2019 PFS final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of the Promoting Interoperability performance category to zero percent, including MIPS eligible clinicians that are hospital-based, ambulatory surgical center-based, non-patient facing clinicians, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists; occupational therapists; qualified speech-language pathologists or qualified audiologist; clinical psychologists; and registered dieticians or nutrition professionals (81 FR 77238 through 77245, 82 FR 53680 through 53687, and 83 FR 59819 through 59820, respectively). For the same reasons discussed above regarding our use of data reflecting the actual number of Promoting Interoperability data submissions received, these estimates already account for the reweighting policies in the CY 2017 and CY 2018 Quality Payment Program final rules,

including exceptions for MIPS eligible clinicians who have experienced a significant hardship (including clinicians who are in small practices), as well as exceptions due to decertification of an EHR (81 FR 77240 through 77243 and 82 FR 53680 through 53686).

In section III.K.3.c.(4)(f)(iii), we propose to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We propose that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. We also propose to revise § 414.1380(c)(2)(iii) to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the proposed revised definition of a hospital-based MIPS eligible clinician or the definition of a non-patient facing MIPS eligible clinician as defined in § 414.1305. We believe these proposals could result in a decrease in the number of data submissions for the Promoting Interoperability performance category, but we do not currently have the data necessary to determine how many groups would elect to forego submission. As additional information becomes available in future years, we will revisit the impact of this policy and adjust our burden estimates accordingly.

As discussed in section III.K.3.c.(4)(d)(i)(B) of this rule, we propose to allow clinicians to satisfy the optional bonus Query of PDMP measure by submitting a ''yes/no'' attestation, rather than reporting a numerator and denominator. In the CY 2019 PFS final rule, we updated our burden assumptions from 3 hours to 2.67 hours to reflect the change from 5 base measures, 9 performance measures, and 4 bonus measures to the reporting of 4 base measures (83 FR 60013 through 60014). Due to a lack of data regarding the number of health care providers who would submit data for bonus Promoting Interoperability measures, we have consistently been unable to estimate burden related to the reporting of bonus measures and are therefore unable to account for any change in burden due to the proposed change to a ''yes/no'' attestation for the Query of PDMP measure. If we have better data in the future, we may reassess our burden assumptions and whether we can reasonably quantify the burden associated with the reporting of bonus measures.

We assume that MIPS eligible clinicians scored under the APM scoring standard, as described in section III.K.3.c.(5)of this rule, would continue to submit Promoting Interoperability data the same as in 2017. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. In the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822–59823). Burden estimates for this proposed rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TIN as ACO participants. As we receive updated information which reflects the actual number of Promoting Interoperability data submissions submitted by Shared Savings Program ACO participants, we will update our burden estimates accordingly.

TABLE 87—ESTIMATED NUMBER OF RESPONDENTS TO SUBMIT PROMOTING INTEROPERABILITY PERFORMANCE DATA ON BEHALF OF CLINICIANS

	Number of respondents
Number of individual clinicians to submit Promoting Interoperability (a)	81,358
Number of groups to submit Promoting Interoperability (b)	12,569
Subtract: Number of groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (c)	80
Add in: Number of virtual groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period (d)	16
Number of groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period (e) = (b) − (c) + (d)	12,505
Total Respondents in 2020 MIPS performance period (CY 2020 Proposed Rule) (f) = (a) + (e)	93,863
*Total Respondents in 2019 MIPS performance period (CY 2019 Final Rule) (g)	93,869
Difference between CY 2020 Proposed Rule and CY 2019 Final Rule (h) = (f) − (g)	−6

We estimate the time required for an individual or group to submit Promoting Interoperability data to be 2.67 hours. As previously discussed, beginning with the 2021 performance period and for future years, we propose to require that QCDRs and qualified registries support three performance categories: Quality, improvement activities, and Promoting Interoperability. Based on our review of 2019 qualified registries and QCDRs, we have determined that 70 percent and 72 percent of these vendors, respectively, already support reporting for these performance categories. For clinicians who currently utilize qualified registries or QCDRs that have not previously offered the ability to report Promoting Interoperability or improvement activity data, we believe this would result in a reduction of burden as it would simplify MIPS reporting. In order to estimate the impact on reporting burden, we would need to correlate the specific individual clinicians and groups who submitted quality performance category data via the MIPS CQM/QCDR collection type that are required to report data for both the quality and Promoting Interoperability performance categories

with the specific qualified registries or QCDRs that are affected by this proposal. Currently, we do not have the necessary information to perform this correlation and are therefore unable to estimate the resulting impact on burden. If data becomes available in the future which enables us to perform this analysis, we will update our burden estimates at that time.

As shown in Table 88, the total burden estimate for submission of data on the specified Promoting Interoperability objectives and measures is estimated to be 250,301 hours (93,853 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data) at a cost of $22,532,126 (250,301 hr × $90.02/hr).

TABLE 88—ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION

	Burden estimate
Number of individual clinicians to submit Promoting Interoperability (a)	81,358
Number of groups to submit Promoting Interoperability (b)	12,505
Total (c) = (a) + (b)	93,863
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a) * (b)	250,301
Labor rate for a computer systems analyst to submit Promoting Interoperability data (d)	$90.02/hr
Total Annual Cost (e) = (a) * (d)	$22,532,126

As shown in Table 89, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of −16 hours (−6 respondents × 2.67 hr/respondent) at a cost of −$1,440 (−16 hr × $90.02/hr).

TABLE 89—CHANGE IN ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	250,317
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	250,301
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−16
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$22,533,566
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$22,532,126
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$1,440

g. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule does not propose any new or revised collection of information requirements related to the nomination of Promoting Interoperability measures. However, we propose to adjusted our currently approved burden estimates based on data from the 2018 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Consistent with our requests for stakeholder input on quality measures and improvement activities, we also request potential measures for the Promoting Interoperability performance category that measure patient outcomes, emphasize patient safety, support improvement activities and the quality performance category, and build on the advanced use of CEHRT using 2015 Edition standards and certification criteria. Promoting Interoperability measures may be submitted via the Call for Promoting Interoperability Performance Category Measures Submission Form that includes the measure description, measure type (if applicable), reporting requirement, and CEHRT functionality used (if applicable). This rule does not propose any changes to that form.

We estimate 28 proposals will be submitted for new Promoting Interoperability measures, based on the number of proposals submitted during the CY 2018 nomination period. This is a decrease of 19 from the estimate currently approved by OMB (47 proposals) under the aforementioned control number. The 2019 Call for Promoting Interoperability Measures process ends on July 1, 2019; assuming updated information is available, we will update our estimate in the final rule. We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $109.36/hr for a practice administrator to make a strategic decision to nominate that activity and submit an activity to us via email and 0.2 hours at $202.86/hr for a clinician to review the nomination. As shown in Table 90, we estimate an annual burden of 14 hours (28 proposals × 0.5 hr/response) at a cost of $2,055 (28 × [(0.3 hr × $109.36/hr) + (0.2 hr × $202.86/hr)].

TABLE 90—ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES

	Burden estimate
# of Promoting Interoperability Measure Nominations (a)	28
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
Annual Hours Per Respondent (d) = (b) + (c)	0.50
Total Annual Hours (e) = (a) * (d)	14
Cost to Identify and Submit Measure (@practice administrator's labor rate of $109.36/hr) (f)	$32.81
Cost to Identify Improvement Measure (@physician's labor rate of $202.86/hr) (g)	$40.57
Total Annual Cost Per Respondent (h) = (f) + (g)	$73.38
Total Annual Cost (i) = (a) * (h)	$2,055

As shown in Table 91, using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of −9.5 hours at a cost of −$1,394 (−19 respondents × 0.5 hr × $73.38 per respondent).

TABLE 91—CHANGE IN ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	23.5
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	14
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−9.5
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$3,449
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$2.055
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$1,394

h. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

This rule does not propose any new or revised collection of information requirements related to the submission of Improvement Activities data. However, we propose to adjust our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.K.3.c.(3)(d)(iii) of this rule, we are proposing, beginning with the 2020 MIPS performance period and for future years, to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity from at least one clinician to at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. Because eligible clinicians are able to attest to improvement activity measures at the group level, there is no impact on reporting burden as a result of this proposal.

As previously discussed, beginning with the 2021 performance period and for future years, we are proposing to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability; our discussion of burden for submitting Promoting Interoperability data in section IV.B.7.(f).(3) noted our inability to account for the reduction in burden associated with the proposal. Consistent with our decision not to change our per respondent burden estimate to submit Promoting Interoperability data, we are not changing our per respondent burden estimate to submit improvement activity data as a result of this proposal.

Furthermore, as discussed in section III.K.3.c.(3)(e)(i) of this rule, we are proposing to establish removal factors to consider when proposing to remove improvement activities from the Inventory. However, we do not believe this would affect reporting burden, because respondents would still be required submit the same number of improvement activities and this proposal would not require respondents to submit any additional information. We are also proposing for the CY 2020 performance period and future years to: Add 2 new improvement activities, modify 7 existing improvement activities, and remove 15 existing improvement activities. Because MIPS eligible clinicians are still required to submit the same number of activities, we do not expect these proposals to affect our currently approved burden estimates. In addition, in order for an eligible clinician or group to receive credit for being a patient-centered medical home or comparable specialty practice, the eligible clinician or group must attest in the same manner as any other improvement activity.

While our proposals do not add additional reporting burden, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2018 Quality Payment Program final rule provides: (1) That for activities that are performed for at least a continuous 90 days during the performance period, MIPS eligible clinicians must submit a ''yes'' response

for activities within the Improvement Activities Inventory (82 FR 53651); (2) that the term ''recognized'' is accepted as equivalent to the term ''certified'' when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS (82 FR 53649); and (3) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655).

In the CY 2017 Quality Payment Program final rule, we described how we determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77817 through 77831). If, based on our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities. We anticipate that MIPS APMs in the 2019 MIPS performance period will not need to submit additional improvement activities as the models will already meet the maximum improvement activities performance category score.

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group through direct, log in and upload submission types, and CMS Web Interface will also submit improvement activities data. In the 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category through a MIPS CQM or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type, the proposals discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this rule requiring qualified registries and QCDRs to support the reporting of quality, improvement activities, and Promoting Interoperability performance categories would help to alleviate this issue. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Our CY 2018 Quality Payment Program final rule burden estimates assumed that all APM Entities will receive the maximum CMS-assigned improvement activities score (82 FR 53921 through 53922).

As represented in Table 92, based on 2017 MIPS performance period data, we estimate that 102,754 clinicians will submit improvement activities as individuals during the 2020 MIPS performance period and 15,761 groups will submit improvement activities on behalf of clinicians. Similar to the process shown in Table 87 for groups submitting Promoting Interoperability data, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period. In addition, as previously discussed regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we have updated our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or members of an APM in the 2017 MIPS performance period but will be in the 2019 MIPS performance period, and would therefore not be required to submit improvement activities data.

Our burden estimates assume there will be no improvement activities burden for MIPS APM participants. We will assign the improvement activities performance category score at the APM Entity level. We also assume that the MIPS APM models for the 2020 MIPS performance period will qualify for the maximum improvement activities performance category score and, as such, APM Entities will not submit any additional improvement activities.

TABLE 92—ESTIMATED NUMBERS OF ORGANIZATIONS SUBMITTING IMPROVEMENT ACTIVITIES PERFORMANCE CATEGORY DATA ON BEHALF OF CLINICIANS

	Count
# of clinicians to participate in improvement activities data submission as individuals during the 2020 MIPS performance period (a)	102,754
# of Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (b)	15,825
Subtract: # of groups to submit improvement activities on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (c)	80
Add in: # of Virtual Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (d)	16
# of Groups and Virtual Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (e)	15,761
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2020 MIPS performance period (CY 2020 Proposed Rule) (f) = (a) + (b) + (e)	118,515
* Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (CY 2019 Final Rule) (g)	136,004
Difference between CY 2020 Proposed Rule and CY 2019 Final Rule (h) = (g) − (f)	−17,489

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

Consistent with the CY 2019 PFS final rule, we estimate that the per response time required per individual or group is 5 minutes at $90.02/hr for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set

of authenticated credentials (83 FR 60016).

As shown in Table 93, we estimate an annual burden of 9,876 hours (118,515 responses × 5 minutes/60) at a cost of $889,060 (9,876.25 hr × $90.02/hr).

TABLE 93—ESTIMATED BURDEN FOR IMPROVEMENT ACTIVITIES SUBMISSION

	Burden estimate
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (a).	118,515.
Total Annual Hours Per Respondent (b)	5 minutes.
Total Annual Hours (c)	9,876.25.
Labor rate for a computer systems analyst to submit improvement activities (d)	$90.02/hr.
Total Annual Cost (e) = (a) * (d)	$889,060.

As shown in Table 94, using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of −1,457 hours (−17,489 responses × 5 minutes/60) at a cost of −$131,197 (−1,457 hr $90.02/hr).

TABLE 94—CHANGE IN ESTIMATED BURDEN FOR IMPROVEMENT ACTIVITIES SUBMISSION

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	11,334
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	9,876
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−1,457
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,020,257
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$889,060
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$131,197

i. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of improvement activities. However, we have adjusted our currently approved burden estimates based on data from the 2018 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule, for the 2018 and future MIPS performance periods, stakeholders were provided an opportunity to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). The 2018 Annual Call for Activities lasted from February 1, 2018 through March 1, 2018, during which we received 128 nominations of activities which were evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2019 Improvement Activities Inventory. Based on the number of improvement activity nominations received in the CY 2018 Annual Call for Activities, we estimate that we will receive 128 nominations for the 2020 Annual Call for Activities, which is an increase of 3 from the 125 nominations currently approved by OMB. The 2019 Annual Call for Activities ends on July 1, 2019; assuming updated information is available, we will update our estimate in the final rule.

We estimate 1.2 hours at $109.36/hr for a practice administrator or equivalent to make a strategic decision to nominate and submit that activity and 0.8 hours at $202.86/hr for a clinician's review. As shown in Table 95, we estimate an annual burden of 256 hours (128 nominations × 2 hr/nomination) at a cost of $37,571 (128 × [(1.2 hr × $109.36/hr) + (0.8 hr × $202.86/hr)]).

TABLE 95—ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES

	Burden estimate
# of Nominations of New Improvement Activities (a)	128
# of Hours Per Practice Administrator to Identify and Propose Activity (b)	1.2
# of Hours Per Clinician to Identify Activity (c)	0.8
Annual Hours Per Respondent (d) = (b) + (c)	2
Total Annual Hours (e) = (a) * (d)	256
Cost to Identify and Submit Activity (@practice administrator's labor rate of $109.36/hr) (f)	$131.23
Cost to Identify Improvement Activity (@physician's labor rate of $202.86/hr) (g)	$162.29

TABLE 95—ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES—Continued

	Burden estimate
Total Annual Cost Per Respondent (h) = (f) + (g)	$293.52
Total Annual Cost (i) = (a) * (h)	$37,571

As shown in Table 96, using our unchanged currently approved per respondent burden estimate, the increase in the number of nominations results in an adjustment of 6 hours at a cost of $881 {3 activities × [(1.2 hr × $109.36/hr) + (0.8 hr × $202.86/hr)]}.

TABLE 96—CHANGE IN ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	250
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	256
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	6
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$36,690
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$37,571
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$881

j. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy, including for the 10 episode-based measures we are proposing to include in the cost performance category as discussed in section III.K.3.c.(2)(b)(iii) of this rule. Moreover, the provisions of this proposed rule do not result in the need to add or revise or delete any claims data fields. Therefore, we are not proposing any new or revised collection of information requirements or burden for MIPS eligible clinicians resulting from the cost performance category.

k. Quality Payment Program ICRs Regarding Partial QP Elections (§§ 414.1310(b)(ii) and 414.1430)

This rule does not propose any new or revised collection of information requirements related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we propose to adjust our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section III.K.4.d.(2)(b), we propose that, beginning for eligible clinicians who become Partial QPs in the 2020 MIPS performance period, Partial QP status will only apply to the TIN/NPI combination through which Partial QP status is attained. Any Partial QP election will only apply to TIN/NPI combination through which Partial QP status is attained so that an eligible clinician who is a Partial QP for only one TIN/NPI combination may still report under MIPS for other TIN/NPI combinations. This proposal will potentially increase the total number of Partial QP elections to participate in MIPS if clinicians achieve Partial QP status under multiple TIN/NPI combinations.

As shown in Table 97, based on our predictive QP analysis for the 2020 QP performance period, which accounts for the increase in QP and Partial QP thresholds, we estimate that 12 APM Entities and 2,010 eligible clinicians will make the election to participate as a Partial QP in MIPS representing approximately 15,500 Partial QPs, an increase of 1,941 from the 81 elections currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we estimate an annual burden of 505.5 hours (2,022 respondents × .25 hr/election) at a cost of $45,080 (505.5 hours × $90.02/hr).

TABLE 97—ESTIMATED BURDEN FOR PARTIAL QP ELECTION

	Burden estimate
# of respondents making Partial QP election (6 APM Entities, 75 eligible clinicians) (a)	2,022
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a) * (b)	505.5
Labor rate for computer systems analyst (d)	$90.02/hr
Total Annual Cost (d) = (c) * (d)	$45,505

As shown in Table 98, using our unchanged currently approved per respondent burden estimate, the increase in the number of Partial QP elections results in an adjustment of 485.25 (1,941 elections × 0.25hr) at a cost of $43,682 (485.25 hr × $90.02/hr).

TABLE 98—CHANGE IN ESTIMATED BURDEN FOR PARTIAL QP ELECTION

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	20.25
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	505.5
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	485.25
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,823
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$45,505
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$43,682

l. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1440) and Eligible Clinician Initiated Process (§ 414.1445)

As indicated below, the proposed requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer Initiated Process (§ 414.1440)

This rule does not propose any new or revised collection of information requirements related to the Payer-Initiated Process. However, we propose to adjust our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. As mentioned above, the adjusted burden will be submitted to OMB for approval.

As shown in Table 99, based on the actual number of requests received in the 2018 QP performance period, we estimate that in CY 2020 for the 2021 QP performance period 110 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (10 Medicaid payers, 50 Medicare Advantage Organizations, and 50 remaining other payers), a decrease of 105 from the 215 total requests currently approved by OMB under the aforementioned control number. We estimate it will take 10 hours at $90.02/hr for a computer system analyst per arrangement submission. In aggregate, we estimate an annual burden of 1,100 hours (110 submissions × 10 hr/submission) at a cost of $99,022 (1,100 hr × $90.02/hr).

TABLE 99—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS

	Burden estimate
# of other payer payment arrangements (15 Medicaid, 100 Medicare Advantage Organizations, 100 remaining other payers) (a)	110
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	1,100
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost for Other Payer Advanced APM determinations (e) = (a) * (d)	$99,022

As shown in Table 100, using our unchanged currently approved per respondent burden estimate, the decrease in the number of payer-initiated requests from 215 to 110 results in an adjustment of −1,050 hours (−105 requests × 10 hr) at a cost of −$94,521 (−1,050 hr × $90.02/hr).

TABLE 100—CHANGE IN ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	2,150
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	1,100
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−1,050
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$193,543
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$99,022
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$94,521

(2) Eligible Clinician Initiated Process (§ 414.1445)

This rule does not propose any new or revised collection of information requirements or burden related to the Eligible-Clinician Initiated Process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule does not propose any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. However, we propose to adjust our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2017 Quality Payment Program final rule provided that either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) Payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). The rule also specified that if we do not receive sufficient information to complete our evaluation of another payer arrangement and to make QP determinations for an eligible clinician using the All-Payer Combination Option, we will not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we explained that in order for us to make QP determinations under the All-Payer Combination Option using either the payment amount or patient count method, we will need to receive all of the payment amount and patient count information: (1) Attributable to the eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885). We also finalized that eligible clinicians and APM Entities will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option (82 FR 53885).

The CY 2018 Quality Payment Program final rule also noted that we will need this payment amount and patient count information for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 (82 FR 53885). We noted that the timing may be challenging for APM Entities or eligible clinicians to submit information for the August 31 snapshot date. If we receive information for either the March 31 or June 30 snapshots, but not the August 31 snapshot, we will use that information to make QP determinations under the All-Payer Combination Option. This payment amount and patient count information is to be submitted in a way that allows us to distinguish information from January 1 through March 31, January 1 through June 30, and January 1 through August 31 so that we can make QP determinations based on the two finalized snapshot dates (82 FR 30203 through 30204).

The CY 2018 Quality Payment Program final rule specified that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

In the CY 2019 PFS final rule, we finalized the addition of a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single (the same) APM Entity (83 FR 59936). This option will therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for which all clinicians who have reassigned billing rights to the TIN are participating in a single APM Entity. To make QP determinations under the All-Payer Combination Option at the TIN level as finalized using either the payment amount or patient count method, we will need to receive, by December 1 of the calendar year that is 2 years to prior to the payment year, all of the payment amount and patient count information: (1) Attributable to the eligible clinician, TIN, or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician(s) during the QP performance period for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31.

As shown in Table 101, we assume that 20 APM Entities, 448 TINs, and 83 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in 2019, and increase of 242 from the 309 total submissions currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at $109.36/hr for a practice administrator to complete this submission. In aggregate, we estimate an annual burden of 2,755 hours (551 respondents × 5 hr) at a cost of $301,287 (2,755 hr × $109.36/hr).

TABLE 101—ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS

	Burden estimate
# of APM Entities submitting data for All-Payer QP Determinations (a)	20
# of TINs submitting data for All-Payer QP Determinations (b)	448
# of eligible submitting data for All-Payer QP Determinations (c)	83
Hours Per respondent QP Determinations (d)	5
Total Hours (g) = [(a) *(d)] + [(b) * (d)] + [(c) * (d)]	2,755

TABLE 101—ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS—Continued

	Burden estimate
Labor rate for a Practice Administrator (h)	$109.36/hr
Total Annual Cost for Submission of Data for All-Payer QP Determinations (i) = (g) * (h)	$301,287

As shown in Table 102, using our unchanged currently approved per respondent burden estimate, the increase in the number of data submissions from 309 to 551 results in an adjustment of 1,210 hours (242 requests × 5 hr) at a cost of $132,326 (1,210 hr × $109.36/hr).

TABLE 102—CHANGE IN ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,545
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	2,755
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	1,210
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$168,961
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$301,287
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$132,326

m. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule does not propose any new or revised collection of information requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. However, we propose to adjust our currently approved burden estimates based on data from the 2018 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). Subject to renewal, the control number is currently set to expire on January 31, 2022. It was last approved on January 29, 2019, and remains active.

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 11,516 (0.10 × 115,163 voluntary MIPS participants) clinicians and groups, a decrease of 101 from the currently approved estimate of 11,617. This decrease is due to the availability of updated estimates of QPs and APM participation for the 2020 performance period. Voluntary MIPS participants are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements set out in the CY 2019 PFS final rule but have elected to submit data to MIPS. As discussed in the Regulatory Impact Analysis section of the CY 2019 PFS final rule, we estimate that 33 percent of clinicians that exceed one (1) of the low-volume criteria, but not all three (3), will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter (83 FR 60050).

In section III.K.3.h.(6) of this rule, we propose to publicly report (1) an indicator if a MIPS eligible clinician is scored using facility-based measurement beginning with Year 3 (2019 performance information available for public reporting in late 2020) and (2) aggregate MIPS data beginning with Year 2 (2018 performance information available for public reporting in late 2019). We believe it is possible that the percentage of voluntary participants electing not to participate in public reporting may change as a result of this proposals, we lack the ability to predict the behavior of clinicians' response to this proposal. Table 103 shows that for these voluntary participants, we estimate it will take 0.25 hours at $90.02/hr for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,879 hours (11,516 requests × 0.25 hr/request) at a cost of $259,168 (2,879 hr × $90.02/hr).

TABLE 103—ESTIMATED BURDEN FOR VOLUNTARY PARTICIPANTS TO ELECT OPT OUT OF PERFORMANCE DATA DISPLAY ON PHYSICIAN COMPARE

	Burden estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	11,516
Total Annual Hours per Opt-out Requester (b)	0.25
Total Annual Hours for Opt-out Requester (c) = (a) * (b)	2,879
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost for Opt-out Requests (e) = (a) * (d)	$259,168

As shown in Table 104, using our unchanged currently approved per respondent burden estimate, the decrease in the number of opt outs by voluntary participants from 11,617 to 11,516 results in an adjustment of 25.25 hours (101 requests × 0.25 hr) at a cost of −$2,273 (25.25 hr × $90.02/hr).

TABLE 104—CHANGE IN ESTIMATED BURDEN FOR VOLUNTARY PARTICIPANTS TO ELECT OPT OUT OF PERFORMANCE DATA DISPLAY ON PHYSICIAN COMPARE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	2,904.25
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	2,879.00
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−25.25
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$261,441
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$259,168
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$2,273

n. Summary of Annual Quality Payment Program Burden Estimates

Table 105 summarizes this proposed rule's burden estimates for the Quality Payment Program. To understand the burden implications of the policies proposed in this rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2019 PFS final rule into the 2020 MIPS performance period. Our estimated baseline burden estimates reflect the availability of more accurate data to account for all potential respondents and submissions across all the performance categories, more accurately reflect the exclusion of QPs from all MIPS performance categories, and better estimate the number of third-parties likely to self-nominate as qualified registries and QCDRs, as well as the number of measures submitted per QCDR. The baseline burden estimate is 3,312,523 hours at a cost of $315,630,967. This baseline burden estimate is lower than the burden approved for information collection related to the CY 2019 PFS final rule due to updated data and assumptions. The difference of 1,619 hours and $147,173 between this baseline estimate and the total burden shown in Tables 105 and 107 is the burden associated with the proposals to require QCDRs to submit measure testing data to require proposed quality measures and QCDR measures to be linked to existing cost measures, improvement activities, and MIPS Value Pathways, if possible at the time of self-nomination and to describe the quality improvements services they intend to support.

TABLE 105: Summary of Proposed Quality Payment Program Burden Estimates and Requirements

Requirement	Currently Approved Responses *	Proposed Responses	Change in Responses	Currently Approved Total Burden Hours*	Proposed Total Burden Hours	Change in Total Burden Hours
§ 414.1400 Registry self- nomination	150	290	140	450	870	420
§ 414.1400 QCDR self-nomination	200	91	-109	2,400	2912	512
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type	257,260	109,951	-147,309	3,653,092	1,561,304	-2,091,788
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type	81,981	116,591	34,610	744,633	1,058,996	314,363
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type	51,861	51,787	-74	414,888	414,296	-592
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface	286	104	-182	17,637.7	6,413.7	-11,224
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface	67	51	-16	16.75	12.75	-4
(Quality Performance Category) Call for Quality Measures	140	26	-114	630	143	-487
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	6,041	6,025	-16	1,510	1,506	-4
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission	93,869	93,863	-6	250,317	250,301	-16
(Promoting Interoperability Performance Category) Call for Promoting Interoperability Measures	47	28	-19	23.5	14	-9.5
§ 414.1360 (Improvement Activities Performance Category) Data Submission	136,004	118,515	-17,489	11,334	9,876	-1,457
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities	125	128	3	250	256	6
§ 414.1430 Partial Qualifying APM Participant (QP) Election	81	2,024	1,943	20.25	506	485.75
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	215	110	-105	2,150	1,100	-1,050
§ 414.1440 Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	309	551	242	1,545	2,755	1,210
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants	11,617	11,516	-101	2,904.25	2,879	-25.25
TOTAL	**640,253**	**511,651**	**-128,602**	**5,103,801**	**3,314,118**	**-1,789,683**

*Currently approved under OMB control number 0938-1314 (CMS-10621).

Table 106 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this proposed rule. We have divided the reasons for our change in burden into those related to new policies and those related to adjustments in burden from continued Quality Payment Program Year 3 policies that reflect updated data and revised methods.

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TABLE 106: Reasons for Change in Burden Compared to the Currently Approved CY 2019 Information Collection Burdens

QPP Table	Changes in burden due to CY 2020 Proposed Rule policies	Adjustments in burden from continued CY 2019 Final Rule policies due to revised methods or updated data
Table 65: Qualified Registry Self-Nomination	None.	Increase in number of respondents due to availability of data indicating number of existing QCDRs which would not meet previously finalized QCDR requirements effective beginning in 2020 performance period.
Table 67: QCDR Self-Nomination	*Increase of 11.5 hours (1 hour per proposed measure) per QCDR self-nomination due to proposed policy to require QCDRs to provide a linkage between proposed QCDR measures and related cost measures, improvement activities, and MIPS Value Pathways.* *Increase of 5.75 hours (0.5 hour per proposed measure) per QCDR nomination due to proposed policy to require QCDRs to provide measure testing data at the time of self-nomination* *Increase of 0.25 hour per QCDR to describe the quality improvements services they intend to support as part of their self-nomination.*	Decrease in number of respondents due to availability of data indicating number of existing QCDRs which would not meet previously finalized QCDR requirements effective beginning in 2020 performance period. Increase in burden per respondent due to revised estimate of average number of measures per QCDR for which information is submitted.
Table 73: Quality Performance Category Medicare Part B Claims Collection Type	None.	Decrease in number of respondents due to use of updated data incorporating limitation on submission of quality data via Medicare Part B claims to small practices. Decrease in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 75: Quality Performance Category QCDR/ MIPS CQM Collection Type	None.	Increase in number of respondents due to use of updated data incorporating limitation on submission of quality data via Medicare Part B claims to small practices. and our assumption that affected clinicians will submit via the MIPS CQM collection type. Net decrease in total number of respondents (number of individual submitters decreased while the number of group submitters increased) due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 77: Quality Performance Category eCQM Collection Type	None.	Net decrease in total number of respondents (number of individual submitters decreased while the number of group submitters increased) due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.

QPP Table	Changes in burden due to CY 2020 Proposed Rule policies	Adjustments in burden from continued CY 2019 Final Rule policies due to revised methods or updated data
Table 79: Quality Performance Category CMS Web Interface	None.	Decrease in number of respondents due to updated data from the 2018 MIPS performance period.
Table 81: Registration for CMS Web Interface	None.	Decrease in number of respondents due to updated data from the 2018 registration period.
Table 83: Call for Quality Measures	*Increase of 1 hour per measure due to proposed requirement to link nominated measures to existing cost measures or improvement activities.*	Decrease in number of measures submitted due to updated data.
Table 86: Reweighting Applications for Promoting Interoperability and Other Performance Categories	None.	Decrease in number of applications submitted due to updated data.
Table 88: Promoting Interoperability Performance Category Data Submission	None.	Increase in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 90: Call for Promoting Interoperability Measures	None.	Decrease in number of measures submitted due to updated data.
Table 93: Improvement Activities Submission	None.	Decrease in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 95: Nomination of Improvement Activities	None.	Increase in number of activities nominated due to updated data.
Table 97: Partial QP Election	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 99: Other Payer Advanced APM Identification: Other Payer Initiated Process	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 101: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 103: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	None.	Decrease in the number of respondents due to updated projections for the number of voluntary participants in the 2020 MIPS performance period.

C. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 107: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number**	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*
§§ 403.902 and 403.904 ("Nature of Payment" Categories)***	0938-1237	400	400	5 - 30	5,895	44.92	264,804
		1,600	1,600	2 - 5	7,767	varies	410,941
§§ 403.902 and 403.904 (Standardizing Data Reporting for Covered Drugs, Devices, Biologicals, or Medical Supplies)***	0938-1237	450	450	20 - 100	24,840	44.92	1,115,813
		850	850	10 – 40	21,100	varies	1,013,740
		750	750	2 - 10	5,637	varies	311,384
Medicare Enrollment of Opioid Treatment Programs	0938-0685	633	633	2	1,900	37.50	262,523
Provider Agreement as Part of Enrollment Process	0938-0832-	633	633	0.167	53	varies	12,501
Quality Payment Program (See Subtotal Under Table 105)	0938-1314	379,749	-128,635	varies	-1,789,733	varies	-170,169,740
TOTAL		384,432	-123,919	Varies	-1,722,544	Varies	-166,778,034

* As it relates to the PRA, this rule will not impose any non-labor costs.

**OMB and CMS' PRA package ID numbers: OMB 0938-1237 (CMS-10495), OMB 0938-0685 (CMS-855B), and OMB 0938-1314 (CMS-10621).

***The burden for these changes to the Open Payments program represent one-time system changes.

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D. Submission of Comments

We have submitted a copy of this rule to OMB for its review of the rule's proposed information collection requirements and burden. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at *https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html*, or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on the proposed information collection requirements and burden. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1715–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule makes payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA), section 603 of the Bipartisan Budget Act of 2015, the Consolidated Appropriations Act of 2016, the Bipartisan Budget Act of 2018, and sections 2005 6063, and 6111 of the SUPPORT for Patients and Communities Act of 2018. This proposed rule also makes changes to payment policy and other related policies for Medicare Part B.

This proposed rule is necessary to make policy changes under Medicare fee-for-service. Therefore, we included a detailed regulatory impact analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explained the selection of these regulatory approaches that we believe adhere to statutory requirements and, to the extent feasible, maximize net benefits.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this proposed rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other

providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, *see* the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The PFS does not reimburse for services provided by rural hospitals; the PFS pays for physicians' services, which can be furnished by physicians and non-physician practitioners in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule, if finalized, is considered an E.O. 13771 regulatory action. We estimate the rule generates $3.46 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are proposing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2019 with payment rates for CY 2020 using CY 2018 Medicare utilization. The payment impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for CY 2015 and beyond. The update adjustment factor for CY 2020, as required by section 53106 of the Bipartisan Budget Act of 2018, is 0.00 percent before applying other adjustments.

To calculate the proposed CY 2020 CF, we multiplied the product of the current year CF and the update adjustment factor by the budget neutrality adjustment described in the preceding paragraphs. We estimated the CY 2020 PFS CF to be 36.0896 which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.00 percent update adjustment factor specified under

section 1848(d)(18) of the Act. We estimate the CY 2020 anesthesia CF to be 22.2774, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 108—CALCULATION OF THE PROPOSED CY 2020 PFS CONVERSION FACTOR

CY 2019 Conversion Factor		36.0391
Statutory Update Factor	0.00 percent (1.0000)	
CY 2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
CY 2020 Conversion Factor		36.0896

TABLE 109—CALCULATION OF THE PROPOSED CY 2020 ANESTHESIA CONVERSION FACTOR

CY 2019 National Average Anesthesia Conversion Factor		22.2730
Statutory Update Factor	0.00 percent (1.0000)	
CY 2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
CY 2020 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment.	−0.12 percent (0.9988)	
CY 2020 Conversion Factor		22.2774

Table 110 shows the payment impact on PFS services of the policies contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 110 (CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 110.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2018 utilization and CY 2019 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2020 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 110: CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	0%	0%	0%	0%
Anesthesiology	$1,993	0%	0%	0%	0%
Audiologist	$70	0%	0%	0%	1%
Cardiac Surgery	$279	-1%	-1%	0%	-1%
Cardiology	$6,595	0%	0%	0%	0%
Chiropractor	$750	0%	0%	-1%	-1%
Clinical Psychologist	$787	1%	2%	0%	3%
Clinical Social Worker	$781	0%	3%	0%	3%
Colon And Rectal Surgery	$162	0%	1%	0%	1%
Critical Care	$346	0%	0%	0%	1%
Dermatology	$3,541	0%	1%	-1%	0%
Diagnostic Testing Facility	$697	0%	-2%	0%	-2%
Emergency Medicine	$3,021	1%	0%	1%	1%
Endocrinology	$488	0%	0%	0%	0%
Family Practice	$6,019	0%	0%	0%	0%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	0%	0%	0%	0%
General Surgery	$2,031	0%	0%	0%	0%
Geriatrics	$187	0%	0%	0%	0%
Hand Surgery	$226	0%	0%	0%	1%
Hematology/Oncology	$1,673	0%	0%	0%	0%
Independent Laboratory	$592	0%	1%	0%	1%
Infectious Disease	$640	0%	0%	0%	0%
Internal Medicine	$10,507	0%	0%	0%	0%
Interventional Pain Mgmt	$885	0%	0%	0%	1%
Interventional Radiology	$432	0%	-2%	0%	-2%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	0%	0%	0%	1%
Neurology	$1,503	-1%	3%	0%	2%
Neurosurgery	$802	0%	0%	-1%	-1%
Nuclear Medicine	$50	0%	1%	0%	1%
Nurse Anes / Anes Asst	$1,291	0%	0%	0%	0%
Nurse Practitioner	$4,503	0%	0%	0%	0%
Obstetrics/Gynecology	$620	0%	1%	0%	1%
Ophthalmology	$5,398	-2%	-3%	0%	-4%
Optometry	$1,325	0%	-1%	0%	-2%
Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-2%
Orthopedic Surgery	$3,734	0%	0%	0%	1%
Other	$34	0%	0%	0%	1%
Otolarngology	$1,225	0%	0%	0%	0%
Pathology	$1,203	0%	0%	0%	0%
Pediatrics	$62	0%	0%	0%	0%
Physical Medicine	$1,110	0%	0%	0%	0%
Physical/Occupational Therapy	$4,248	0%	0%	0%	0%
Physician Assistant	$2,637	0%	0%	0%	0%
Plastic Surgery	$369	0%	0%	0%	0%
Podiatry	$1,998	0%	1%	0%	1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Portable X-Ray Supplier	$94	0%	0%	0%	0%
Psychiatry	$1,120	0%	0%	0%	1%
Pulmonary Disease	$1,658	0%	0%	0%	0%
Radiation Oncology And Radiation Therapy Centers	$1,756	0%	0%	0%	0%
Radiology	$4,971	0%	0%	0%	-1%
Rheumatology	$534	0%	0%	0%	0%
Thoracic Surgery	$352	-1%	0%	0%	-1%
Urology	$1,739	0%	1%	0%	1%
Vascular Surgery	$1,203	0%	-2%	0%	-2%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

* Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2020 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including clinical social workers, neurology, emergency medicine, and podiatry reflect increases relative to other physician specialties. These increases can largely be attributed to finalized increases in value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee and CMS review, increased payments as a result of finalized updates to supply and equipment pricing, and the continuing implementation of the adjustment to indirect PE allocation for some office-based services.

The estimated impacts for several specialties, including ophthalmology and optometry, reflect decreases in payments relative to payment to other physician specialties as a result of revaluation of individual procedures reviewed by the AMA's relative value scale update committee (RUC) and CMS. The estimated impacts for other specialties, including vascular surgery, reflect decreased payments as a result of continuing implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased-in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 1 percent increase for CY 2020 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 110), including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in Table 110 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 110 displays the estimated CY 2020 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2020 PFS proposed rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

c. Estimated Impacts Related to Proposed Changes for Office/Outpatient E/M Services for CY 2021

Although we are not proposing changes to E/M coding and payment for CY 2020, we are proposing certain changes for CY 2021. We provide the following impact estimate only for illustrative purposes. We believe these estimates provide insight into the magnitude of potential changes for certain physician specialties. Table 111 illustrates the estimated specialty level impacts associated with implementing the RUC-recommended work values for the office/outpatient E/M codes, as well as the revalued HCPCS add-on G-codes for primary care and certain types of specialty visits in 2020, rather than delaying until CY 2021.

TABLE 111: Estimated Specialty Level Impacts of Proposed E/M Payment and Coding Policies if Implemented for CY 2021

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Allergy/Immunology	$236	4%	3%	0%	7%
Anesthesiology	$1,993	-5%	-1%	0%	-7%
Audiologist	$70	-4%	-2%	0%	-6%
Cardiac Surgery	$279	-5%	-2%	-1%	-8%
Cardiology	$6,595	2%	1%	0%	3%
Chiropractor	$750	-5%	-3%	-1%	-9%
Clinical Psychologist	$787	-7%	0%	0%	-7%
Clinical Social Worker	$781	-7%	0%	0%	-6%
Colon And Rectal Surgery	$162	-3%	-1%	-1%	-4%
Critical Care	$346	-5%	-1%	0%	-6%
Dermatology	$3,541	0%	1%	-1%	-1%
Diagnostic Testing Facility	$697	-1%	-4%	0%	-4%
Emergency Medicine	$3,021	-6%	-2%	1%	-7%
Endocrinology	$488	11%	5%	1%	16%
Family Practice	$6,019	8%	4%	1%	12%
Gastroenterology	$1,713	-2%	-1%	-1%	-4%
General Practice	$405	5%	2%	0%	8%
General Surgery	$2,031	-3%	-1%	0%	-4%
Geriatrics	$187	2%	1%	0%	3%
Hand Surgery	$226	-1%	0%	0%	-1%
Hematology/Oncology	$1,673	8%	4%	1%	12%
Independent Laboratory	$592	-3%	-1%	0%	-4%
Infectious Disease	$640	-3%	-1%	0%	-3%
Internal Medicine	$10,507	2%	2%	0%	4%
Interventional Pain Mgmt	$885	4%	3%	1%	8%
Interventional Radiology	$432	-3%	-3%	0%	-6%
Multispecialty Clinic/Other Phys	$148	-2%	0%	0%	-2%
Nephrology	$2,164	-2%	0%	0%	-2%
Neurology	$1,503	2%	5%	0%	8%
Neurosurgery	$802	-3%	-1%	-2%	-6%
Nuclear Medicine	$50	-4%	0%	0%	-5%
Nurse Anes / Anes Asst	$1,291	-7%	-2%	0%	-9%
Nurse Practitioner	$4,503	5%	3%	0%	8%
Obstetrics/Gynecology	$620	4%	3%	0%	7%
Ophthalmology	$5,398	-4%	-5%	0%	-10%
Optometry	$1,325	-2%	-3%	0%	-5%
Oral/Maxillofacial Surgery	$71	-1%	-1%	-1%	-4%
Orthopedic Surgery	$3,734	-1%	0%	0%	-2%
Other	$34	-3%	-2%	0%	-5%
Otolarngology	$1,225	3%	2%	0%	5%
Pathology	$1,203	-5%	-3%	-1%	-8%
Pediatrics	$62	3%	2%	0%	6%
Physical Medicine	$1,110	-2%	0%	0%	-2%
Physical/Occupational Therapy	$4,248	-4%	-3%	0%	-8%
Physician Assistant	$2,637	4%	2%	0%	7%
Plastic Surgery	$369	-3%	-1%	-1%	-5%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Podiatry	$1,998	0%	1%	0%	1%
Portable X-Ray Supplier	$94	-1%	-3%	0%	-4%
Psychiatry	$1,120	4%	3%	0%	7%
Pulmonary Disease	$1,658	0%	1%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-2%	-2%	0%	-4%
Radiology	$4,971	-5%	-3%	0%	-8%
Rheumatology	$534	9%	5%	1%	15%
Thoracic Surgery	$352	-5%	-2%	-1%	-7%
Urology	$1,739	4%	4%	0%	8%
Vascular Surgery	$1,203	-2%	-3%	0%	-5%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

** Column F May Not Equal The Sum Of Columns C, D, And E Due To Rounding.*

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Overall, those specialties that bill higher level established patient visits, such as endocrinology or family practice, see the greatest increases as those codes were revalued higher relative to the rest of the office/outpatient E/M code set. Those specialties that see the greatest decreases are those that do not generally bill office/outpatient E/M visits. Other specialty level impacts are primarily driven by the extent to which those specialties bill using the office/outpatient E/M code set and the relative increases to the particular office/outpatient E/M codes predominantly billed by those specialties. We note that any potential coding changes and recommendations in overall valuation for new and existing codes between the CY 2020 proposed rule and the CY 2021 final rule could impact the actual change in overall RVUs for office/outpatient visits relative to the rest of the PFS. Given the various factors that will be considered by the variety of stakeholders involved in the CPT and RUC processes, we do not believe we can estimate with any degree of certainty what the impact of potential changes might be. We also, note, however, that any changes in coding and payment for these services would be subject to notice and comment rulemaking.

As discussed elsewhere in this section of the proposed rule, we estimate this approach would lead to burden reduction for practitioners, while allowing a year of preparatory time and time for potential refinement over the next year as we take into account any feedback from stakeholders on these proposed changes.

D. Effect of Proposed Changes Related to Telehealth

As discussed in section II.F. of this proposed rule, we are proposing to add three new codes, HCPCS codes GYYY1, GYYY2, and GYYY3, to the list of Medicare telehealth services for CY 2020. Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, we estimate there will only be a negligible impact on PFS expenditures from these additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. The restrictions placed on Medicare telehealth by the statute limit the magnitude of utilization; however, we believe there is value in allowing physicians and patients the greatest flexibility when appropriate.

E. Other Provisions of the Proposed Regulation

1. Effect of Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section II.G of this proposed rule, Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act establishes a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) for episodes of care beginning on or after January 1, 2020. The Substance Abuse and Mental Health Services Administration (SAMHSA) currently performs regulatory certification of OTPs. Currently, SAMHSA certifies about 1,700 OTPs. They are located predominately in urban areas, tend to be free-standing facilities, and provide a range of services, including medication-assisted treatment (MAT). The payor mix for OTPs currently includes Medicaid, private payors, TRICARE, as well as individual pay patients. The total estimated Part B net impact, including FFS and Medicare Advantage, over 10 years is $1,024,000,000. In developing this estimate, it was assumed that the average treatment length would be 12 months in duration and the average rate per week in CY 2020 was assumed to be $148, which is a weighted average of the rates we are proposing for the bundled payments for treatment with methadone, buprenorphine, and naltrexone. These rates were assumed to be updated annually by the Medicare Economic Index (MEI). We assumed that the impact in the first year would be reduced by 50 percent due to potential delays in provider certification and system modifications. Additionally, any change to fee-for-service benefits has an associated impact on payments to Medicare Advantage plans so an adjustment was made to reflect this, based on the projected distribution of spending in each year. The estimate also accounts for the impact on the program due to the change in the Part B premium as a result of this provision. The Part B enrollment and MEI assumptions were based on the President's Fiscal Year 2020 Budget baseline that was released in March of 2019. As with all estimates, and particularly those for new separately billable services, this outcome is highly uncertain because the available information on which to base estimates is limited and is not directly

applicable to a new Medicare payment. The cost and utilization estimates are based on Medicare and Medicaid claims data for beneficiaries with OUD, together with statistics about the types of services typically furnished at OTPs.

It is difficult for us to predict how coverage of OTPs will specifically affect the market. We anticipate current OTPs may expand access to care for Medicare beneficiaries since they will be able to receive payment from Medicare for services furnished to beneficiaries when they previously were unable to do so. Coverage may also create financial incentives to establish new OTPs. However, since TRICARE, Medicaid, and some private payers already pay for OTP services, it is less clear whether the presence of Medicare payment rates will have any effect on current rates for OTP services or on new rates should additional private coverage be established.

2. Changes to the Ambulance Physician Certification Statement Requirement

This proposed rule would clarify the requirements at §§ 410.40 and 410.41 regarding the requirements for physician certification and non-physician certification statements and expand the list of staff members who can sign non-physician certification statements. While we believe that clarification of the regulatory provisions associated with physician certification and non-physician certification statements is needed and would be well received by stakeholders, we do not believe that these clarifications would have any substantive monetary or impact the amount of time needed to complete the certification statements. We believe the primary benefit of the clarification would be for providers and suppliers in preparing and submitting the original certification statements. It is feasible the clarification could result in fewer claims being denied. However, hypothetically, these denials are likely a small subset of the ambulance claim denials and those denied for technical PCS issues are likely appealed and overturned.

Moreover, we have examined the impact of expanding the list of individuals who may sign the non-physician certification statement. This added flexibility in accessing additional individuals to sign a non-physician certification statement would be needed only when the physician was unavailable. Thus, while we anticipate that some providers would use the increased flexibility, the precise impact is not calculable.

3. Medicare Ground Ambulance Services Data Collection System

As discussed in section III.B.2. of this proposed rule, section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act, which requires the Secretary to develop a data collection system to collect cost, revenue, utilization, and other information determined appropriate with respect to providers and suppliers of ground ambulance services. In section III.B.4 through III.B.7. of this proposed rule, we describe our proposals that would implement this section, including the data that would be collected through the data collection system, sampling methodology, requirements for reporting data, payment reductions that would apply to ground ambulance providers and suppliers that fail to sufficiently report data and that do not qualify for a hardship exemption, informal review process that would be available to ground ambulance providers and suppliers that are subject to a payment reduction, and our policies for making the data available to the public.

We estimate that ground ambulance providers and suppliers would need to engage in two primary activities with respect to these proposals, both of which would require them to incur cost and burden: Data collection and data reporting. The data collection activity includes: (1) Reviewing instructions to understand the data required for reporting; (2) accessing existing data systems and reports to obtain the required information; (3) obtaining required information from other entities where appropriate; and (4) if necessary, developing processes and systems to collect data that are not currently collected, but that they would be required to report under the data collection system. The data reporting activity includes entering the collected information in CMS's proposed web-based data collection system.

To estimate the data collection impact, we assumed that each ground ambulance organization that is selected to submit data for a year would take up to 20 hours to collect the required data, which would include 4 hours to review the instructions and 16 hours to collect the required data. These estimates were informed by our discussions with ambulance organizations during stakeholder engagements and through more in-depth interviews with nine ambulance organizations for the purpose of soliciting feedback on data collection instrument items as described in section III.B.3. and III.B.4. of this proposed rule. Most participants indicated that they would be able to provide some of the required information with an investment of 1–2 hours and complete information with additional hours to collect the missing data. Many participants indicated that they would need to reach out to other staff at the organization, at contracted organizations (such as billing companies), or at other entities (such as municipal government financial staff for government ambulance organizations) to collect required information that was not in the organization's accounting or billing systems. Some participants indicated that their organization would need to adjust data collection processes or collect new data over the course of a year to ensure that required data was available in the appropriate format prior to submission.

Actual data collection and reporting will vary depending on the mix of employees at sampled ambulance organizations, the staff with available time to dedicate to data collection and data reporting activities at each organization, the staff in different roles that already perform similar activities in each organization, and whether billing services are contracted out or conducted internally.

Because we expect that the staff (by category) that will contribute to data collection and reporting will be highly variable across ground ambulance organizations, we calculated a blended mean wage for the purposes of estimating burden. Table 112 lists the Standard Occupational Classification (SOC) categories contributing to the blended wage, the mean wage for each SOC specific to North American Industry Classification System (NAICS) industry code 621910 (Ambulance Services), and the relative contribution of each SOC to the blended mean. The source mean wage and employment data is from the Bureau of Labor Statistics May 2018 Occupational Employment Statistics data (available from *https://download.bls.gov/pub/time.series/oe/*) for the indicated SOC and NAICS codes, which was most recently available wage and employment data set. We assumed that financial clerks (SOC category 433000) would account for 25 percent of the total data collection and reporting effort, and that six other SOC categories would contribute to the remaining 75 percent (*see* Table 112).

TABLE 112—ESTIMATED MEAN HOURLY WAGES FOR OCCUPATIONS INVOLVED IN DATA COLLECTION

D–6	Mean hourly wage ($)	Weight (% effort) *
Top Executives (111000)	51.49	17
Other Management Occupations (119000)	39.23	12
Business and Financial Operations Occupations (130000)	28.60	15
Secretaries and Administrative Assistants (436010)	18.11	10
Other Office and Administrative Support Workers (439000)	16.20	10
Financial Clerks (433000)	18.51	25
First-Line Supervisors of Office and Administrative Support Workers (431011)	27.92	10
Blended Mean Hourly Wage	28.91	100

* **Note:** Weights may not sum to 100 percent due to rounding. Source: Bureau of Labor Statistics Occupational Employment Statistics, May 2018, available from *https://download.bls.gov/pub/time.series/oe/.*

In addition, we calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. Although we recognize that fringe benefits and overhead costs may vary significantly by employer, and that there are different accepted methods for estimating these costs, doubling the mean blended wage rate to estimate total cost is an accepted method to provide a reasonably accurate estimate. Therefore, assuming a mean blended wage of $28.91 for data collection, and assuming the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, we calculated at a wage plus benefits estimate of $57.82 per hour of data collection. To calculate at the total data collection cost per sampled ground ambulance organization, we multiplied the time required for data collection by the burdened hourly wage (20 hours * $57.82/hour) for a total of $1,156.

We discussed several sampling options in section III.B.5. of this proposed rule. Our proposed sampling rate of 25 percent would yield an expected 2,690 respondents in the first sample, resulting in a total estimated data collection cost of $3,110,684 (2,690 respondents * $1,156 per respondent).

To estimate the cost of data reporting, we assumed it will require 3 hours to enter, review, and submit information into the proposed web-based data collection system. The estimate of 3 hours was also informed by interviews with nine ambulance organizations to solicit feedback on the data instrument items under consideration. We included time for staff to review the collected data before entering it into the data collection system. We also assumed that staff responsible for reporting the data would have the same blended hourly wage used to estimate data collection costs above ($28.91) as the staff that collected the data. Again, assuming the cost of overhead at 100 percent of the mean hourly wage, we calculated at a wage plus benefits estimate of $57.82. Therefore, we estimate a per-respondent cost for data submission of $173.46 (3 hours * $57.82/hour). To calculate the total cost for data reporting under a 25 percent sampling rate, we multiplied the number of ground ambulance organizations sampled annually by the time required for data entry times the total hourly wage estimate, for a total of $466,603 across all respondents (2,690 respondents * 3 hours * $57.82/hour).

Adding the total data collection and reporting costs yields a total annual impact for ground ambulance organizations of $3,577,287 ($3,110,684 for data collection [2,690 respondents * 20 hours * $57.82/hour] + $466,603 total cost for data submission [2,690 respondents * 3 hours * $57.82/hour]) with a 25 percent sampling rate. Our estimate of total annual impact would be lower at $1,430,649 ($1,244,042 for data collection [1,076 respondents * 20 hours * $57.82/hour] + $186,606 for data submission [1,076 respondents * 3 hours * $57.82/hour]) under a 10 percent sampling rate alternative and higher at $7,153,244 ($6,220,212 for data collection [5,379 respondents * 20 hours * $57.82/hour] + $933,032 for data submission [5,379 respondents * 3 hours * $57.82/hour]) under a 50 percent sampling rate. In all cases, the estimated cost of collecting and reporting data is $1,330 per organization sampled ($1,156 for data collection [20 hours * $57.82/hour] + $173.46 for data submission [3 hours * $57.82/hour]). The per-organization estimate reflects an average. Based on discussions with ambulance organizations to provide feedback on instrument items, we do not anticipate that larger or smaller ambulance organizations in terms of transport volume, costs, or revenue will face systematically more or less burden in data collection or reporting. While larger organizations generally have higher transport volumes, costs, and revenue, and more complex financial arrangements that may increase reporting burden, they also tend to have existing data collection and reporting processes and staff that will reduce the additional effort required to submit the required data. On the other hand, while smaller organizations have less data to collect and report, they may not have current processes in place to begin collecting some required data.

b. Hardship Exemption Process

As discussed in section III.B.7.b. of this proposed rule, we are proposing a process for ground ambulance organizations to request and for CMS to grant significant hardship exemptions from the 10 percent payment reduction. To request a significant hardship exemption, we are proposing that a ground ambulance organization would be required to complete and submit a request form that we would make available on the Ambulances Services Center website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.*

We estimate that 25 percent of the total number of ground ambulance organizations will be selected each year as the representative sample to report the required information under the data collection system. That is, 25 percent out of the total 10,758 NPIs, or 2,690 ambulance providers and suppliers.

While we expect that few, if any, ground ambulance organizations will request a hardship exception, we do not have experience in collecting data from ground ambulance organizations that could be used to develop an estimate, so we are basing our estimate on the total number of organizations being surveyed. As a result, we estimate that a total of 2,690 ground ambulance organizations would apply for a hardship exemption, and that it would take 15 minutes for each of these ground ambulance organizations 15 minutes to complete and submit the request form.

We assumed for purposes of this estimate that the mix of staff responsible for completing this form would have the same blended hourly wage used to estimate the data collection and data reporting costs. We also calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, as we did above. As a result, we estimated that the total cost burden associated with the completion and submission of the hardship exemption request form would be approximately $38,884.

c. Informal Review Process

As discussed in section III.B.7.c. of this proposed rule, we are proposing a process in which a ground ambulance organization may seek an informal review of our determination that it is subject to the 10 percent reduction.

We estimate that a collection of information burden of 15 minutes for a ground ambulance provider or supplier who is requesting an informal review to gather the requested information and send an email to our AMBULANCEODF mailbox.

Again, we are using the total number of ambulance organizations survey each year to develop our estimates. Therefore, a total of 40,350 minutes (15 × 2,690) or 672.5 hours for 2,690 ambulance providers and suppliers to complete this form. Taking into account the same blended mean hourly wage and fringe benefits as we did for our other estimates, we estimate that the total for all sampled ambulance providers and suppliers to submit the form would be approximately $38,884.

4. Intensive Cardiac Rehabilitation (ICR)

As discussed in section III.C. of this proposed rule, we are adding stable, chronic heart failure (CHF) (defined as patient with left ventricular ejection fraction of 35 percent or less and NYHA class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks) to the list of covered conditions for ICR, as well as, the ability for use to use the NCD process to add additional covered conditions for ICR. Heart failure impacts approximately 5.7 million adults,[141] and approximately 80 percent of individuals over age 65 have heart failure.[142] (The majority (86 percent) of Medicare beneficiaries are over age 65.[143]) We estimate 4,560,000 beneficiaries over age 65 have heart failure.

The uptake by beneficiaries has historically been low for CR and ICR. From February 2014 to 2017, after stable CHF was added to the covered conditions for CR, only 439,888 claims were processed for this service with a diagnosis code of CHF. Less than 1 percent of beneficiaries with heart failure utilized CR. Given that the uptake of ICR has been even lower than CR, we expect the same trend (low uptake) for intensive cardiac rehabilitation due to the nature of these programs which entail rehabilitation through lifestyle modification. We conducted a claims analysis that examined claims prior to and after a 2014 NDC that added stable CHF to the list of covered conditions for CR. Prior to the implementation of stable CHF as a covered condition for CR, 1.8 percent of claims for CR included a diagnosis code for CHF. After implementation, 4.7 percent of claims for CR included a diagnosis code for CHF. Therefore, for ICR, which has historically been utilized much less than CR (for example, when all CR and ICR claims are combined, only 1 percent of the claims are for ICR), we anticipate there may be a similar slight percentage increase in claims for ICR for treatment of stable CHF. Assuming a 4.7 percent increase in ICR claims due to adding stable CHF as a covered condition, we estimate an increase of 3,378 claims annually. For 2019, the facility and non-facility prices for CR and ICR are the same, and the average price is $120.93. Therefore, based on our estimated increase in claims, at an average price of $120.93, the estimated total cost of adding stable, chronic heart failure to the list of covered conditions for ICR is estimated at $408,502 annually. From 2010–2017, the median number of ICR visits per calendar year was 18 visits per beneficiary. Therefore, based on our expected increase in the number of claims (3,378), the estimated number of beneficiaries covered would be 187. Based on these estimates, we estimate there will only be a negligible impact on Medicare expenditures from this proposed change.

Additionally, we do not anticipate providers currently offering ICR would need to obtain any specialized technology and equipment to treat ICR patients with stable CHF beyond what they would obtain for ICR patients seeking treatment for the existing six covered conditions.

When this proposed rule is finalized, we will cover the seven cardiac conditions that constitute the vast majority of cardiac conditions that CR and ICR can treat. Due to the breadth of the proposed and existing covered conditions, we do not anticipate the need to use the NCD process to add additional covered conditions to CR and ICR in the near future.

Lastly, while CR and ICR have low utilization at this point in time, an increase in the number of CR and/or ICR providers in underserved areas could result in an increase in utilization due to increased availability/proximity to services. However, we are not able to accurately quantify the number of entities that would seek approval as CR or ICR programs. Additionally, we acknowledge, that the expansion of coverage to ICR could generate attention around the importance of CR/ICR and may increase beneficiary utilization.

5. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

In the Medicaid Promoting Interoperability Program, to keep electronic clinical quality measure (eCQM) specifications current and minimize complexity, we propose to align the eCQMs available for Medicaid EPs in 2020 with those available for MIPS eligible clinicians for the CY 2020 performance period. We anticipate that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, as many EPs are expected to report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on those eCQMs for 2020. Not implementing this alignment could lead to increased burden because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program, if they opt to report on newly added eCQMs for MIPS. We expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2020 to maintain current eCQM lists and specifications. State expenditures to make any systems changes required as a result of this proposal would be eligible for 90 percent Federal financial participation.

For 2020, we propose to require that Medicaid EPs report on any six eCQMs that are relevant to the EP's scope of practice, including at least one outcome

[141] Centers for Disease Control, Heart Failure Fact Sheet, *https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_heart_failure.htm.*

[142] Vigen, Rebecca et al. ''Aging of the United States population: impact on heart failure.'' Current heart failure reports vol. 9,4 (2012): 369–74. doi:10.1007/s11897–012–0114–8.

[143] CMS, 2019 Fast Facts, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html.*

measure, or if no applicable outcome measure is available or relevant, at least one high priority measure, regardless of whether they report via attestation or electronically. This policy would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established in § 414.1335(a)(1). If no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, he or she could report on any six eCQMs that are relevant. This proposal would be a continuation of our policy for 2019 and we believe it would create no new burden for EPs or states.

We also propose that the 2020 eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program who have demonstrated meaningful use in a prior year would be a minimum of any continuous 274-day period within CY 2020. We are proposing to shorten the reporting period from a full calendar year to enable states to take attestations for 2020 as early as October 1, 2020. We believe this would improve states' flexibility as they move toward the end of the Medicaid Promoting Interoperability Program and the December 31, 2021 statutory deadline to make incentive payments. This should add no additional burden for EPs or CEHRT vendors, as Certified EHR Technology (CEHRT) should be able to run eCQM reports for any number of days and during any time period. The proposed eCQM reporting period would be a minimum and EPs could continue to report on a full calendar year if they wish. As in previous years, the 2020 eCQM reporting period for EPs attesting to meaningful use for the first time would be any continuous 90-day period within the calendar year.

Finally, we are proposing to change Medicaid policy for 2021 related to EP Meaningful Use Objective 1, Measure 1 (Conduct or review a security risk analysis (SRA)). We are proposing to allow Medicaid EPs to conduct an SRA at any time during CY 2021, even if the EP conducts the SRA after attesting to meaningful use of CEHRT to the state. A Medicaid EP who has not completed an SRA for CY 2021 by the time he or she attests to meaningful use of CEHRT for CY 2021 would be required to attest that he or she will complete the required SRA by December 31, 2021. Currently, this measure must be completed in the same calendar year as the EHR reporting period. This may occur before, during, or after the EHR reporting period, though if it occurs after the EHR reporting period it must occur before the provider attests to meaningful use of CEHRT or before the end of the calendar year, whichever comes first. In practice, this means that EPs do not attest to meaningful use of CEHRT before completing this measure. However, due to the changes we previously made to the EHR and eCQM reporting period timelines for CY 2021, all Medicaid EPs are expected to attest to meaningful use of CEHRT on or before October 31, 2021. Accordingly, if we did not propose to change the deadline for conducting the SRA, Medicaid EPs would no longer have the option of completing an SRA at the end of the calendar year, and would likely have to complete one well before December 2021. If an EP typically conducts the security risk analysis at the end of each year, this timeline could create burden for the EP, and may not be optimal for protecting information security, because it could disrupt the intervals between security risk analyses. We have also heard feedback from health care providers that SRAs are generally conducted for a whole clinic and the current requirement would create burden on non-EP health care providers in 2021. We believe our proposal would prevent additional burden for both EPs and non-EP health care providers.

This proposal could create burden for states, as they might have to adjust their pre-payment and post-payment verification plans and conduct more thorough audits for this meaningful use objective. However, states are already required to conduct adequate oversight of the Medicaid Promoting Interoperability Program, including routine tracking and verification of meaningful use attestations (*see* 42 CFR 495.318(b), 495.332(c), and 495.368), and we are not proposing to change that requirement for 2021. We have established at 42 CFR 495.322(b) that 90 percent Federal financial participation will be available for state administrative expenditures related to Medicaid Promoting Interoperability Program audits and appeals that are incurred on or before September 30, 2023.

6. Medicare Shared Savings Program

In section III.F.1.b. of this proposed rule, we summarize certain modifications to the quality measure set used to assess the quality performance of ACOs participating in the Shared Savings Program based on proposed changes made to the CMS Web Interface measures under the Quality Payment Program in section III.I.3.b.(1). Specifically, we are proposing: (1) The addition of one CMS Web Interface measure; (2) the removal of one CMS Web Interface Measure; (3) revisions to the numerator guidance for ACO–17—Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention; and (4) reverting ACO–43—Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) to pay-for-reporting for 2 years to account for a substantive change in the measure.

The net result of these proposed modifications to the Shared Savings Program quality measure set would be a measure set of 23 measures. These proposed changes would have no impact on the number of measures an ACO is required to report; therefore, there is no expected change in reporting burden for ACOs.

7. Open Payments

a. Expanding the Definition of ''Covered Recipient'' (§§ 403.902, 403.904, and 403.908)

Our initial estimate based on the available information is that there will be approximately $10 million dollar per year in increased burden to reporting entities and the new covered recipient groups for submitting, collecting, retaining, and reviewing data. This estimate is based on existing burden calculations. It assumes that there will be 734,000 new records (~7 percent increase) reported about 205,000 (~33 percent increase) covered recipients.

We also believe there will be costs to reporting entities for updating their systems and reporting processes. However, we are unable to estimate these costs because they will vary depending on the reporting entity's individual circumstances.

As explained in section IV.5. of this proposed rule, section 6111(c) of the SUPPORT Act states that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the changes to the definition of a covered recipient. Therefore, a detailed breakdown is not provided in that section. The above estimates however, do provide a regulatory impact analysis of this provision.

b. Modification of the ''Nature of Payment'' Categories (§§ 403.902 and 403.904)

We anticipate minor additional costs for system updates associated with our proposed provision to modify the ''nature of payment'' categories. As we indicated in section III.F. of this proposed rule, said provisions are intended to add clarity. They will not increase the amount of information to be reported. Data already reported to us may simply be reported in a different category. We propose these changes

only to be made prospectively and do *not* propose to have manufactures and GPOs to make changes to previously reported data. This provision would, generally speaking, allow reporting entities to better characterize the nature of a payment and would not constitute a new requirement. Hence, the expected impact is minimal.

c. Standardizing Data Reporting (§§ 403.902 and 403.904)

Approximately 850 entities (approximately 53 percent), have reported a transaction that could require the addition of a device identifier if this proposed rule becomes final. The total cost of the addition of this new data element cannot be estimated because it would depend on: (1) Whether the entity already tracks this data element and (2) the extent to which the entity would need to update their system to be able to report this data element.

8. Medicare Enrollment of Opioid Treatment Programs

As stated previously in this proposed rule, we propose that OTP providers be required to not only enroll in Medicare, but also (1) pay an application fee at the time of enrollment and (2) submit a set of fingerprints for a national background check (via FBI Applicant Fingerprint Card FD–258) from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the OTP.

a. Application Fee

The application fees for each of the past 3 calendar years (CY) were or are $560 (CY 2017), $569, (CY 2018), and $586 (CY 2019). Consistent with § 424.518, the differing fee amounts were predicated on changes/increases in the Consumer Price Index (CPI) for all urban consumers (all items; United State city average, CPI–U) for the 12-month period ending on June 30 of the previous year. While we cannot predict future changes to the CPI, we note that the fee amounts between 2017 and 2019 increased by an average of $13 per year. We believe this is a reasonable barometer with which to establish estimates (strictly for purposes of this proposed rule) of the fee amounts in the first 3 CYs of this rule (that is, 2020, 2021, and 2022). We thus project a fee amount of $599 in 2020, $612 for 2021, and $625 for 2022.

Applying these prospective fee amounts to the number of projected applicants in the rule's first 3 years, we estimate a cost to enrollees of $1,058,433 (or 1,767 × $599) in the first year, $41,004 (or 67 × $612) in the second year, and $41,250 (or 66 × $625) in the third year.

b. Fingerprinting

Based on the experiences of the provider community to date, we estimate that it would take each owner (BLS: Top Executives) approximately 2 hours at $123.32/hr to obtain and submit the fingerprints. (According to the most recent BLS wage data for May 2018, the mean hourly wage for the general category of ''Top Executives'' is $61.66 (*see http://www.bls.gov/oes/current/oes_nat.htm#43-0000).* With fringe benefits and overhead, the figure is $123.32.)

As mentioned in the preamble of this proposed rule, SAMHSA statistics indicate that there are currently about 1,677 active OTPs; of these, approximately 1,585 have full certifications and 92 have provisional certifications.

Although we do not have specific data on the matter, we project, for purposes of our proposed burden estimates, a total of 1,500 such direct or indirect ownership interests in OTP providers that would require the submission of fingerprints over the first 3 years. This 1,500 figure is less than the 1,900 projected applicants (discussed in the ICR section of this rule) in the first 3 years following the final rule's publication because some applicants may have non-profit business structures and, thus, would not have owners. Furthermore, our estimation of individual owners who would qualify to submit fingerprints is based on a sampling of similar provider types, including DMEPOS suppliers (high risk), MDPP suppliers (high risk), rural health clinics (limited risk) and others.

Applying this figure to the aforementioned per year breakdown of applicants, we estimate a first year burden of 2,790 hours at a cost of $344,063 (2,790 hr × $123.32/hr). We obtained the 2,790 hour estimate by first dividing 1,767 (the number of first-year applicants) by 1,900, resulting in a figure of 0.93. We then multiplied 0.93 by 1,500 (the number of ownership interests over the 3-year period) and thereafter by 2 hours.

Applying this same formula, we project a second-year time estimate of 106 hours (or 0.0353 × 1,500 applicants × 2 hr) at a cost of $13,072 (106 hr × $123.32/hr), and a third-year estimate of 104 hours (or 0.0347 × 1,500 applicants × 2 hr) at a cost of $12,825 (104 hr × $123.32/hr). In aggregate, we estimate a burden of 3,000 hours (2,790 hr + 106 hr + 104 hr) at a cost of $369,960 ($344,063 + $13,072 + $12,825). When annualized over the 3-year period, we estimate an annual burden of 1,000 hours (3,000 hours/3) at a cost of $123,320 ($369,960/3).

9. Deferring to State Scope of Practice Requirements

a. Ambulatory Surgery Centers

As of May 2019 there were 5,767 Medicare-participating ASCs. We are proposing to revise § 416.42 to allow an anesthetist, or a physician, to perform the required examination before surgery for anesthesia risk and of the procedure to be performed. We proposed this revision to reduce ASC compliance burden and provide for patient assessment and care continuity while maintaining patient safety and care. At § 416.42(a)(1), we propose to allow an anesthetist, in addition to a physician, to perform the required pre-surgical risk and evaluation examination. This change would provide flexibility and allow either a physician or an anesthetist to perform the pre-surgical examination. In total, ASCs provided about 6.4 million services in 2016.[144] We assume that 30 percent of all procedures would utilize the services of a nurse anesthetist instead of a physician for this requirement, which would reduce the cost of the examination. We estimate the pre-surgical evaluation to take 15 minutes to complete. We are assuming these estimates based on previous experience and conversations with stakeholders. We acknowledge the uncertainty with these estimates and invite public comment on our assumptions to articulate the most accurate information in the final rule calculations. According to 2018 Bureau of Labor Statistics data, the hourly cost for a physician (including fringe benefits and overhead calculated at 100 percent of the mean hourly wage) is approximately $203 ($51 for 15 minute evaluation), and the hourly cost for a nurse anesthetist is approximately $168 ($42 for 15 minute evaluation). Assuming 1.92 million procedures annually, we can predict a savings of approximately $17.3 million (($51 − $42) × 1.92 million). We have used our best estimate as to the percentage of pre-surgical evaluations by anesthetists overall, however, we welcome any comments and evidence-based information that would inform our ability to provide the most accurate cost savings estimates.

b. Hospice

We are proposing to revise § 418.106 to permit hospices to accept orders for drugs from attending physicians who are physician assistants. We do not

[144] MEDPAC, Ambulatory surgical centers services 2017, p. 136.

believe that are any associated financial impacts for hospices.

10. Changes Due to Updates to the Quality Payment Program

In section III.K. of this proposed rule, we included our proposed policies for the Quality Payment Program. In this section of the proposed rule, we present the overall and incremental impacts to the number of expected QPs and associated APM Incentive Payments. In MIPS, we estimate the total MIPS eligible population and the payment impacts by practice size for the 2020 MIPS performance period based on various proposed policies to modify the MIPS final score and the proposed new performance threshold and additional performance threshold.

Although the submission period for the second MIPS performance period ended in early 2019, the final data sets were not available in time to incorporate into the CY 2020 PFS proposed rule analysis. We intend to use data from the 2018 MIPS performance period for the final rule.

a. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

From 2019 through 2024, through the Medicare Option, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs, for the applicable performance period, will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. In addition, beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The APM Incentive Payment is separate from and in addition to the payment for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year would not need to report to MIPS and would not receive a MIPS payment adjustment to their Part B PFS payments. Eligible clinicians who do not become QPs, but meet a lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs will not receive the APM Incentive Payment. For the 2020 QP Performance Period, we define Partial QPs to be eligible clinicians in Advanced APMs who collectively have at least 40 percent, but less than 50 percent, of their payments for Part B covered professional services through an APM Entity, or collectively furnish Part B covered professional services to at least 25 percent, but less than 35 percent, of their Medicare beneficiaries through an APM Entity. If the Partial QP elects to be scored under MIPS, they would be subject to all MIPS requirements and would receive a MIPS payment adjustment. This adjustment may be positive, negative, or neutral. If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although the statute establishes overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the fourth payment year (2022 payment year) of the Quality Payment Program in detail.

In section III.K.4.e.(3)(b)(ii) of this proposed rule, we propose to amend the marginal risk standard finalized in § 414.1420(d)(5) by amending paragraph (d)(5)(i) to provide that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in with exceptions for large losses and small losses as described in 414.1420(d). We do not yet have experience with QP and Partial QP Determinations under the All-Payer Combination Option as it will be operational for the first time this fall. To date, we have only determined a modest number of payment arrangements from non-Medicare payers that meet the Other Payer Advanced APM criteria. However, we expect this added flexibility in the marketplace may increase the number of arrangements in this category. Based on our analysis there are 12,000 providers within 5 percent of performance year 2020 QP thresholds in Advanced APMs, and therefore, could potentially benefit from participation in Other Payer Advanced APMs. Assuming a static marketplace, there are between 50–100 eligible clinicians that would benefit from the change in the marginal risk requirement at this time (that is, in 2020 QP performance period). This is because there are likely to be only a small number of eligible clinicians who both (1) participate in the models we determined were not Other Payer Advanced APMs, but would become Other Payer Advanced APMs under the proposed policy, and (2) have QP scores just below the QP threshold. While this number may grow in the future as payers adopt payment arrangements designed to reflect the change in the marginal risk requirement, we anticipate the incremental impact of this proposal will have a small impact on the number of clinicians that meet the QP threshold and the total number of payment arrangements that are determined to be Other Payer Advanced APMs.

Overall, we estimated that between 175,000 and 225,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum APM incentive payment based on 5 percent of their Part B allowable charges for covered professional services in the preceding year. These allowable charges for QPs are estimated to be between approximately $9,000 million and $12,000 million in total for the 2020 performance year. The analysis for this proposed rule used the APM Participation Lists for the Predictive QP determination file for 2019. We estimate that the total lump sum APM Incentive Payments will be approximately $500–600 million for the 2022 Quality Payment Program payment year.

In section VI.E.10., we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2020 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2020 QP

Performance Period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2020 QP Performance Period:

- Next Generation ACO Model, Comprehensive Primary Care Plus (CPC+) Model;
- Comprehensive ESRD Care (CEC) Model (Two-Sided Risk Arrangement);
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative);
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Oncology Care Model (Two-Sided Risk Arrangements);
- Medicare ACO Track 1+ Model;
- Bundled Payments for Care Improvement Advanced;
- Maryland Total Cost of Care Model (Maryland Care Redesign Program; Maryland Primary Care Program);
- Primary Care First; and
- Medicare Shared Savings Program (Track 2, Basic Track Level E, and the ENHANCED Track).

We used the APM Participant Lists and Affiliated Practitioner Lists, as applicable, (*see* 81 FR 77444 through 77445 for information on the APM participant lists and QP determinations) for the Predictive QP determination file for 2019 to estimate QPs, total Part B allowed charges for covered professional services, and the aggregate total of APM incentive payments for the 2020 QP Performance Period. We examine the extent to which Advanced APM participants would meet the QP Thresholds of having at least 50 percent of their Part B covered professional services or at least 35 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

b. Estimated Number of Clinicians Eligible for MIPS Eligibility

(1) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior To Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the 2020 MIPS performance period in this proposed rule, our scoring model used the first determination period from the 2018 MIPS performance period eligibility file as described in the CY 2018 Quality Payment Program final rule (82 FR 53587 through 53592). The first determination period from the 2018 MIPS performance period eligibility file was selected to maximize the overlap with the performance period data used in the model. In addition, since the low-volume threshold was finalized in the CY 2019 PFS final rule (83 FR 60075) to be based on covered professional services (services for which payment is made under, or is based on, the PFS and that are furnished by an eligible clinician), this eligibility file provided the information to base the low-volume threshold on covered professional services rather than all items and services under Part B. We included 1.5 million clinicians (*see* Table 113) who had PFS claims from September 1, 2016 to August 31, 2017 and included a 30-day claim run-out. We excluded from our analysis individual clinicians who were affected by the automatic extreme and uncontrollable policy finalized for the 2017 MIPS performance period/2019 MIPS payment year in the CY 2019 PFS final rule (83 FR 59876) as we are unable to predict how these clinicians would perform in a year where there was no extreme and uncontrollable event.

Clinicians are ineligible for MIPS (and are excluded from MIPS payment adjustment) if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group. Therefore, we excluded these clinicians when calculating those clinicians eligible for MIPS. We also excluded clinicians participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration for whom the waivers of MIPS reporting requirements and the associated payment consequences are applicable, as finalized in the CY 2019 PFS final rule (83 FR 59890).

For the estimated MIPS eligible population for the 2022 MIPS payment year, we restricted our analysis to clinicians who are a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); a physical therapist, occupational therapist, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional as finalized in the CY 2019 PFS final rule (83 FR 60076).

As noted previously, we excluded QPs from our scoring model since these clinicians are not MIPS eligible clinicians. To determine which QPs should be excluded, we used the QP List for the 2019 predictive file that contains current participation in Advanced APMs as of January 15, 2019, using all available data because these data were available by TIN and NPI, could be merged into our model and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2020 QP performance period. We assumed that all Partial QPs would elect to participate in MIPS and included them in our scoring model and eligibility counts. The projected number of QPs excluded from our model is 124,413 for the 2019 QP performance period due to the expected growth in APM participation. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2020 Medicare QP Performance Period; hence, our model may underestimate or overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We also excluded newly enrolled Medicare clinicians from our model. To identify newly enrolled Medicare clinicians, we used the indicator that was used for the 2017 MIPS performance period/2019 MIPS payment year. Finally, we excluded the MAQI participants with a MIPS exclusion for the 2019 MIPS performance period.

(b) Assumptions Related To Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (that is, TIN/NPI) or group (that is, TIN or APM entity) levels based on how data are submitted or at the APM Entity level if the clinician is part of a MIPS APM Entity scored under the APM scoring standard. To determine who is a MIPS APM participant, we used the latest 2019 predictive file that contains current participation in MIPS APMs as of January 15, 2019, using all available data. We identified all clinicians in our eligible population who are in the 2019 predictive file and evaluated them as an APM Entity. We also evaluated clinicians as APM Entities if they are in our eligible population and associated with an APM Entity for the 2017 performance period but are no longer billing for Medicare (because they may have changed practices).[145] If a MIPS

[145] A total of approximately 222,000 clinicians were included in our model and scored using the APM scoring standard. These clinicians are represented in the individual and group eligibility

eligible clinician is determined to not be scored as a MIPS APM, then their reporting assumption is based on their reporting for the CY 2017 MIPS performance period. If no data are submitted and the TIN/NPI is not associated with an APM Entity during the performance period, then the low-volume threshold is applied at the TIN/NPI level. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment.

Table 113 presents the estimated MIPS eligibility status and the associated PFS allowed charges for the 2020 MIPS performance period after using Quality Payment Program Year 1 data and applying the proposed policies for the 2020 MIPS performance period.

For the purposes of modeling, we made assumptions on group reporting to apply the low-volume threshold. One extreme and unlikely assumption is that no practices elect group reporting and the low-volume threshold would always be applied at the individual level. Although we believe a scenario in which only these clinicians would participate as individuals is unlikely, this assumption is important because it quantifies the minimum number of MIPS eligible clinicians. For this proposed rule model, we estimate there were approximately 221,000 clinicians [146] who would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 113, we identify clinicians under this assumption as having ''required eligibility.''

We anticipate that groups that submitted to MIPS as a group will continue to do so for the CY 2020 MIPS performance period. Using this group assumption and including those identified with MIPS APM entities in our scoring model, we increased the number of MIPS eligible clinicians by 566,000 clinicians. In Table 113, we identify these clinicians who do not meet the low-volume threshold individually but are anticipated to submit to MIPS as a group or MIPS APM as having ''group eligibility.'' With the availability of CY 2017 Quality Payment Program Year 1 data, we can identify group reporting through the submission of improvement activities, Promoting Interoperability, or quality performance category data.

To model the opt-in policy finalized in the CY 2019 PFS final rule (83 FR 59735), we assumed that 33 percent of the clinicians who exceed at least one but not all low-volume threshold criteria and submitted data to CY 2017 MIPS performance period would elect to opt-in to MIPS. We selected a random sample of 33 percent of clinicians without accounting for performance. We believe this assumption of 33 percent opt-in participation is reasonable because some clinicians may choose not to submit data due to performance, practice size, or resources or alternatively, some may submit data, but elect to be a voluntary reporter and not be subject to a MIPS payment adjustment based on their performance. This 33 percent participation assumption is identified in Table 113 as ''Opt-In eligibility''. In this proposed rule analysis, we estimate an additional 31,000 clinicians would be eligible through this policy for a total MIPS eligible population of approximately 818,000. The leads to an associated $68 billion allowed PFS charges estimated to be included in the 2020 MIPS performance period.

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rows in Table 113 depending on whether they would have exceeded the low volume threshold as an individual or because they were part of an APM entity group submission.

[146] The count of 220,981 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (203,027 MIPS eligible clinicians), as well as those who did not participate (17,954 MIPS eligible clinicians).

TABLE 113: Description of MIPS Eligibility Status for CY 2022 MIPS Payment Year Using the CY 2020 PFS Proposed Assumptions**

		CY 2020 PFS Proposed Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	203,027	$48,306
	Do not participate in MIPS	17,954	$4,054
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	566,164	$14,145
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	31,246	$1,497
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**818,391***	68,002
Not MIPS Eligible			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or(2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	385,635	$9,277
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	77,450	$403
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	202,684	$9,322
Total Number of Clinicians Not MIPS Eligible		665,769	19,002
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,484,160	87,004

* Estimated MIPS Eligible Population

** This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 13,000 clinicians and $2,763 million in PFS allowed charges).

*** Allowed charges estimated using 2016 and 2017 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

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There are approximately 386,000 clinicians who are not MIPS eligible, but could be if their practice decides to participate or they elect to opt-in. We describe this group as ''Potentially MIPS eligible''. These clinicians would be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group and all clinicians that could elect to opt-into MIPS do elect to opt-in. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate that the MIPS eligible clinician population could be as high as 1.2 million clinicians.

Finally, there are some clinicians who would not be MIPS eligible either

because they or their group are below the low-volume threshold on all three criteria (approximately 77,000) or because they are excluded for other reasons (approximately 203,000).

Since eligibility among many clinicians is contingent on submission to MIPS as a group, APM participation or election to opt-in, we will not know the number of MIPS eligible clinicians until the submission period for the 2020 MIPS performance period is closed. For this impact analysis, we used the estimated population of 818,391 MIPS eligible clinicians described above.

c. Estimated Impacts on Payments to MIPS Eligible Clinicians

(1) Summary of Approach

In sections III.K.3.c., III.K.3.d. and III.K.3.e. of this proposed rule, we present several proposals which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VI.E.10.c.(2) of this RIA as we describe our methodology to estimate MIPS payments for the 2022 MIPS payment year. We note that many of the MIPS policies from the CY 2019 Quality Payment Program final rule were only defined for the 2019 MIPS performance period and 2021 MIPS payment year (including the performance threshold, the additional performance threshold, the policy for redistributing the weights of the performance categories, and many scoring policies for the quality performance category) which precludes us from developing a baseline for the 2020 MIPS performance period and 2022 MIPS payment year if there was no new regulatory action. Therefore, our impact analysis looks at the total effect of the proposed MIPS policy changes on the MIPS final score and payment adjustment for CY 2020 MIPS performance period/CY 2022 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is a value determined by their performance in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As discussed in section VI.E.10.c.(2) of this proposed rule, we used the most recently available data from the Quality Payment Program which is generally data submitted for the 2017 MIPS performance period. We will use 2018 MIPS performance period data for the impact analysis in the final rule should that data become available.

The estimated payment impacts presented in this proposed rule reflect averages by practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues that clinicians earn would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System, that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2020 Quality Payment Program for this proposed rule, we used CY 2017 Quality Payment Program Year 1 performance period data. Our scoring model includes the 818,391 estimated number of MIPS eligible clinicians as described in section VI.E.10.b.(1)(b) of this RIA.

To estimate the impact of MIPS on eligible clinicians, we generally used the Quality Payment Program Year 1 submission data, including data submitted for the quality, improvement activities, and Promoting Interoperability (which was called advancing care information for the 2017 MIPS performance period) performance categories, CAHPS for MIPS and CAHPS for ACOs, the total per capita cost measure, Medicare Spending Per Beneficiary (MSPB) clinician measure and other data sets.[147] We calculated a hypothetical final score for the 2020 MIPS performance period/2022 MIPS payment year for each MIPS eligible clinician using score estimates described in this section for quality, cost, Promoting Interoperability, and improvement activities performance categories.

We did not model virtual groups since we had fewer than 10 virtual groups register for the 2019 performance period, which was not a sufficiently large number of virtual groups to model separately for this RIA. We will revisit modeling virtual groups separately once we receive virtual group submissions in future years.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a similar methodology described in the CY 2019 PFS final rule (83 FR 60053 through 60054) with the following modifications that reflect the newly proposed policies for the 2020 MIPS performance period and improvement to our modeling methodology. As proposed in section III.K.3.c.(1)(c)(ii) of this proposed rule, we increased the data completeness requirement for the CY 2020 performance period from 60 percent to 70 percent.

We also applied modifications that were previously finalized including the validation process that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77289 through 77291) and applying the topped out scoring cap that was finalized (82 FR 53721 through 53727) to the measures subject to the scoring cap for the 2019 MIPS performance period.

Finally, our model applied the APM scoring standard policies finalized in the CY 2019 PFS final rule (83 FR 59754) as modified by the proposals in section III.K.3.c.(5)(c)(i)(B) of this proposed rule to MIPS eligible clinicians identified as being scored as a MIPS APM in the eligibility section VI.E.10.b.(1)(b) of this proposed rule. As described in section III.K.3.c.(5)(c)(i)(B) of this proposed rule, we are proposing to apply a minimum score of 50 percent, or an 'APM Quality Reporting Credit', under the MIPS quality performance category for certain APM entities participating in MIPS. In our model, this proposed 'APM Quality Reporting Credit' was implemented for APM Entities that do not use Web Interface. We also propose in sections III.K.3.c.(5)(c)(i)(A) of this proposed rule to calculate an aggregated APM Entity quality score from submitted MIPS data by the participants in an APM Entity if the APM quality data cannot be used.

As described in section VI.E.10.b.(1).(b). of this proposed rule, we are using the 2019 predictive file that contains current participation in MIPS APMs as of January 15, 2019, using all available data to identify who is an APM participant. In the case of MIPS APM entities that report Web Interface, if the APM Entity existed in 2017, we calculated a score based on the Web Interface submission from the 2017 performance period. If the APM Entity did submit Web Interface data for the 2017 performance period, we calculated an aggregate score based on individual

[147] 2016 PQRS and Value Modifier data was used for the improvement score for the quality performance category. We also incorporated some additional data sources when available to represent more current data.

submissions similar to how we estimate aggregate scores for MIPS APM entities that do not utilize Web Interface. If the APM Entity is new for 2019 (and therefore did not have the ability to submit Web Interface for the 2017 performance period), we used the average Web Interface score because we would anticipate the new APM Entities would report quality using Web Interface in the future. For MIPS APMs that do not utilize the Web Interface, we estimated the APM Entity quality performance category score by taking the higher of the group and individual quality scores for the clinicians in the APM Entity and calculating the average for the APM Entity. Clinicians were assigned a score of 0 if they did not submit quality data to MIPS. For the MIPS APMs that do not utilize Web Interface only, we then applied the proposed APM Quality Reporting Credit policy to add 50 percent to the MIPS quality score for APM Entities submitting to MIPS as proposed in section III.K.3.c.(5)(c)(i)(B) of this proposed rule. All quality performance category scores would be capped at 100 percent after receiving the 50 percent APM Quality Reporting Credit.

(b) Methodology To Estimate the Cost Performance Category Score

In section III.K.3.c(2)(b)(iii) of this proposed rule, we propose to add 10 episode-based measures to the cost performance category beginning with the 2020 performance period in addition to the 8 episode-based measures finalized in the CY 2019 PFS final rule (83 FR 59767). In section III.K.3.c.(2)(b)(v) of this rule, we propose to revise the total per capita cost and MSPB clinician measures.

We estimated the cost performance category score using all measures included in section III.K.3.c.(2)(b)(viii) of this proposed rule. The total per capita cost measure performance was estimated based on the proposed revised measure using claims data from October 2016 through September 2017. The MSPB clinician measure performance was estimated based on the proposed revised measure using claims data from January through December of 2017. For the episode-based measures, we used the specifications for the 8 episode-based measures finalized in the CY 2019 PFS final rule (83 FR 35902 through 35903), the proposed specifications for the 10 new episode-based measures discussed in section III.K.3.c.(2)(b)(iii) of this proposed rule and claims data from January through December of 2017. Cost measures scored if the clinicians or groups met or exceed the case volume: 20 for the total per capita cost measure, 35 for MSPB clinician, 10 for procedural episode-based measures, and 20 for acute inpatient medical condition episode-based measures. The cost measures are calculated for both the TIN/NPI and the TIN, except for the lower gastrointestinal hemorrhage measure, which we propose in section III.K.3.c.(2)(vi)(B) of this proposed rule to calculate only for groups. For clinicians participating as individuals, the TIN/NPI level score was used if available and if the minimum case volume was met. For clinicians participating as groups, the TIN level score was used, if available, and if the minimum case volume was met. For clinicians with no measures meeting the minimum case requirement, we did not estimate a score for the cost performance category, and the weight for the cost performance category was reassigned to the quality performance category. The raw cost measure scores were mapped to scores on the scale of 1–10, using benchmarks based on all measures that met the case minimum and if the group or clinician exceeded the low-volume threshold during the relevant performance period. For the episode-based cost measures, separate benchmarks were developed for TIN/NPI level scores and TIN level scores. For each clinician, a cost performance category score was calculated as the average of the measure scores available for the clinician.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As finalized in the CY2019 PFS final rule (83 FR 59856), we determine the eligible clinician's MIPS cost and quality performance category score in facility-based measurement based on Hospital VBP Program Total Performance Score for eligible clinicians or groups who meet the eligibility criteria, which we designed to identify those who primarily furnish services within a hospital. We estimate the facility-based score using the scoring policies finalized in the CY2018 Quality Payment Program final rule (82 FR 53763). In section III.K.3.d.(1)(c) of this proposed rule, we are only proposing technical changes for clarity and those changes do not affect the facility-based policies. In the CY 2019 PFS final rule (83 FR 60054 through 60055), we were unable to incorporate the facility-based logic fully into our model. For this proposed rule, we have new datasets that allow us to more completely model facility-based measurement.

We used data from the feedback reports for the first determination period for the 2019 performance period, which is from October 1, 2017 to September 30, 2018 to attribute clinicians and groups to hospitals and assign the specific Hospital VBP Program Total Performance Score. Although the time period for facility-based eligibility does not align with the MIPS eligibility and performance period data, these facility-based eligibility data were used because we did not have attribution data available for the matching performance period and the use of actual attribution data was preferable to using proxy data. If a Hospital VBP Program Total Performance Score could not be assigned to a clinician, in instances in which the attributed facility does not participate in the Hospital VBP program, that clinician was determined as not eligible for facility-based measurement and assumed to participate in MIPS via other methods. In some cases, a group or clinician may have changed practices and would not have an associated facility-based indicator in the feedback reports (because the feedback reports used a different time period). In those cases, if the TIN or TIN–NPI was facility-based in the 2017 MIPS performance period, we estimated a facility-based score by taking the median MIPS quality and cost performance score. We are not requiring eligible clinicians to opt-in to facility-based measurement; it is possible that a MIPS eligible clinician or a group is automatically eligible for facility-based measurement, but they participate in MIPS as an individual or a group. In these cases, we used the higher combined quality and cost performance category score, as reflected in the final score, from facility-based scoring compared to the combined quality and cost performance category score from MIPS submission-based scoring.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimated the Promoting Interoperability performance category score using the methodology described in the CY 2019 PFS final rule (83 FR 60055) with the following modifications that reflect the newly proposed policies for the 2020 MIPS performance period.

In section III.K.3.c.(4)(d)(i)(B)(aa) of this proposed rule, we proposed to modify the Query of PDMP measure to a yes/no response. The Query of PDMP measure was not modeled because the measure was not available in the 2017 MIPS performance period submissions data.

In section III.K.3.c.(4)(f)(iii) of this proposed rule, we proposed to revise the definition of hospital-based MIPS eligible clinician to include groups and virtual groups. We also proposed that a

hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician. In section III.K.3.c.(4)(f)(iv) of this proposed rule, we proposed revisions to also account for a group or virtual group that meets the definition of a non-patient facing MIPS eligible clinician such that the group or virtual group only has to meet a threshold of more than 75 percent. Also, as described in sections III.K.3.c.(4)(f)(iii) and III.K.3.c.(4)(f)(iv) of this proposed rule, we proposed to assign a zero percent weight for the Promoting Interoperability performance category for groups defined as hospital-based and non-patient facing, and redistribute the points associated with the Promoting Interoperability performance category to another performance category or categories. Therefore, in our impact analysis model, a group was only assigned a zero percent weight for the Promoting Interoperability performance category and the points for Promoting Interoperability performance category was redistributed if: (1) All the TIN/NPIs were eligible for reweighting as established at § 414.1380(c)(2)(iii) for MIPS eligible clinicians submitting data as a group or virtual group, or (2) the group met the proposed revised definition of a hospital-based MIPS eligible clinician as proposed in section III.K.3.c.(4)(f)(iii) of this proposed rule or the definition of a non-patient facing MIPS eligible clinician, as proposed in section III.K.3.c.(4)(f)(iv) of this proposed rule, as defined in § 414.1305. We also incorporated into our model the proposed policy to continue automatic reweighting for NPs, PAs, CNSs and CRNAs, physical therapists, occupational therapist, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals as described in sections III.K.3.c.(4)(f)(i) and III.K.3.c.(4)(f)(ii) of this proposed rule.

In our model, for the APM participants identified in section VI.E.10.b.(1).(b).of this proposed rule, we simulated MIPS APM Entity scores by using submitted Promoting Interoperability data by groups or individuals that we identified as being in a MIPS APM to calculate an APM Entity score.

All other proposed policies for the Promoting Interoperability performance category described in section III.K.3.c.(4) of this proposed rule did not impact our modeling methodology for this performance category because either the data were not available in the 2017 MIPS performance period submissions data or the proposed changes reflect the modeling strategy previously used and described in the CY 2019 PFS final rule (83 FR 60055). For example, since the Verify Opioid Treatment Agreement measure was not modeled in the CY 2019 PFS final rule (83 FR 60055) because the measure was not available in the 2017 MIPS performance period submissions data, the proposed removal of this measure did not impact our impact analysis methodology for this proposed rule.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on CY 2017 Quality Payment Period Year 1 data and APM participation in the 2017 MIPS performance period. In section III.K.3.c.(3)(d)(iii) of this proposed rule, we are proposing to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent for the improvement activities performance category beginning with the CY 2020 performance year and future years. We did not incorporate this proposed change into our model because we did not have the information to model this proposal. For the APM participants identified in section VI.E.10.b.(1)(b) of this proposed rule, we assigned an improvement activity performance category score of 100 percent.

Clinicians and groups not participating in a MIPS APM were assigned their CY 2017 Quality Payment Program Year 1 improvement activities performance category score.

(f) Methodology To Estimate the Complex Patient Bonus

In section III.K.3.d.(2)(a) of this proposed rule, we are proposing to continue the complex patient bonus. Consistent with the policy to define complex patients as those with high medical risk or with dual eligibility, our scoring model used the complex patient bonus information calculated for the 2018 performance period data, because this variable was available in time for the publication of this proposed rule. If the clinician did not have a complex patient bonus score from the 2018 performance period data (because the bonus was from a different performance period), we proxied a score using the methods described in the CY 2019 PFS final rule (83 FR 59869) to supplement the gap in data.

(g) Methodology To Estimate the Final Score

As proposed in sections III.K.3.c.(1)(b), III.K.3.c.(2)(a), and summarized in section III.K.3.d.(2)(b) of this proposed rule, our model assigns a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, and adding the complex patient bonus. After adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points equal to 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for the Promoting Interoperability due to a significant hardship or other type of exception, the weight for the Promoting Interoperability performance category was redistributed to the quality performance category. For MIPS eligible clinicians who did not have a cost performance category score, the weight for the cost performance category was redistributed to the quality and Promoting Interoperability performance categories.

In our scoring model, we did not address scenarios where a zero percent weight would be assigned to the quality performance category or the improvement activities performance category. We applied the remaining reweighting scenarios described in detail in section III.K.3.d.(2)(b)(ii) of this proposed rule and in the CY 2019 PFS Final Rule (83 FR 59871 through 83 FR 59878).

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we applied a hierarchy to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available (for example if a clinician qualifies for a score for an APM entity and a group score, we select the APM entity score).

We then calculated the parameters of an exchange function in accordance

with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages and additional payment adjustment for exceptional performance (as finalized under § 414.1405), using a performance threshold of 45 points and the additional performance threshold of 80 points (as proposed in sections III.K.3.e.(2) and III.K.3.e.(3) of this proposed rule). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the paid amount for covered professional services furnished by the MIPS eligible clinician. We considered other performance thresholds which are discussed in section VI.F.2. of this RIA.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that $586 million would be redistributed through budget neutrality and that $500 million would be distributed to MIPS eligible clinicians that meet or exceed the additional performance threshold. The model further estimates that the maximum positive payment adjustments are 5.8 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance.

Table 114 shows the impact of the payment adjustments by practice size and based on whether clinicians are expected to submit data to MIPS. We estimate that a smaller proportion of clinicians in small practices (1–15 clinicians) who participate in MIPS will receive a positive or neutral payment adjustment compared to larger sized practices. In aggregate, the cohort of clinicians in small practices participating in MIPS and who submit to MIPS receive a 0.9 percent increase in total paid amount, which is lower than the comparative payment increases received by the cohort of MIPS eligible clinicians in larger-sized practices. Table 114 also shows that 87.3 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. We want to highlight that we are using 2017 performance period submissions data for these calculations, and it is likely that there will be changes that we cannot account for at this time. For example, the 2017 performance period was the first year of the program, and it was considered a ''Pick Your Pace'' year of participation. With ''Pick Your Pace'', clinicians could begin slowly participating in MIPS at their own pace by determining how much data to submit and their level of participation. Specifically, the performance threshold was set at 3 points, and submission of one quality measure or attesting to one improvement activity would allow a clinician to meet or exceed the performance threshold. In the second and third years of the program, the performance thresholds increased, along with the data submission requirements to avoid a negative payment adjustment. At this time, we are not able to estimate the impact of these policy changes using Year 1 performance period data, but we anticipate having additional information based on 2018 (year 2) data submissions when conducting the impact analysis for the final rule.

The combined impact of negative and positive adjustments and the additional positive adjustments for exceptional performance as a percent of paid amount among those that do not submit data to MIPS was not the maximum negative payment adjustment of 9 percent possible because these clinicians do not all receive a final score of zero. Indeed, some MIPS eligible clinicians that do not submit data to MIPS may receive final scores above zero through performance on the cost performance category, which utilizes administrative claims data and does not require separate data submission to MIPS. Among those who we estimate would not submit data to MIPS, 90 percent are in small practices (16,116 out of 17,954 clinicians who do not submit data). To address participation concerns, we have policies targeted towards small practices including technical assistance and special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs. We also note this participation data is generally based off participation for the 2017 performance period and that participation may change for the 2020 performance period. As stated above, the 2017 performance period was the first year of MIPS, which was a ''Pick Your Pace'' year, and we believe that the level of participation and amount of data submitted will likely change in ensuing years. For example, we note in section III.K.1.a. of this proposed rule that we have published participation rates for the 2018 performance period and those rates differ from the 2017 performance period participation rates, where a slight increase in participation was observed. We did not have the submission data in time for this analysis, but we intend to update our data for the final rule.

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TABLE 114: MIPS Estimated Payment Year 2022 Impact on Total Estimated Paid Amount by Participation Status and Practice Size*[a]

Practice Size*	Number of MIPS eligible clinicians	Percent MIPS Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent MIPS Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent MIPS Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount**
Among those submitting data* **					
1) 1-15	145,457	76.5%	41.2%	23.5%	0.9%
2) 16-24	42,691	81.9%	40.8%	18.1%	1.1%
3) 25-99	189,603	85.3%	44.4%	14.7%	1.3%
4) 100+	422,686	92.5%	62.4%	7.5%	2.1%
Overall	**800,437**	87.3%	53.2%	12.7%	1.4%
Among those not submitting data					
1) 1-15	16,116	0.0%	0.0%	100.0%	-8.1%
2) 16-24	674	0.0%	0.0%	100.0%	-8.2%
3) 25-99	953	0.0%	0.0%	100.0%	-8.3%
4) 100+	211	0.0%	0.0%	100.0%	-8.5%
Overall	17,954	**0.0%**	**0.0%**	**100.0%**	-8.2%

*Practice size is the total number of TIN/NPIs in a TIN.

**2016 and 2017 data used to estimate 2020 performance period payment adjustments. Payments estimated using 2016 and 2017 dollars trended to 2022. The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.

***Includes facility-based clinicians whose quality data is submitted through hospital programs.

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e. Potential Costs of Compliance With the Promoting Interoperability and Improvement Activities Performance Categories for Eligible Clinicians

(1) Potential Costs of Compliance With Promoting Interoperability Performance Category

In section III.K.3.c.(4)(d)(i)(B)(aa) of this proposed rule, we propose to allow clinicians and groups to satisfy the optional bonus Query of PDMP measure by submitting a ''yes/no'' attestation, rather than reporting a numerator and denominator. As discussed in the Collection of Information section of this proposed rule, we are not changing our burden assumptions to account for this proposal due to a lack of information regarding the number of clinicians reporting bonus measures combined with our currently approved burden estimates being based only on the reporting of required measures. However, we do believe that for clinicians or groups who report this measure, there will be a reduction in reporting burden compared to what would have been required to submit the measure without this proposed change related to the elimination of the need to perform calculations prior to submitting a numerator and denominator. As data availability allows, we will reassess the inclusion of this burden in the Collection of Information in the future.

In sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this rule, beginning with the 2021 performance period and for future years, we are proposing to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In the Collection of Information section, we discussed the potential burden reduction associated with simplifying MIPS reporting for clinicians who currently utilize qualified registries or QCDRs that have not previously offered the ability to report Promoting Interoperability or improvement activity data. We believe it is also possible that some MIPS eligible clinicians may elect to begin utilizing qualified registries or QCDRs as a result this proposed policy and its potential for simplifying their MIPS reporting combined with the benefits of improving the quality of care provided to their patients. We do not have information with which to estimate the number of clinicians who may pursue this option, therefore we cannot quantify the associated costs, cost savings, and benefits consistent with the CY 2018 Quality Payment Program final rule (82 FR 53946).

(2) Potential Costs of Compliance With Improvement Activities Performance Category

In section III.K.3.c.(3)(d)(iii) of this proposed rule, we are proposing, beginning with the 2020 MIPS performance period and for future years, to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity from at least one clinician to at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. In addition, we are proposing changes to the

Improvement Activities Inventory to: (1) Establish removal factors to consider when proposing to remove improvement activities from the Inventory; (2) remove 15 improvement activities for the CY 2020 performance period and future years contingent on our proposed removal factors being finalized; (3) modify 7 existing improvement activities for the CY 2020 performance period and future years; and (4) add two new improvement activities for the CY 2020 performance period and future years.

Given groups' familiarity with the improvement activities in the Improvement Activities Inventory, we assume that a group would find applicable and meaningful activities to complete that are not specific to practice size, specialty, or practice setting and would apply to at least 50 percent of individual MIPS eligible clinicians in the group. Therefore, an increase in the minimum threshold for a group to receive credit for the improvement activities performance category should not present additional complexity or burden. We also anticipate that the vast majority of clinicians performing improvement activities, to comply with existing MIPS policies, would continue to perform the same activities under the policies established in this proposed rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175). Most of the improvement activities in Improvement Activities Inventory remain unchanged for the 2020 MIPS performance period and most clinicians are likely to have selected improvement activities that were unaffected by the changes. Of the activities that were removed, modified, or added, many were duplicative which means many clinicians or groups would be able to continue the activity, but it would be reported under a different activity in the Improvement Activities Inventory.

Our proposal to establish removal factors when proposing to remove improvement activities from the Improvement Activities Inventory would provide guidance for clinicians or groups on the considerations for the removal of improvement activities and would not present additional burden. The proposed changes to the Improvement Activities Inventory that include the modification, removal, and addition of improvement activities provide clarity, avoid duplication, and provide more options for clinicians to select improvement activities that are appropriate for their clinical practice and would not present additional burden. Furthermore, in this proposed rule, we are proposing to end and remove the Study on Factors Associated with Reporting Quality Measures beginning with the 2020 MIPS performance period. In the CY 2019 PFS final rule, we finalized a sample size of 200 clinicians, each of which completed a 15-minute survey both prior to and after submitting MIPS data (83 FR 60058). As a result of ending the study, we estimate a reduction in burden of 100 hours and $20,286 (200 clinicians × 0.5 hours × $202.86).

f. Potential Costs of Compliance for Third Party Intermediaries

Based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that all third party intermediaries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. As previously discussed in section III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this proposed rule, beginning with the 2021 performance period and for future years, we are proposing to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In section III.K.3.g.(1), we further state that we anticipate using the QCDR and qualified registry self-nomination vetting process to assess which of these entities will be subject to the proposed requirement to support reporting the Promoting Interoperability performance category and which entities would be subject to an exception based on which clinician types they serve and whether those clinician types are eligible for reweighting of the Promoting Interoperability performance category as discussed in section III.K.3.c.(4). Based on our review of qualified registries and QCDRs approved to submit data for the 2019 MIPS performance period, 70 percent of qualified registries and 72 percent of QCDRs already offer support for the quality, improvement activities, and Promoting Interoperability performance categories. We believe this proposal could result in the remaining qualified registries and QCDRs incurring additional costs to upgrade information technology systems in order to make this ability available to clinicians, with less cost incurred by entities who would be subject to an exception for the Promoting Interoperability performance category. However, given that each of these entities and their information technology systems are unique, and there is no method of determining which entities may have already begun the process of developing this ability, we are unable to determine the impact of transitioning from allowing this ability as an option to requiring it. Also, given that the majority of these entities have already begun offering the ability to submit data on behalf of the improvement activities and Promoting Interoperability performance categories, we assume they have done so because they believe the benefits outweigh the costs and is therefore, in their best financial interests to do so.

We are also proposing in section III.K.3.g.(3)(a)(ii) of this proposed rule, beginning with the 2021 performance period, to require qualified registries and QCDRs to provide the following as part of the performance feedback given at least 4 times a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure and/or QCDR measure) within the QCDR. We understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. As finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77367 through 77386 and 82 FR 53812), qualified registries and QCDRs are required to provide feedback on all of the MIPS performance categories that the qualified registry or QCDR reports at least 4 times a year. Given that we are not proposing a significant change but are instead proposing to modify and strengthen the existing policy, we do not anticipate a significant increase in cost or effort for Third Party Intermediaries to comply with this proposal. In alignment with our proposal above, we are also proposing to require QCDRs to provide services to clinicians and groups to foster improvement in the quality of care provided to patients, by providing educational services in quality improvement and leading quality improvement initiatives. Similar to the requirement to support submission of Promoting Interoperability and improvement activity data, we believe this proposal could result in QCDRs incurring additional costs. We are unable to create a baseline of current service offerings for each QCDR, which would be needed in order to determine

the incremental costs associated with providing any additional services required by this proposal. We believe that by offering these services, additional MIPS eligible clinicians may be encouraged to utilize these entities, thereby increasing membership and potentially offsetting some of the costs the QCDR would have to incur.

In section III.K.3.g.(3)(c)(i)(B)(cc), we are proposing that in order for a QCDR measure to be considered for use in the program beginning with the 2021 performance period and future years, all QCDR measures submitted for self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. Beginning with the 2021 performance period and future years, we are proposing in section III.K.3.g.(3)(c)(i)(B)(dd) to also require QCDRs to collect data on the potential QCDR measure, appropriate to the measure type, as defined in the CMS Blueprint for the CMS Measures Management System, prior to self-nomination. The testing process for quality measures is dependent on the measure type (for example, a measure that is specified as an eCQM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards which further illustrate these differences based on measure type.[148] Additionally, the costs associated with testing vary based on the complexity of the measure and the developing organization. The Journal of the American Medical Association states that the costs associated with quality measures are generally unknown or unreported.[149] While we understand the proposed policy will result in additional costs for QCDRs to develop measures, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, we are unable to determine the financial impact of this proposal on QCDRs beyond the likelihood of it being more than trivial. Likewise, we understand that some QCDRs already perform measure testing prior to submission for approval while others do not. This variability makes it difficult to estimate the incremental impact of this regulation.

In section III.K.3.g.(3)(c)(i)(A)(bb) of this rule, we are proposing to amend § 414.1400 to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. Because the choice to license a QCDR measure is an elective business decision made by individual QCDRs and we have little insight into both the specific terms and frequency of agreements made between entities, we are unable to account for the financial impact of licensing QCDR measures for each QCDR. In aggregate across all QCDRs, the financial impact would be zero as fees paid by one QCDR will be collected by another QCDR.

In section III.K.3.g.(3)(c)(i)(B)(ee) of this rule, we propose, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. We are unable to account for the financial impact of measure harmonization, as the process and outcomes will likely vary substantially depending on a number of factors, including: Extent of duplication with other measures, number of QCDRs involved in harmonizing toward a single measure, and number of measures being harmonized among the same QCDRs. We intend to identify only those QCDR measures which are duplicative to such an extent as to assume harmonization will not be overly burdensome, however, because the harmonization process will occur between QCDRs without our involvement, we are unable to predict or quantify the associated effort.

We understand that some QCDRs may believe the proposals to require measure harmonization and encourage QCDRs to license their measures to other QCDRs as a consideration for measure approval may result in a reduced ability for QCDRs to differentiate themselves in the marketplace. We note that in addition to the suite of measures offered by a QCDR and their relevance to individual clinicians and groups, ease of incorporating a QCDR's measures into existing practice workflows, as well as integration into broader quality improvement programs are two examples of distinguishing characteristics for clinicians to consider when selecting a QCDR. In addition, clinicians may also consider cost (if any); recommendations, support, or endorsements from specialty societies; the number of other users submitting data to the QCDR; the specific educational services and quality improvement initiatives offered; and the specific performance feedback information provided as part of the required reports provided at least 4 times a year. We believe that the impact these proposals may have on the perceived differentiated value of certain QCDRs is counterbalanced by the need to promote more focused quality measure development towards outcomes that are meaningful to patients, families and their providers.

In this proposed rule, we are proposing to formalize a number of factors we would take into consideration for approving and rejecting QCDR measures for the MIPS program beginning with the 2020 performance period and future years. With regard to approving QCDR measures, we are proposing the following: (1) 2-year QCDR measure approval process, and (2) participation plan for existing QCDR measures that have failed to reach benchmarking thresholds.

As discussed in section III.K.3.g.(3)(c)(ii)(B), we are proposing to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described in section III.K.3.g.(3)(c). The 2-year approvals would be subject to the following conditions whereby the multi-year approval will no longer apply if the QCDR measure is identified as: Topped

[148] *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx.*

[149] Schuster, Onorato, and Meltzer. ''Measuring the Cost of Quality Measurement: A Missing Link in Quality Strategy'', Journal of the American Medical Association. 2017; 318(13):1219–1220. *https://jamanetwork.com/journals/jama/fullarticle/2653111?resultClick=1.*

out; duplicative of a new, more robust measure; reflects an outdated clinical guideline; requires measure harmonization, or if the QCDR self-nominating the measure is no longer in good standing. We believe this will result in reduced burden for QCDRs as they will no longer be required to submit each measure for approval annually. However, because we are unable to predict which previously approved QCDR measures will be removed or retained in future years, we are likewise unable to predict the impact on future burden associated with QCDRs submitting measures for approval. Beginning with the 2021 performance period, we are proposing that in instances where an existing QCDR measure has been in MIPS for 2 years and has failed to reach benchmarking thresholds due to low adoption, where the QCDR believes the low-reported QCDR measure is still important and relevant to a specialist's practice, that the QCDR may submit to CMS a QCDR measure participation plan, to be submitted as part of their self-nomination. Because we are unable to predict the frequency with which existing QCDR measures will meet the proposed criteria for allowing QCDRs to submit a measure participation plan or the likelihood of QCDRs electing to submit a plan, we are unable to estimate the impact associated with this proposal.

As discussed in section III.K.3.g.(3)(c)(i)(B)(bb) of this proposed rule, beginning with the 2021 performance period and future years, we are proposing that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measures (as found in section III.K.3.c.(3) of this proposed rule), (b) improvement activities (as found in Appendix 2: Improvement Activities Tables), or (c) CMS developed MIPS Value Pathways (as described in section III.K.3.a. of this proposed rule). We do not assume any additional impact beyond the 1 hour per QCDR measure discussed in the Collection of Information section.

g. Assumptions & Limitations

We note several limitations to our estimates of MIPS eligible clinicians' eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2022 MIPS payment year. We based our analyses on the data prepared to support the 2018 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*),[150] participant lists using the 2019 predictive APM Participation List, which contains the 2018 fourth snapshot and any additional TIN/NPIs until January 15, 2019, CY 2017 Quality Payment Program Year 1 data and CAHPS for ACOs. The scoring model results presented in this proposed rule assume that CY 2017 Quality Payment Program Year 1 data submissions and performance are representative of CY 2020 Quality Payment Program data submissions and performance. The estimated performance for CY 2020 MIPS performance period using Quality Payment Program Year 1 data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2017 MIPS performance period/2019 MIPS payment year was significantly lower (3 out of 100 points) than the performance threshold for the 2020 MIPS performance period/2022 MIPS payment year (45 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that 33 percent of the opt-in eligible clinicians that participated in the CY 2017 Quality Payment Program Year 1 would elect to opt-in to the MIPS program. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policies.

There are additional limitations to our estimates: (1) Because we used historic data, we assumed participation in the three performance categories in MIPS Year 1 would be similar to MIPS Year 4 performance; and (2) to the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 114. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify in detail.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our proposed policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, would result in different payment rates, and therefore, result in different estimates than those shown in Table 110 (CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty).

1. Alternatives Considered Related to Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs

We considered several possibilities for pricing the oral medications, namely methadone and buprenorphine (oral), included in the OTP payment bundles. As described in section II.G. of this proposed rule, we are proposing to use ASP-based payment for oral OTP drugs; however, in the event we do not receive manufacturer-submitted ASP pricing data for these drugs, we are also considering several other alternative pricing mechanisms to determine the pricing of the drug components of the bundles that include these medications, including the methodology under Section 1847A of the Act; Medicare Part D Prescription Drug Plan Finder data; WAC; and NADAC data. For methadone, we also consider an alternative using the TRICARE payment rate for methadone in its OTP bundled payment. In Table 14, we display the estimated initial drug payment rates for the proposed pricing approach for the oral drugs and each of the alternatives, based on data files posted at the time of the drafting of this proposed rule. We used the TRICARE payment rate for methadone to estimate the payment rates for the methadone payment bundles and NADAC data to estimate the payment rates for the buprenorphine (oral) payment bundles, and to derive the impact estimates.

For methadone, we believe using Medicare Part D Prescription Drug Plan Finder Data to price the medication would have minimal impact on the RIA estimate since the rate is very close to the TRICARE payment rate. Using WAC-based pricing for methadone would likely increase the impact estimate marginally since WAC-based pricing is slightly higher than the TRICARE payment rate. Since NADAC pricing for methadone is significantly less than the TRICARE payment rate, using NADAC pricing would significantly decrease the impact estimates, especially because the

[150] The time period for this eligibility file (September 1, 2016 to August 31, 2017) maximizes the overlap with the performance data in our model.

vast majority of patients receiving OUD treatment services at OTPs are receiving methadone.

For buprenorphine (oral), the Medicare Part D Prescription Drug Plan Finder data is very similar to NADAC pricing. Therefore we believe there would be minimal changes in the estimated impacts from using this alternative data source. Since WAC-based pricing is slightly higher than NADAC pricing, we note that using WAC-based pricing would increase the estimated impacts marginally.

We also considered several alternatives for the update factor used in updating the payment rates for the non-drug component of the bundled payment for OUD treatment services, including the Bureau of Labor Statistics Consumer Price Index for All Items for Urban Consumers (CPI–U) (Bureau of Labor Statistics #CUUR0000SA0 (*https://www.bls.gov/cpi/data.htm*)) and the IPPS hospital market basket reduced by the multifactor productivity adjustment. Based on a CMS forecast of projected rates, we believe that the projected MEI and CPI–U rates are anticipated to be similar, and thus using the CPI–U as an update factor would have minimal effect on estimated impacts. Since the projected IPPS hospital market basket rate is generally higher than the projected MEI rate, using the IPPS hospital market basket rate would result in higher estimated impacts.

2. Alternatives Considered Related to Payment for E/M Services

In developing our proposed policies for office/outpatient E/M visits effective January 1, 2021, we considered a number of alternatives. For reasons discussed in section II.P. of this proposed rule, we did not include either the extended office/outpatient E/M HCPCS code GPR01 or the single blended payment rates for combined visit levels 2 through 4 that were finalized in the CY 2019 final rule for CY 2021 in our considerations. Our alternatives also did not include the revaluation of global surgical services, as recommended by the AMA RUC, which incorporated the revised office/outpatient E/M code values. We note that in all of the alternatives we considered, the valuation for all codes in the office/outpatient E/M code set would increase. Therefore, all specialties for whom the office/outpatient codes represent a significant portion of their billing would also see payment increases while those specialties who do not report those codes would see overall payment decreases. Any variation in the magnitude of the increases or decreases are a result of a specialties overall billing patterns.

We did, however, consider proposing to eliminate both add-on codes, HCPCS code GCG0X and HCPCS code GPC1X, that were finalized in the CY 2019 final rule for CY 2021. Our stated rationale in the CY 2019 final rule for developing HCPCS code GPC1X (83 FR 59625 through 59653) was to more accurately account for the type and intensity of E/M work performed in primary care-focused visits beyond the typical resources reflected in the single payment rate for the levels 2 through 4 visits. The reason for finalizing HCPCS code GCG0X, as stated in the CY 2019 FR (83 FR 59625 through 59653) GCG0X was to reflect additional resource costs for inherently complex services that are non-procedural. We considered whether these two add-on codes would still be necessary in the context of the revised descriptors and valuations for office/outpatient E/M services. We considered an alternative, therefore, in which we adopted the RUC's recommended values but excluded the two HCPCS add-on G-codes. In reviewing the results of this policy option, we observed that our concerns about capturing the work associated with visits that are part of ongoing, comprehensive primary care and/or care management for patients having a single, serious, or complex chronic condition were still present. The specialty level impacts associated with this alternative are displayed in Table 115. The specialties that benefited most from this alternative, such as Endocrinology and Rheumatology, are those that primarily bill levels 3–5 established patient office/outpatient E/M visits, as those visit levels had the greatest increases in valuation among the overall office/outpatient E/M code set.

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TABLE 115: Estimated Specialty Specific Impacts of Accepting the RUC Recommended Values but Deleting Both HCPCS G codes GCG0X and GPC1X if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	6%
Anesthesiology	$1,993	-3%	-1%	0%	-4%
Audiologist	$70	-3%	-1%	0%	-4%
Cardiac Surgery	$279	-4%	-1%	-1%	-5%
Cardiology	$6,595	1%	1%	0%	1%
Chiropractor	$750	-4%	-2%	-1%	-7%
Clinical Psychologist	$787	-4%	0%	0%	-4%
Clinical Social Worker	$781	-4%	1%	0%	-4%
Colon And Rectal Surgery	$162	-1%	0%	0%	-1%
Critical Care	$346	-3%	-1%	0%	-3%
Dermatology	$3,541	1%	2%	-1%	2%
Diagnostic Testing Facility	$697	0%	-3%	0%	-3%
Emergency Medicine	$3,021	-3%	-1%	1%	-4%
Endocrinology	$488	7%	3%	1%	10%
Family Practice	$6,019	5%	2%	0%	7%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	3%	1%	0%	5%
General Surgery	$2,031	-1%	0%	0%	-2%
Geriatrics	$187	1%	1%	0%	2%
Hand Surgery	$226	0%	1%	0%	1%
Hematology/Oncology	$1,673	5%	2%	1%	8%
Independent Laboratory	$592	-2%	0%	0%	-2%
Infectious Disease	$640	-2%	-1%	0%	-3%
Internal Medicine	$10,507	1%	1%	0%	2%
Interventional Pain Mgmt	$885	2%	2%	0%	4%
Interventional Radiology	$432	-2%	-2%	0%	-4%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	-1%	0%	0%	-1%
Neurology	$1,503	1%	4%	0%	6%
Neurosurgery	$802	-2%	0%	-1%	-3%
Nuclear Medicine	$50	-2%	0%	0%	-2%
Nurse Anes / Anes Asst	$1,291	-5%	-1%	0%	-6%
Nurse Practitioner	$4,503	2%	1%	0%	4%
Obstetrics/Gynecology	$620	2%	2%	0%	4%
Ophthalmology	$5,398	-3%	-4%	0%	-7%
Optometry	$1,325	0%	-2%	0%	-2%
Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-1%
Orthopedic Surgery	$3,734	0%	1%	0%	1%
Other	$34	-1%	-1%	0%	-2%
Otolarngology	$1,225	2%	1%	0%	3%
Pathology	$1,203	-3%	-2%	0%	-5%
Pediatrics	$62	2%	1%	0%	3%
Physical Medicine	$1,110	0%	0%	0%	0%
Physical/Occupational Therapy	$4,248	-3%	-2%	0%	-5%
Physician Assistant	$2,637	2%	1%	0%	4%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Plastic Surgery	$369	-1%	0%	-1%	-2%
Podiatry	$1,998	2%	2%	0%	4%
Portable X-Ray Supplier	$94	-1%	-1%	0%	-3%
Psychiatry	$1,120	2%	1%	0%	3%
Pulmonary Disease	$1,658	0%	0%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-1%	-1%	0%	-2%
Radiology	$4,971	-3%	-2%	0%	-5%
Rheumatology	$534	6%	3%	1%	9%
Thoracic Surgery	$352	-3%	-1%	0%	-5%
Urology	$1,739	2%	2%	0%	5%
Vascular Surgery	$1,203	-1%	-2%	0%	-3%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

We also considered, as an alternative, proposing CMS refinements to the RUC recommendations for two of the CPT codes. Consistent with our generally established policies for reviewing work RVUs recommended by the RUC, we observed that the increase in work RVU for CPT codes 99212 and 99214 (levels 2 and 4 for established patients) seemed disproportionate to the increase in total time for these services, particularly in comparison with the work to time relationships among the other seven E/M code revaluations. For CPT code 99212, we observed that the total time for furnishing this service increased by 2 minutes (13 percent increase), but that the recommended work RVU increased by nearly 50 percent from 0.48 to 0.70. We reviewed other CPT codes with similar times as the survey code and identified a potential crosswalk to CPT code 76536 (*Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation*), with a work RVU of 0.56. We therefore considered decreasing the work RVU for CPT code 99212 to 0.56. For CPT code 99214, the total time increased from 40 to 49 minutes, which is a 23 percent change, while the work RVU increased from 1.50 to 1.92 (28 percent increase). We considered a crosswalk to CPT code 73206 (*Computed tomographic angiography, upper extremity, with contrast material(s), including noncontrast images, if performed, and image postprocessing*), with a work RVU of 1.81 and total time of 50 minutes. The refinements we considered for the RUC recommendations are shown in Table 116.

TABLE 116—CURRENT, RUC RECOMMENDED AND CMS REFINED OFFICE/OUTPATIENT E/M WORK RVUS

CPT/HCPCS	Current work RVU (current)	RUC-recommended work RVU	Alternative: CMS-refined work RVU
99201	0.48	NA	NA
99202	0.93	0.93	0.93
99203	1.42	1.6	1.6
99204	2.43	2.6	2.6
99205	3.17	3.5	3.5
99211	0.18	0.18	0.18
99212	0.48	0.7	0.56
99213	0.97	1.3	1.3
99214	1.5	1.92	1.81
99215	2.11	2.8	2.8
99XXX	NA	0.61	0.5
GPC1X	0.25	NA	0.33
GCG0X	0.25	NA	0.33

Table 117 illustrates the specialty level impacts of refining the RUC recommendations. Under this alternative those specialties who frequently bill CPT code 99212 or CPT code 99214, such as dermatology and family practice, respectively, experience more modest increases relative to other alternatives.

TABLE 117: Estimated Specialty Specific Impacts of CMS Refined Values if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	6%
Anesthesiology	$1,993	-3%	-1%	0%	-4%
Audiologist	$70	-2%	-1%	0%	-4%
Cardiac Surgery	$279	-3%	-1%	0%	-5%
Cardiology	$6,595	1%	1%	0%	1%
Chiropractor	$750	-3%	-2%	-1%	-6%
Clinical Psychologist	$787	-4%	0%	0%	-3%
Clinical Social Worker	$781	-4%	1%	0%	-3%
Colon And Rectal Surgery	$162	-1%	0%	0%	-1%
Critical Care	$346	-2%	-1%	0%	-3%
Dermatology	$3,541	1%	2%	-1%	2%
Diagnostic Testing Facility	$697	0%	-3%	0%	-3%
Emergency Medicine	$3,021	-3%	-1%	1%	-3%
Endocrinology	$488	5%	2%	1%	8%
Family Practice	$6,019	4%	2%	1%	6%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	3%	1%	0%	4%
General Surgery	$2,031	-1%	0%	0%	-2%
Geriatrics	$187	1%	1%	0%	2%
Hand Surgery	$226	0%	1%	0%	1%
Hematology/Oncology	$1,673	5%	2%	1%	8%
Independent Laboratory	$592	-2%	0%	0%	-2%
Infectious Disease	$640	-2%	0%	0%	-2%
Internal Medicine	$10,507	1%	1%	0%	2%
Interventional Pain Mgmt	$885	2%	2%	1%	4%
Interventional Radiology	$432	-1%	-2%	0%	-4%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	-1%	0%	0%	-1%
Neurology	$1,503	1%	4%	0%	5%
Neurosurgery	$802	-1%	0%	-1%	-3%
Nuclear Medicine	$50	-2%	0%	0%	-2%
Nurse Anes / Anes Asst	$1,291	-4%	-1%	0%	-5%
Nurse Practitioner	$4,503	2%	1%	0%	4%
Obstetrics/Gynecology	$620	2%	2%	0%	4%
Ophthalmology	$5,398	-3%	-4%	0%	-7%
Optometry	$1,325	0%	-2%	0%	-2%
Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-1%
Orthopedic Surgery	$3,734	0%	1%	0%	1%
Other	$34	-1%	-1%	0%	-2%
Otolarngology	$1,225	2%	2%	0%	3%
Pathology	$1,203	-3%	-2%	0%	-5%
Pediatrics	$62	2%	1%	0%	3%
Physical Medicine	$1,110	0%	0%	0%	1%
Physical/Occupational Therapy	$4,248	-3%	-2%	0%	-5%
Physician Assistant	$2,637	2%	1%	0%	4%
Plastic Surgery	$369	-1%	0%	-1%	-2%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Podiatry	$1,998	2%	2%	0%	4%
Portable X-Ray Supplier	$94	-1%	-1%	0%	-2%
Psychiatry	$1,120	1%	1%	0%	3%
Pulmonary Disease	$1,658	0%	0%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-1%	-1%	0%	-2%
Radiology	$4,971	-3%	-2%	-1%	-5%
Rheumatology	$534	5%	2%	1%	8%
Thoracic Surgery	$352	-3%	-1%	0%	-4%
Urology	$1,739	2%	2%	0%	5%
Vascular Surgery	$1,203	-1%	-2%	0%	-3%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

We also considered an alternative that reflected CMS refinements to the three CPT codes as described above and also included the consolidated, redefined and revalued HCPCS add-on G code, GPC1X.

Table 118 illustrates the specialty level impacts associated with making refinements to the RUC recommended values for the office/outpatient E/M code set and also making separate payment for HCPCS add-on code GPC1X. These impacts are similar to what we are proposing, with slight less positive impacts for those specialties who bill CPT codes 99212 or 99214.

TABLE 118: Estimated Specialty Specific Impacts of CMS Refined Values with HCPCS add-on G code GPC1X if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	7%
Anesthesiology	$1,993	-5%	-1%	0%	-6%
Audiologist	$70	-4%	-2%	0%	-6%
Cardiac Surgery	$279	-5%	-2%	-1%	-7%
Cardiology	$6,595	1%	1%	0%	3%
Chiropractor	$750	-5%	-3%	-1%	-9%
Clinical Psychologist	$787	-6%	0%	0%	-6%
Clinical Social Worker	$781	-6%	0%	0%	-6%
Colon And Rectal Surgery	$162	-3%	0%	0%	-3%
Critical Care	$346	-4%	-1%	0%	-5%
Dermatology	$3,541	0%	1%	-1%	-1%
Diagnostic Testing Facility	$697	0%	-3%	0%	-4%
Emergency Medicine	$3,021	-5%	-2%	1%	-6%
Endocrinology	$488	10%	4%	1%	15%
Family Practice	$6,019	7%	3%	1%	11%
Gastroenterology	$1,713	-2%	-1%	-1%	-4%
General Practice	$405	5%	2%	0%	7%
General Surgery	$2,031	-3%	-1%	0%	-4%
Geriatrics	$187	1%	2%	0%	3%
Hand Surgery	$226	-1%	0%	0%	-1%
Hematology/Oncology	$1,673	7%	4%	1%	12%
Independent Laboratory	$592	-2%	-1%	0%	-4%
Infectious Disease	$640	-2%	0%	0%	-3%
Internal Medicine	$10,507	2%	2%	0%	4%
Interventional Pain Mgmt	$885	4%	3%	1%	8%
Interventional Radiology	$432	-2%	-3%	0%	-5%
Multispecialty Clinic/Other Phys	$148	-2%	0%	0%	-2%
Nephrology	$2,164	-2%	0%	0%	-2%
Neurology	$1,503	2%	5%	0%	8%
Neurosurgery	$802	-3%	-1%	-2%	-6%
Nuclear Medicine	$50	-3%	0%	0%	-4%
Nurse Anes / Anes Asst	$1,291	-6%	-2%	0%	-8%
Nurse Practitioner	$4,503	4%	3%	0%	7%
Obstetrics/Gynecology	$620	4%	3%	0%	7%
Ophthalmology	$5,398	-4%	-5%	0%	-9%
Optometry	$1,325	-2%	-3%	0%	-5%
Oral/Maxillofacial Surgery	$71	-1%	-1%	-1%	-3%
Orthopedic Surgery	$3,734	-1%	0%	0%	-2%
Other	$34	-3%	-2%	0%	-5%
Otolarngology	$1,225	3%	2%	0%	5%
Pathology	$1,203	-4%	-3%	-1%	-8%
Pediatrics	$62	3%	2%	0%	5%
Physical Medicine	$1,110	-2%	0%	0%	-2%
Physical/Occupational Therapy	$4,248	-4%	-4%	0%	-8%
Physician Assistant	$2,637	4%	2%	0%	7%
Plastic Surgery	$369	-2%	-1%	-1%	-4%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Podiatry	$1,998	0%	1%	0%	1%
Portable X-Ray Supplier	$94	-1%	-3%	0%	-4%
Psychiatry	$1,120	4%	3%	0%	7%
Pulmonary Disease	$1,658	0%	1%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-2%	-2%	0%	-4%
Radiology	$4,971	-4%	-3%	0%	-8%
Rheumatology	$534	8%	4%	1%	13%
Thoracic Surgery	$352	-4%	-2%	-1%	-7%
Urology	$1,739	4%	4%	0%	8%
Vascular Surgery	$1,203	-2%	-3%	0%	-4%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

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3. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold and the additional performance threshold, as the critical factors affecting the distribution of payment adjustments. We ran two separate models with performance thresholds of 35 and 50 respectively (as an alternative to the proposed performance threshold of 45) to estimate the impact of a more moderate and a more aggressive increase in the performance threshold. A lower performance threshold would be a more gradual transition and could potentially allow more clinicians to meet or exceed the performance threshold. The lower performance threshold would lower the amount of budget neutral dollars to redistribute and increase the number of clinicians with a positive payment adjustment, but the scaling factor would be lower. In contrast, a more aggressive increase would likely lead to higher positive payment adjustments for clinicians that exceed the performance threshold because the budget neutral pool would be redistributed among fewer clinicians. We ran each of these models using the proposed additional performance threshold of 80. In the model with a performance threshold of 35, we estimate that $466 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 5.3 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 8.2 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with a performance threshold of 50, we estimate that $644 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 6.1 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 15.5 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. We proposed a performance threshold of 45 because we believe increasing the performance threshold to 45 points was not unreasonable or too steep, but rather a moderate step that encourages clinicians to gain experience with all MIPS performance categories. We refer readers to section III.K.3.e.(2) of this proposed rule for additional rationale on the selection of the performance threshold.

To evaluate the impact of modifying the additional performance threshold, we ran two models with additional performance thresholds of 75 and 85 as an alternative to the proposed 80 points. We ran each of these models using a performance threshold of 45. The benefit of the model with the additional performance threshold of 75 would maintain the additional performance threshold that was in year 3. In the model with the additional performance threshold of 75, we estimate that $586 million would be redistributed through budget neutrality, and there would be a maximum payment adjustment of 4.8 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 12.7 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with an additional performance threshold of 85, we estimate that $586 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 8.3 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance among those that submit data. Also, that 12.7 percent of MIPS eligible clinicians will receive a negative payment adjustment among those that submit data. We proposed the additional performance threshold at 80 points because we believe raising the additional performance threshold would incentivize continued improved performance while accounting for policy changes in the fourth year of the program. We refer readers to section III.K.3.e.(3) of this proposed rule for additional rationale on the selection of additional performance threshold.

G. Impact on Beneficiaries

1. Medicare PFS

There are a number of changes in this proposed rule that will have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, will have a positive impact and improve the quality and value of care provided to Medicare providers and beneficiaries.

2. Quality Payment Program

There are several changes in this rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new

proposed measures include patient-reported outcomes, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcomes are factors frequently of interest to patients when making decisions about treatment. Similarly, our proposals in section III.K.3.g.(2) of this rule will improve the caliber and value of QCDR measures.

H. Burden Reduction Estimates

1. Payment for E/M Services

In the CY 2019 PFS final rule, we finalized proposals that we made in response to comments received from RFIs released to the public under our Patients Over Paperwork Initiative. Specifically, we finalized proposals that focused on simplifying the medical documentation payment framework for office/outpatient E/M services and allowing greater flexibility on the components practitioners could choose to document when billing Medicare for office/outpatient E/M visits. In that rule we discussed the specific changes to documentation requirements and estimated significant reductions in the amount of time that practitioners would spend documenting office/outpatient E/M visits, furthering our goal of allowing practitioners more time spent with patients. As discussed earlier in section II.P. of this proposed rule, we are proposing to adopt the revised office/outpatient E/M code set. Our new proposals reflect our ongoing dialog with the practitioner community and take into account the significant revisions the AMA/CPT editorial panel has made to the guidelines for the office/outpatient E/M code set. We note that as part of its efforts to revise the guidelines, the AMA has also estimated a reduction in the amount of time practitioners would spend documenting office/outpatient E/M visits. The AMA asserts that its revisions to the office/outpatient E/M code set will accomplish similar, albeit greater burden reduction in comparison with CMS' approach, as finalized in the CY 2019 PFS final rule, and is more intuitive and in line with the current practice of medicine. We reviewed the AMA's estimates and acknowledge that overall the AMA's approach does result in burden reduction that are consistent with our broader goals discussed above. In comparison to our estimates of burden reduction, as discussed in the CY 2019 final rule, the AMA's estimates show less documentation burden to practitioners, the difference resulting from CMS' finalized policies that allow use of add-on codes to reflect additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits that the current E/M coding and visit levels do not fully recognize (FR 83 59638). The AMA estimates reflect assumptions that the time spent documenting appropriate application of the add-on codes may result in additional burden to practitioners. We disagree with this assumption. In addition to proposing to redefine and revalue HCPCS G code add-on GPC1X to be more understandable and easy to report for purposes of medical documentation and billing, and proposing to delete HCPCS G-code add-on GCG0X, we believe that while an initial setup period is expected for practices to establish workflows that incorporate appropriate use of the add-on code, practices should be able to automate the appropriate use of the add-on code in a short period of time. Even so, our proposal to adopt the AMA's revised office/outpatient E/M code set is consistent with our goal of burden reduction and aligns with the policy principles that underlay what we finalized in the CY 2019 PFS final rule. The AMA's estimates of burden reduction as related to office/outpatient E/M documentation and other materials pertinent to the AMA/CPT and AMA/RUCs recent efforts to revise the office/outpatient E/M code set are available at *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*.

2. Beneficiary Liability

Many proposed policy changes could result in a change in beneficiary liability as it relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/,* the CY 2019 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.92, which means that in CY 2019, a beneficiary would be responsible for 20 percent of this amount, or $21.98. Based on this proposed rule, using the CY 2020 CF, the CY 2020 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures public use file, is $110.43, which means that, in CY 2020, the final beneficiary coinsurance for this service would be $22.09.

I. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $874.88 (8.0 hours × $109.36). Therefore, we estimated that the total cost of reviewing this regulation is $13,399,662 ($874.88 × 15,316 reviewers).

J. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 119 and 120 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2019 to CY 2020 based on the FY 2020 President's Budget baseline.

TABLE 119—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2020 Annualized Monetized Transfers	Estimated increase in expenditures of $0.3 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 120—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2020 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Beneficiaries to Federal Government.

K. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

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

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 403.902 is amended—
■ a. By adding in alphabetical order the definitions of ''Certified nurse midwife'', ''Certified registered nurse anesthetist'', and ''Clinical nurse specialist'';
■ b. By revising the definition of ''Covered recipient'';
■ c. By adding in alphabetical order the definitions of ''Device identifier'', ''Long term medical supply or device loan'', ''Non-teaching hospital covered recipient'', ''Nurse practitioner'', ''Physician assistant'', ''Short term medical supply or device loan'', and ''Unique device identifier''.

The additions and revisions read as follows:

§ 403.902 Definitions.

* * * * *

Certified nurse midwife means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

Certified registered nurse anesthetist means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

* * * * *

Clinical nurse specialist means, an individual who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(2) Holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

* * * * *

Covered recipient means—

(1) Any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife who is not a bona fide employee of the applicable manufacturer that is reporting the payment; or

Device identifier is the mandatory, fixed portion of a unique device identifier (UDI) that identifies the specific version or model of a device and the labeler of that device (as described at 21 CFR 801.3 in paragraph (1) of the definition of ''Unique device identifier'').

* * * * *

Long term medical supply or device loan means the loan of supplies or a device for 91 days or longer.

Non-teaching hospital covered recipient means a person who is one or more of the following: Physician, physician assistant, nurse practitioner, clinical nurse specialist, certified

registered nurse anesthetist, or certified nurse-midwife.

* * * * *

Nurse practitioner means a nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

* * * * *

Physician assistant means a physician assistant who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

* * * * *

Short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

* * * * *

Unique device identifier means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 830.20 (mirrored from 21 CFR 801.3).

■ 3. Section 403.904 is amended by:

■ a. Revising paragraphs (c)(1), (c)(3) introductory text, (c)(3)(ii) and (iii), (c)(8), (e)(2) introductory text, (e)(2)(xiv);

■ b. Adding paragraph (e)(2)(xi);

■ c. Revising paragraph (e)(2)(xv);

■ d. Adding paragraph (e)(2)(xviii); and

■ e. Revising paragraphs (f)(1) introductory text, (f)(1)(i)(A) introductory text, (f)(1)(i)(A)(*1*), (f)(1)(i)(A)(*3*), (f)(1)(i)(A)(5), (f)(1)(iv), (f)(1)(v), (h)(5), (h)(7), and (h)(13).

The revisions and addition read as follows:

§ 403.904 Reports of payments or other transfers of value to covered recipients.

* * * * *

(c) * * *

(1) *Name of the covered recipient.* For non-teaching hospital covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (NPPES) (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

* * * * *

(3) *Identifiers for non-teaching hospital covered recipients.* In the case of a covered recipient the following identifiers:

* * * * *

(ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a non-teaching hospital covered recipient, the field may be left blank, indicating that the applicable manufacturer could not find one.

(iii) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license), and the State(s) in which the license is held.

* * * * *

(8) *Related covered drug, device, biological or medical supply.* Report the marketed or brand name of the related covered drugs, devices, biologicals, or medical supplies, and therapeutic area or product category unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply.

(i) For drugs and biologicals—

(A) If the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on *clinicaltrials.gov*.

(B) Any regularly used identifiers must be reported, including, but not limited to, national drug codes.

(ii) For devices, if the device has a unique device identifier (UDI), then the device identifier (DI) portions of it must be reported, as applicable.

(iii) Applicable manufacturers may report the marketed name and therapeutic area or product category for payments or other transfers of value related to a non-covered drug, device, biological, or medical supply.

(iv) Applicable manufacturers must indicate if the related drug, device, biological, or medical supply is covered or non-covered.

(v) Applicable manufacturers must indicate if the payment or other transfer of value is not related to any covered or non-covered drug, device, biological or medical supply.

* * * * *

(e) * * *

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xviii) of this section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

* * * * *

(xi) Debt forgiveness.

* * * * *

(xiv) Compensation for serving as faculty or as a speaker for a medical education program.

(xv) Long term medical supply or device loan.

* * * * *

(xviii) Acquisitions.

* * * * *

(f) * * *

(1) Research-related payments or other transfers of value to covered recipients, including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) * * *

(A) If paid to a non-teaching hospital covered recipient, all of the following must be provided:

(*1*) The non-teaching hospital covered recipient's name as listed in the NPPES (if applicable).

* * * * *

(*3*) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license) and State(s) in which the license is held.

* * * * *

(*5*) Primary business address of the non-teaching hospital covered recipient(s).

* * * * *

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section); for drugs and biologicals, the relevant National Drug Code(s), if any; and for devices and medical supplies, the relevant device identifier, if any, and the therapeutic area or product category if a marketed name is not available.

(v) Information about each non-teaching hospital covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

* * * * *

(h) * * *

(5) Short term medical supply or device loan.

* * * * *

(7) A transfer of anything of value to a non-teaching hospital covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

* * * * *

(13) In the case of a non-teaching hospital covered recipient, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

* * * * *

■ 4. Section 403.908 is amended by revising paragraphs (g)(2)(ii) introductory text to read as follows:

§ 403.908 Procedures for electronic submission of reports.

* * * * *

(g) * * *

(2) * * *

(ii) Covered recipients—

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 5. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 6. Section 410.20 is amended by adding paragraph (e) to read as follows:

§ 410.20 Physicians' services.

* * * * *

(e) *Medical record documentation.* The physician may review and verify (sign/date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team including, as applicable, notes documenting the physician's presence and participation in the services.

■ 7. Section 410.40 is amended—

■ a. By redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively;

■ b. By adding new paragraph (a);

■ c. In newly redesignated paragraph (b)(1) by removing the reference ''paragraphs (d) and (e)'' and adding in its place the reference ''paragraphs (e) and (f)''; and

■ d. By revising newly redesignated paragraphs (e)(2)(i), (e)(3)(i), and (e)(3)(iii) through (e)(3)(v).

The additions and revision reads as follows:

§ 410.40 Coverage of ambulance services.

(a) *Definitions.* As used in this section, the following definitions apply:

Non-physician certification statement means a statement signed and dated by an individual which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met and who meets all of the criteria in paragraphs (i) through (iii) of this definition. The statement need not be a stand-alone document and no specific format or title is required.

(i) Has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished;

(ii) Who must be employed:

(A) By the beneficiary's attending physician; or

(B) By the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported;

(iii) Is among the following individuals, with respect to whom all Medicare regulations and all applicable State licensure laws apply:

(A) Physician assistant (PA).

(B) Nurse practitioner (NP).

(C) Clinical nurse specialist (CNS).

(D) Registered nurse (RN).

(E) Licensed practical nurse (LPN).

(F) Social worker.

(G) Case manager.

(H) Discharge planner.

Physician certification statement means a statement signed and dated by the beneficiary's attending physician which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met. The statement need not be a stand-alone document and no specific format or title is required.

* * * * *

(e) * * *

(2) * * *

(i) Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a physician certification statement dated no earlier than 60 days before the date the service is furnished.

* * * * *

(3) * * *

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a physician certification statement within 48 hours after the transport, certifying that the medical necessity requirements of paragraph (e)(1) of this section are met.

* * * * *

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, or non-physician certification statement must be obtained.

(iv) If the ambulance provider or supplier is unable to obtain the required physician or non-physician certification statement within 21 calendar days following the date of the service, the ambulance supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (e)(3)(iii) of this section.

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the physician or non-physician certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

* * * * *

■ 8. Section 410.41 is amended by revising the section heading and paragraph (c)(1) to read as follows:

§ 410.41 Requirements for ambulance providers and suppliers.

* * * * *

(c) * * *

(1) Bill for ambulance services using CMS-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification is on file, if required.

* * * * *

■ 9. Section 410.49 is amended by revising paragraph (b)(1)(vii) and adding paragraph (b)(1)(viii) to read as follows:

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

* * * * *

(b) * * *

(1) * * *

(vii) Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy

for at least 6 weeks, on or after February 18, 2014 for cardiac rehabilitation and on or after February 9, 2018 for intensive cardiac rehabilitation; or

(viii) Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

* * * * *

■ 10. Section 410.59 is amended by—

■ a. Adding paragraphs (a)(4) and (e)(1)(v); and

■ b. Revising paragraphs (e)(2) introductory text, (e)(2)(i) and (v), and (e)(3).

The additions and revisions read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(4) Effective for dates of service on and after January 1, 2020, for occupational therapy services described in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by an occupational therapy assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, ''furnished in whole or in part'' means when the occupational therapy assistant either:

(A) Furnishes all the minutes of a service exclusive of the occupational therapist; or

(B) Furnishes a portion of a service—either concurrently with or separately from the part furnished by the occupational therapist—such that the minutes for that portion of a service furnished by the occupational therapy assistant exceed 10 percent of the total minutes for that service.

* * * * *

(e) * * *

(1) * * *

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is no longer applied as a limitation on incurred expenses for outpatient occupational therapy services, but, is instead applied as a threshold above which claims for occupational therapy services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient occupational therapy includes:

(i) Outpatient occupational therapy services furnished under this section;

* * * * *

(v) Outpatient occupational therapy services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished under section 1834(k)(1)(B) of the Act.

* * * * *

(3) A process for medical review of claims for outpatient occupational therapy services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at or in excess of $3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the $3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the $3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process applies when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, $3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with $3,000 in 2027) by the increase in the Medicare Economic Index for the current year.

■ 11. Section 410.60 is amended by—

■ a. Adding paragraphs (a)(4) and (e)(1)(v); and

■ b. Revising paragraphs (e)(2) introductory text, (e)(2)(i), (ii) and (vi), and (e)(3).

The additions and revisions read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(4) Effective for dates of service on and after January 1, 2020, for physical therapy services described in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by a physical therapist assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, ''furnished in whole or in part'' means when the physical therapist assistant either:

(A) Furnishes all the minutes of a service exclusive of the physical therapist; or

(B) Furnishes a portion of a service either concurrently with or separately from the part furnished by the physical therapist such that the minutes for that portion of a service furnished by the physical therapist assistant exceed 10 percent of the total minutes for that service.

* * * * *

(e) * * *

(1) * * *

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is not applied as a limitation on incurred expenses for outpatient physical therapy and outpatient speech-language pathology services, but is instead applied as a threshold above which claims for physical therapy and speech-language pathology services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record; and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient physical therapy includes:

(i) Outpatient physical therapy services furnished under this section;

(ii) Outpatient speech-language pathology services furnished under § 410.62;

* * * * *

(vi) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished and paid under section 1834(k)(1)(B) of the Act.

(3) A process for medical review of claims for physical therapy and speech-language pathology services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at

or in excess of $3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the $3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the $3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, $3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with $3,000 for 2017) by the increase in the Medicare Economic Index for the current year.

■ 12. Section 410.67 is added to read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

(a) *Basis and scope*—(1) *Basis.* This section implements sections 1861(jjj), 1861(s)(2)(HH), 1833(a)(1)(CC) and 1834(w) of the Act which provide for coverage of opioid use disorder treatment services furnished by an opioid treatment program and the payment of a bundled payment under part B to an opioid treatment program for opioid use disorder treatment services that are furnished to a beneficiary during an episode of care beginning on or after January 1, 2020.

(2) *Scope.* This section sets forth the criteria for an opioid treatment program, the scope of opioid use disorder treatment services, and the methodology for determining the bundled payments to opioid treatment programs for furnishing opioid use disorder treatment services.

(b) *Definitions.* For purposes of this section, the following definitions apply:

Episode of care means a one week (contiguous 7-day) period.

Opioid treatment program means an entity that is an opioid treatment program (as defined in § 8.2 of this title, or any successor regulation) that meets the requirements described in paragraph (c) of this section.

Opioid use disorder treatment service means one of the following items or services for the treatment of opioid use disorder that is furnished by an opioid treatment program that meets the requirements described in paragraph (c) of this section.

(1) Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug, and Cosmetic Act for use in treatment of opioid use disorder.

(2) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.

(3) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements.

(4) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements.

(5) Toxicology testing.

Partial episode of care means an episode of care in which at least one opioid use disorder treatment service, but less than a majority of the opioid use disorder treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record), is furnished.

(c) *Requirements for opioid treatment programs.* To participate in the Medicare program and receive payment, an opioid treatment program must meet all of the following:

(1) Be enrolled in the Medicare program.

(2) Have in effect a certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the opioid treatment program.

(3) Be accredited by an accrediting body approved by the SAMHSA.

(4) Have in effect a provider agreement under part 489 of this title.

(d) *Bundled payments for opioid use disorder treatment services furnished by opioid treatment programs.*

(1) CMS will establish categories of bundled payments for opioid treatment programs as follows:

(i) Categories for each type of opioid agonist and antagonist treatment medication;

(ii) A category for medication not otherwise specified, which must be used for new FDA-approved opioid agonist or antagonist treatment medications for which CMS has not established a category; and

(iii) A category for no medication provided. Each category of bundled payment must consist of a payment amount for a full episode of care and a payment amount for a partial episode of care.

(2) The bundled payment for episodes of care in which a medication is provided must consist of payment for a drug component, reflecting payment for the applicable FDA-approved opioid agonist or antagonist medication in the patient's treatment plan, and a non-drug component, reflecting payment for all other opioid use disorder treatment services reflected in the patient's treatment plan (including dispensing/administration of the medication, if applicable). The payments for the drug component and non-drug component must be added together to create the bundled payment amount. The bundled payment for episodes of care in which no medication is provided shall consist of a single payment amount for all opioid use disorder treatment services reflected in the patient's treatment plan (not including medication or dispensing/administration of such medication).

(i) *Drug component for full episodes of care.* For full episodes of care, the payment for the drug component will be determined as follows, using the most recent data available at time of ratesetting for the applicable calendar year:

(A) For implantable and injectable medications, the payment must be determined using the methodology set forth in section 1847A of the Act, except that the payment amount shall be 100 percent of the ASP if ASP is used.

(B) For oral medications, the payment amount must be 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in part 414, subpart 800 of this chapter and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount must be based on an alternative methodology as determined by the Secretary.

(C) *Exception.* For the drug component of bundled payments in the medication not otherwise specified category under paragraph (d)(1)(B) of this section, the payment amount must be based on the applicable methodology under paragraphs (d)(2)(i)(A) and (d)(2)(i)(B) of this section (applying the most recent available data for such new medication), or invoice pricing until the necessary data become available.

(ii) *Drug component for partial episodes of care.* For partial episodes of care, the payment for the drug

component will be determined as follows:

(A) For oral medications, the amount will be half of the payment amount for the full episode of care.

(B) For injectable and implantable medications, the amount will be the same as the payment amount for the full episode of care.

(iii) *Non-drug component for full episodes of care.* For full episodes of care, the payment for CY 2020 for the non-drug components of the bundled payments will be based on the CY 2019 TRICARE weekly bundled rate for items and services furnished when a patient is prescribed methadone, minus the methadone cost, and adjusted as follows:

(A) For oral medications, no further adjustment.

(B) For injectable medications, to subtract an amount reflecting the cost of dispensing methadone and to add an amount reflecting the CY 2019 non-facility Medicare payment rate for the administration of an injection.

(C) For implantable medications, to subtract an amount reflecting the cost of dispensing methadone and to add an amount reflecting the CY 2019 non-facility Medicare payment rate for insertion, removal, or insertion and removal of the implant, as applicable.

(iv) *Non-drug component for partial episodes of care.* For partial episodes of care, the payment for CY 2020 for the non-drug components of the bundled payments will be based on the CY 2019 TRICARE weekly bundled rate for items and services furnished when a patient is prescribed methadone, minus the methadone cost, adjusted as follows:

(A) For oral medications, to halve the amount.

(B) For injectable medications, to subtract an amount reflecting the cost of dispensing methadone and then to halve the remaining amount. The resulting amount will be added to an amount reflecting the CY 2019 non-facility Medicare payment rate for the administration of an injection.

(C) For implantable medications, to subtract an amount reflecting the cost of dispensing methadone and then to halve the remaining amount. The resulting amount will be added to an amount reflecting the CY 2019 non-facility Medicare payment rate for insertion, removal, or insertion and removal of the implant, as applicable.

(v) *No medication provided, full and partial episodes of care.* The bundled payment amount for CY 2020 for a full episode of care in which no medication is provided will be based on the CY 2019 TRICARE weekly bundled rate for items and services furnished when a patient is prescribed methadone, minus the methadone cost, and minus an amount reflecting the cost of dispensing methadone. The bundled payment amount for CY 2020 for a partial episode of care in which no medication is provided will be half the payment amount for a full episode of care in which no medication is provided.

(3) Adjustments will be made to the bundled payment for the following:

(i) If the opioid treatment program furnishes counseling or therapy services in excess of the amount specified in the beneficiary's treatment plan and for which medical necessity is documented in the medical record, an adjustment will be made for each additional 30 minutes of counseling or individual therapy furnished during the episode of care or partial episode of care.

(ii) The payment amount for the non-drug component and the full bundled payment for an episode of care or partial episode of care in which no medication is provided will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26.

(iii) The payment amount for the non-drug component and the full bundled payment for an episode of care or partial episode of care in which no medication is provided will be updated annually using the Medicare Economic Index described in § 405.504(d).

(4) Payment for medications delivered, administered or dispensed to a beneficiary as part of the bundled payment must be considered a duplicative payment if delivery, administration or dispensing of the same medications was also separately paid under Medicare Parts B or D. CMS will recoup the duplicative payment made to the opioid treatment program.

(e) *Beneficiary cost-sharing.* A beneficiary copayment amount of zero will apply.

■ 13. Section 410.74 is amended by revising paragraph (a)(2)(iv), and adding paragraph (e) to read as follows:

§ 410.74 Physician assistants' services.

(a) * * *

(2) * * *

(iv) Performs the services in accordance with State law and State scope of practice rules for PAs in the State in which the physician assistant's professional services are furnished, with medical direction and appropriate supervision as provided by State law in which the services are performed. In the absence of State law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their professional services.

* * * * *

(e) *Medical record documentation.* For physician assistants' services, the physician assistant may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team, including, as applicable, notes documenting the physician assistant's presence and participation in the service.

■ 14. Section 410.75 is amended by adding paragraph (f) to read as follows:

§ 410.75 Nurse practitioners' services.

* * * * *

(f) *Medical record documentation.* For nurse practitioners' services, the nurse practitioner may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team, including, as applicable, notes documenting the nurse practitioner's presence and participation in the service.

■ 15. Section 410.76 is amended by adding paragraph (f) to read as follows:

§ 410.76 Clinical nurse specialists' services.

* * * * *

(f) *Medical record documentation.* For clinical nurse specialists' services, the clinical nurse specialist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team, including, as applicable, notes documenting the clinical nurse specialist's presence and participation in the service.

■ 16. Section 410.77 is amended by adding paragraph (e) to read as follows:

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

* * * * *

(e) *Medical record documentation.* For certified nurse-midwives' services, the certified nurse-midwife may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team, including, as applicable, notes documenting the certified nurse-midwife's presence and participation in the service.

■ 17. Section 410.105 is amended by adding paragraph (d) to read as follows:

§ 410.105 Requirements for coverage of CORF services.

* * * * *

(d) *Claims.* Effective for dates of service on and after January 1, 2020 physical therapy or occupational therapy services covered as part of a rehabilitation plan of treatment described in paragraph (c) of this section, as applicable—

(1) Claims for such services furnished in whole or in part by a physical therapist assistant or an occupational therapy assistant must be identified with the inclusion of the respective prescribed modifier; and

(2) Effective for dates of service on and after January 1, 2022, such claims are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service as defined at section 1834(k) of the Act.

(3) For purposes of this paragraph, ''furnished in whole or in part'' means when the physical therapist assistant or occupational therapy assistant either—

(i) Furnishes all the minutes of a service exclusive of the respective physical therapist or occupational therapist; or

(ii) Furnishes a portion of a service—either concurrently with or separately from the part furnished by the physical or occupational therapist such that the minutes for that portion of a service exceed 10 percent of the total time for that service.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 18. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 19. Section 411.370 is amended—

■ a. In paragraph (b) introductory text, by removing the phrase ''CMS determines'' and adding in its place the phrase ''CMS will determine''; and

■ b. By revising paragraphs (b)(1), (c) introductory text, (d), and (e).

The revisions read as follows:

§ 411.370 Advisory opinions relating to physician referrals.

* * * * *

(b) * * *

(1) The request must relate to an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. Requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties are not appropriate for an advisory opinion.

* * * * *

(c) *Matters not subject to advisory opinions.* CMS will not address through an advisory opinion—

* * * * *

(d) *Facts subject to advisory opinions.* The requestor must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in § 411.372.

(e) *Acceptance of requests.* (1) CMS does not accept an advisory opinion request or issue an advisory opinion if —

(i) The request is not related to a named individual or entity;

(ii) The request does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information;

(iii) CMS is aware, after consultation with OIG and DOJ, that the same course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(iv) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(2) CMS may elect not to accept an advisory opinion request if it determines, after consultation with OIG and DOJ, that the course of action described is substantially similar to a course of conduct that is under investigation or is the subject of a proceeding involving the Department or other law enforcement agencies, and issuing an advisory opinion could interfere with the investigation or proceeding.

* * * * *

■ 20. Section 411.372 is amended by revising paragraphs (b)(4)(i) and (ii), (5), (6), and (8)(ii) to read as follows:

§ 411.372 Procedure for submitting a request.

* * * * *

(b) * * *

(4) * * *

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including:

(A) The purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved); and

(B) Any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal service or employment contracts, leases, deeds, pension or insurance plans, or financial statements (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

* * * * *

(5) The identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and § 411.354), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) A discussion of the specific issues or questions to be addressed by CMS including, if possible, a discussion of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

* * * * *

(8) * * *

(ii) The chief executive officer, or other authorized officer, of the requestor, if the requestor is a corporation;

* * * * *

■ 21. Section 411.375 is amended by revising paragraphs (a) and (b) to read as follows:

§ 411.375 Fees for the cost of advisory opinions.

(a) *Initial payment.* Parties must include with each request for an advisory opinion a check or money order payable to CMS for $250. This initial payment is nonrefundable.

(b) *How costs are calculated.* In addition to the initial payment, CMS will charge an hourly rate of $220. Parties may request an estimate from CMS after submitting a complete request. Before issuing the advisory opinion, CMS calculates the fee for responding to the request.

* * * * *

§ 411.379 [Amended]

■ 22. Section 411.379(e) is amended by removing the phrase ''The 90-day period'' and adding in its place the phrase ''The 60-day period''.

§ 411.380 [Amended]

■ 23. Section 411.380 is amended—

■ a. In paragraph (c)(1), by removing the phrase ''within 90 days'' and adding in its place the phrase ''within 60 days''.

■ b. In paragraph (c)(2), by removing the phrase ''If the 90th day'' and adding in its place the phrase ''If the 60th day''.

■ c. In paragraph (c)(3) introductory text, by removing the phrase ''The 90-day period'' and adding in its place the phrase ''The 60-day period''.

§ 411.384 [Amended]

■ 24. Section 411.384(b) is amended by removing the phrase ''for public inspection during its normal hours of operation and''.

■ 25. Section 411.387 is revised to read as follows:

§ 411.387 Effect of an advisory opinion.

(a) An advisory opinion is binding on the Secretary, and a favorable advisory opinion shall preclude imposition of sanctions under section 1877(g) of the Act with respect to:

(1) The individuals or entities requesting the opinion; and

(2) Individuals or entities that are parties to the specific arrangement with respect to which such advisory opinion has been issued.

(b) The Secretary will not pursue sanctions under section 1877(g) of the Act against any party to an arrangement that CMS determines is indistinguishable in all its material aspects from an arrangement with respect to which CMS issued a favorable advisory opinion.

(c) Individuals and entities may rely on an advisory opinion as non-binding guidance that illustrates the application of the self-referral law and regulations to the specific facts and circumstances described in the advisory opinion.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 26. The authority for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

§ 414.601 [Amended]

■ 27. Section 41.601 is amended by adding the sentence ''Section 1834(l)(17) of the Act requires the development of a data collection system to collect cost, revenue, utilization, and other information determined appropriate from providers of services and suppliers of ground ambulance services.'' to to the end of the section.

■ 28. Section 414.605 is amended by adding the definition of ''ground ambulance organization'' in alphabetical order to read as follows:

§ 414.605 Definitions.

* * * * *

Ground ambulance organization means a Medicare provider or supplier of ground ambulance services.

* * * * *

■ 29. Section 414.610 is amended by adding paragraph (c)(9) to read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(9) *Payment Reduction for Failure to Report Data.* In the case of a ground ambulance organization (as defined at § 414.605) that is selected by CMS under § 414.626(c) for a year that does not sufficiently submit data under § 414.626(b) and is not granted a hardship exemption under § 414.626(d), the payments made under this section are reduced by 10 percent for the applicable period. For purposes of this paragraph, the applicable period is the calendar year that begins following the date that CMS provided written notification to the ground ambulance organization under § 414.626(e)(1) that the ground ambulance did not sufficiently submit the required data.

* * * * *

■ 30. Section 414.626 is added to read as follows:

§ 414.626 Data reporting by ground ambulance organizations.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Data collection period means, with respect to a year, the 12-month period that reflects the ground ambulance organization's annual accounting period.

Data reporting period means, with respect to a year, the 5 month period that begins the day after the last day of the ground ambulance organization's data collection period.

For a year means one of the calendar years from 2020 through 2024.

(b) *Data collection and submission requirement.* Except as provided in paragraph (d) of this section, a ground ambulance organization selected by CMS under paragraph (c) of this section must do the following:

(1) Within 30 days of the date that CMS notifies a ground ambulance organization under paragraph (c)(3) of this section that it has selected the ground ambulance organization to report data under this section, the ground ambulance must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to the ambulance organization's Medicare Administrative Contractor in accordance with CMS instructions on reporting the data collection period.

(2) Collect during its selected data collection period the data necessary to complete the Medicare Ground Ambulance Data Collection Instrument.

(3) Submit to CMS a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to the ground ambulance organization's selected data collection period.

(c) *Representative sample.* (1) *Random sample.* For purposes of the data collection described in paragraph (b) of this section, and for a year, CMS will select a random sample of 25 percent of eligible ground ambulance organizations that is stratified based on:

(i) Provider versus supplier status, ownership (for-profit, non-profit, and government);

(ii) Service area population density (transports originating in primarily urban, rural, and super rural zip codes); and

(iii) Medicare-billed transport volume categories.

(2) *Selection eligibility.* A ground ambulance organization is eligible to be selected for data reporting under this section for a year if it is enrolled in Medicare and has submitted to CMS at least one Medicare ambulance transport claim during the year prior to the selection under paragraph (b)(1) of this section.

(3) *Notification of selection for a year.* CMS will notify an eligible ground ambulance organization that it has been selected to report data under this section for a year at least 30 days prior to the beginning of the calendar year in which the ground ambulance organization must begin to collect data

by posting a list of selected organizations on the CMS web page and providing written notification to each selected ground ambulance organization via email or U.S. mail.

(4) *Limitation.* CMS will not select the same ground ambulance organization under this paragraph (c) in 2 consecutive years, to the extent practicable.

(d) *Hardship exemption.* A ground ambulance organization selected under paragraph (c) of this section may request and CMS may grant an exception to the reporting requirements under paragraph (b) of this section in the event of a significant hardship such as, a natural disaster, bankruptcy, or similar situation that the Secretary determines interfered with the ability of the ground ambulance organization to submit such information in a timely manner for the data collection period selected by the ground ambulance organization.

(1) To request a hardship exemption, the ground ambulance organization must submit a request form (accessed on the Ambulances Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*) to CMS within 90 calendar days of the date that CMS notified the ground ambulance organization that it would receive a 10 percent payment reduction as a result of not submitting sufficient information under the data collection system. The request form must include all of the following:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Ground ambulance organization address.

(iv) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable).

(v) Reason for requesting a hardship exemption.

(vi) Evidence of the impact of the hardship (such as photographs, newspaper or other media articles, financial data, bankruptcy filing, etc.).

(vii) Date when the ground ambulance organization would be able to begin collecting data under paragraph (b) of this section.

(viii) Date and signature of the chief executive officer or other designated personnel of the ground ambulance organization.

(2) CMS will provide a written response to the hardship exemption request within 30 days of its receipt of the hardship exemption form.

(e) *Notification of non-compliance and informal review.* (1) *Notification of non-compliance.* A ground ambulance organization selected under paragraph (c) of this section for a year that does not sufficiently report data under paragraph (b) of this section, and that is not granted a hardship exemption under paragraph (d) of this section, will receive written notification from CMS that it will receive a payment reduction under § 414.610(c)(9).

(2) *Informal review.* A ground ambulance organization that receives a written notification under paragraph (e)(1) of a payment reduction under § 414.610(c)(9) may submit a request for an informal review within 90 days of the date it received the notification by submitting all of the following information:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address with the street location of the ground ambulance organization.

(iv) Ground ambulance organization's selected data collection period and data reporting period.

(v) A statement of the reasons why the ground ambulance organization does not agree with CMS's determination and any supporting documentation.

(f) *Public availability of data.* Beginning in 2022, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

(g) *Limitations on review.* There is no administrative or judicial review under section 1869 or section 1878 of the Act, or otherwise of the data required for submission under paragraph (b) of this section or the selection of ground ambulance organizations under paragraph (c) of this section.

■ 31. Section 414.1305 is amended by—

■ a. Adding the definition of ''Aligned Other Payer Medical Home Model'' in alphabetical order;

■ b. Revising the definition of ''Hospital-based MIPS eligible clinician'';

■ c. Adding the definition of ''MIPS Value Pathway'' in alphabetical order; and

■ d. Revising the definition of ''Rural area''.

The additions and revision read as follows:

§ 414.1305 Definitions.

* * * * *

Aligned Other Payer Medical Home Model means an aligned other payer payment arrangement (not including a Medicaid payment arrangement) operated by a payer formally partnering in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU) with CMS, and is determined by CMS to have the following characteristics:

(1) The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity of care.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

* * * * *

Hospital-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS; and

(2) For the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus

outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period; and

(3) Beginning with the 2022 MIPS payment year, an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period.

* * * * *

MIPS Value Pathway means a subset of measures and activities specified by CMS.

* * * * *

Rural area means a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

* * * * *

■ 32. Section 414.1310 is amended by—

■ a. Revising paragraph (e)(2)(ii); and

■ b. Removing paragraphs (e)(3) through (5);

The revision reads as follows:

§ 414.1310 Applicability.

* * * * *

(e) * * *

(2) * * *

(ii) Individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.

* * * * *

■ 33. Section 414.1315 is amended by revising paragraph (d)(2) to read as follows:

§ 414.1315 Virtual groups.

* * * * *

(d) * * *

(2) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

* * * * *

■ 34. Section 414.1320 is amended by adding paragraph (f) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(f) For purposes of the 2023 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 35. Section 414.1330 is amended by adding paragraphs (b)(4), (5), and (6) to read as follows:

§ 414.1330 Quality performance category.

* * * * *

(b) * * *

(4) 40 percent of a MIPS eligible clinician's final score for MIPS payment year 2022.

(5) 35 percent of a MIPS eligible clinician's final score for MIPS payment year 2023.

(6) 30 percent of a MIPS eligible clinician's final score for MIPS payment year 2024 and future years.

■ 36. Section 414.1335 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(3) * * *

(i) For the 12-month performance period, a group that participates in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

* * * * *

■ 37. Section 414.1340 is amended by adding paragraph (d) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

* * * * *

(d) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

■ 38. Section 414.1350 is amended by—

■ a. Revising paragraphs (b) and (c)(2); and

■ b. Adding paragraphs (d)(4), (5), and (6).

The revisions and additions read as follows:

§ 414.1350 Cost performance category.

* * * * *

(b) *Attribution.* (1) Cost measures are attributed at the TIN/NPI level for the 2017 thorough 2019 performance periods.

(2) For the total per capita cost measure specified for the 2017 through 2019 performance periods, beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

(3) For the Medicare Spending per Beneficiary clinician (MSPB clinician) measure specified for the 2017 through 2019 performance periods, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB clinician measure during the applicable performance period.

(4) For the acute condition episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills at least 30 percent of inpatient evaluation and management (E&M) visits during the trigger event for the episode.

(5) For the procedural episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills a Medicare Part B claim with a trigger code during the trigger event for the episode.

(6) For the acute inpatient medical condition episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who bills inpatient E&M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization.

(7) For the procedural episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(8) Beginning with the 2020 performance period, each cost measure is attributed according to the measure specifications for the applicable performance period.

* * * * *

(c) * * *

(2) For the Medicare spending per beneficiary clinician measure, the case minimum is 35.

* * * * *

(d) * * *

(4) 20 percent of a MIPS eligible clinician's final score for MIPS payment year 2022.

(5) 25 percent of a MIPS eligible clinician's final score for MIPS payment year 2023.

(6) 30 percent of a MIPS eligible clinician's final score for MIPS payment year 2024 and each subsequent MIPS payment year.

■ 39. Section 414.1360 is amended by adding paragraph (a)(2) to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) * * *

(2) *Groups and virtual groups.* Beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, and the NPIs must perform the same activity for the same continuous 90 days in the performance period.

* * * * *

■ 40. Section 414.1370 is amended by amending paragraph (e)(2) to read as follows:

§ 414.1370 APM scoring standard under MIPS.

* * * * *

(e) * * *

(2) For purposes of calculating the APM Entity group score under the APM scoring standard, MIPS scores submitted by virtual groups will not be included.

* * * * *

■ 41. Section 414.1380 is amended—

■ a. In paragraph (b)(1)(i) introductory text by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ b. In paragraph (b)(1)(i)(A)(*1*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ c. By revising paragraph (b)(1)(ii) introductory text;

■ d. By adding paragraph (b)(1)(ii)(C);

■ e. By revising paragraph (b)(1)(v)(A)(*1*)(*i*);

■ f. In paragraph (b)(1)(v)(A)(*1*)(*ii*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ g. In paragraph (b)(1)(v)(B)(*1*)(*i*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ h. In paragraph (b)(1)(vi)(C)(*4*) by removing the phrase ''2020 and 2021 MIPS payment year'' and adding in its place the phrase ''2020 through 2022 MIPS payment years'';

■ i. By revising paragraph (b)(3)(ii)(A) and (C);

■ j. In paragraph (c)(2)(i)(A)(*4*) by removing the phrase ''beginning with the 2021 MIPS payment year'' and adding in its place the phrase ''for the 2021 and 2022 MIPS payment years'';

■ k. In paragraph (c)(2)(i)(A)(*5*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019, 2020, 2021, and 2022'';

■ l. By adding paragraph (c)(2)(i)(A)(*9*);

■ m. By revising paragraph (c)(2)(i)(C) introductory text;

■ n. By adding paragraphs (c)(2)(i)(C)(*10*) and (c)(2)(ii)(D), (E), and (F);

■ o. By revising paragraph (c)(2)(iii) and (c)(3) introductory text; and

■ p. In paragraph (e)(2)(i)(C) by removing the phrase ''Can be attributed'' and adding in its place the phrase ''Can be assigned''.

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) *Benchmarks.* Except as provided in paragraphs (b)(1)(ii)(B) and (C) of this section, benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

* * * * *

(C) Beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines may have the potential to result in inappropriate treatment, CMS will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at paragraph (b)(1)(ii) of this section.

* * * * *

(v) * * *

(A) * * *

(*1*) * * *

(*i*) Each high priority measure must meet the case minimum requirement at paragraph (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

* * * * *

(3) * * *

(ii) * * *

(A) The practice has received accreditation from an accreditation organization that is nationally recognized.

* * * * *

(C) The practice is a comparable specialty practice that has received recognition through a specialty recognition program offered through a nationally recognized accreditation organization; or

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*9*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

* * * * *

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. Except as provided in paragraph (c)(2)(i)(C)(10) of this section, in the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(10) Beginning with the 2020 MIPS payment year, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

* * * * *

(ii) * * *

(D) For the 2022 MIPS payment year:

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Reweighting scenario	Quality (%)	Cost (%)	Improvement Activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	40	20	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	65	20	15	0
No Quality	0	20	15	65
No Improvement Activities	55	20	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	85	15	0
No Promoting Interoperability and no Improvement Activities	80	20	0	0
No Quality and no Improvement Activities	0	20	0	80

(E) For the 2023 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement Activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	35	25	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	50	35	15	0
No Quality	0	40	15	45
No Improvement Activities	45	30	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	65	0	0	35
No Promoting Interoperability and no Quality	0	85	15	0
No Promoting Interoperability and no Improvement Activities	55	45	0	0
No Quality and no Improvement Activities	0	45	0	55

(F) For the 2024 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement Activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	45	40	15	0
No Quality	0	45	15	40
No Improvement Activities	40	35	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	60	0	0	40
No Promoting Interoperability and no Quality	0	85	15	0
No Promoting Interoperability and no Improvement Activities	50	50	0	0
No Quality and no Improvement Activities	0	60	0	40

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(iii) For the Promoting Interoperability performance category to be reweighted in accordance with paragraph (c)(2)(ii) of this section for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting based on the circumstances described in paragraph (c)(2)(i) of this section, or the group or virtual group must meet the definition of a hospital-based MIPS eligible clinician or a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(3) *Complex patient bonus.* For the 2020, 2021 and 2022 MIPS payment years, provided that a MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as follows:

* * * * *

■ 42. Section 414.1385 is amended by revising paragraph (a) to read as follows:

§ 414.1385 Targeted review and review limitations.

(a) *Targeted review.* A MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year. The process for targeted review is as follows:

(1) A MIPS eligible clinician or group (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review.

(2) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year. The targeted review request submission period may be extended as specified by CMS.

(3) A request for a targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not submitted during the targeted review request submission period; or the request is outside of the scope of the targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year. If the targeted review request is denied, there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician or group. If the targeted review request is approved, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician or group.

(4) CMS will respond to each request for a targeted review timely submitted and determine whether a targeted review is warranted.

(5) A request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS's request. Non-responsiveness to CMS's request for additional information may result in a final decision based on the information available, although another request for a targeted review may be submitted before the end of the targeted review request submission period.

(6) If a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to measures, activities, performance categories, and the final score, as well as the MIPS payment adjustment factors.

(7) Decisions based on the targeted review are final, and there is no further review or appeal. CMS will notify the individual or entity that submitted the request for a targeted review of the final decision.

(8) Documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.

* * * * *

■ 43. Section 414.1395 is amended by revising paragraph (a) to read as follows:

§ 414.1395 Public reporting.

(a) *General.* (1) CMS posts on Physician Compare, in an easily understandable format, the following:

(i) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and

(ii) The names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs.

(2) CMS periodically posts on Physician Compare aggregate

information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category.

(3) The information made available under this section will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

* * * * *

■ 44. Section 414.1400 is amended by—

■ a. Revising paragraphs (a)(2) introductory text and (a)(2)(iii);

■ b. Adding paragraphs (a)(4)(v) and (vi),

■ c. Revising paragraph (b)(1),

■ d. Adding paragraphs (b)(2)(iii) and (iv), (b)(3)(iv) through (vii), ;

■ e. Revising paragraph (c)(1);

■ f. Adding paragraphs (c)(2)(i) and (ii); and

■ g. Revising paragraphs (f)(1) introductory text and (f)(3) introductory text.

The revision and addition reads as follows:

§ 414.1400 Third party intermediaries.

(a) * * *

(2) Beginning with the 2021 performance period and all future years, for the following MIPS performance categories, QCDRs and qualified registries must be able to submit data for all categories, and Health IT vendors must be able to submit data for at least one category:

* * * * *

(iii) Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or § 414.1380(c)(2)(i)(C)(*9*)).

* * * * *

(4) * * *

(v) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(vi) Prior to discontinuing services to any MIPS eligible clinician, group, or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third party intermediary according to a CMS approved a transition plan.

* * * * *

(b) * * *

(1) *QCDR self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a QCDR must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing QCDRs that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period. Beginning with the 2023 payment year, QCDRs are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at paragraph (b)(2)(iv) of this section), and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Each QCDR would still be required to submit notification to CMS within the reporting period promptly within the month of realization of the impending deficiency in order to be considered for this exception, as discussed at paragraph (b)(2)(iv) of this section.

(2) * * *

(iii) Beginning with the 2023 MIPS payment year, the QCDR must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives.

(iv) Beginning with the 2023 MIPS payment year, require QCDRs to provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period.

* * * * *

(3) * * *

(iv) QCDR measure considerations for approval include:

(A) Preference for measures that are outcome-based rather than clinical process measures.

(B) Measures that address patient safety and adverse events.

(C) Measures that identify appropriate use of diagnosis and therapeutics.

(D) Measures that address the domain of care coordination.

(E) Measures that address the domain for patient and caregiver experience.

(F) Measures that address efficiency, cost, and resource use.

(G) Beginning with the 2021 performance period—

(*1*) That QCDRs link their QCDR measures to the following at the time of self-nomination:

(*i*) Cost measure,

(*ii*) Improvement activity,

(*iii*) An MVP.

(*2*) In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.

(H) Beginning with the 2020 performance period CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(I) QCDRs should conduct an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and utilize the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development.

(J) Beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved.

(*1*) Beginning with the 2020 performance period, in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure

participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

(*2*) [Reserved]

(v) QCDR measure requirements for approval include:

(A) QCDR Measures that are beyond the measure concept phase of development.

(B) QCDR Measures that address significant variation in performance.

(C) Beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

(D) Beginning with the 2021 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(E) Beginning with the 2020 performance period, areas of duplication identified by CMS should be addressed within a year of the request. If the QCDR measures are not harmonized, CMS may reject the duplicative QCDR measure.

(vi) Beginning with the 2021 performance period, QCDR measures may be approved for 2 years, at CMS discretion, by attaining approval status by meeting QCDR measure considerations and requirements, Upon annual review, CMS may revoke QCDR measure second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; requires QCDR measure harmonization; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

(vii) Beginning with the 2020 performance period, QCDR measure rejection criteria considerations, that include, but are not limited to, the following factors:

(A) QCDR measures that are duplicative, or identical to other QCDR measures or MIPS quality measures that are currently in the program.

(B) QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.

(C) QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.

(D) QCDR measures that meet the topped out definition.

(E) QCDR measures that are process-based, with consideration to whether the removal of the process measure impacts the number of measures available for a specific specialty.

(F) Whether the QCDR measure has potential unintended consequences to a patient's care.

(G) Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.

(H) Whether the previously identified areas of duplication have been addressed as requested.

(I) QCDR measures that split a single clinical practice or action into several QCDR measures.

(J) QCDR measures that are ''check-box'' with no actionable quality action.

(K) QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years.

(L) Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality actions, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.

(M) QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.

(N) QCDR measures that focus on rare events or ''never events'' in the measurement period.

(c) * * *

(1) *Qualified registry self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a qualified registry must self-nominate from September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period. Beginning with the 2023 payment year, qualified registries are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(c)(2)(ii)), and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Each qualified registry would still be required to submit notification to CMS within the reporting period promptly within the month of realization of the impending deficiency in order to be considered for this exception, as discussed at § 414.1400(c)(2)(ii).

(2) * * *

(i) Beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) Beginning with the 2023 MIPS payment year, require qualified registries to provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registries. Exceptions to this requirement may occur if the qualified registries does not receive the data from their clinician until the end of the performance period

* * * * *

(f) * * *

(1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, has submitted a false certification under paragraph (a)(5) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

* * * * *

(3) For purposes of paragraph (f) of this section, CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, including but not limited to, if the submitted data:

* * * * *

■ 45. Section 414.1405 is amended by—

■ a. Adding paragraphs (b)(7) and (8);

■ b. Adding paragraph, (d)(6) and (7); and

■ c. Revising paragraph (f) introductory text.

The additions and revisions read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(7) The performance threshold for the 2022 MIPS payment year is 45 points.

(8) The performance threshold for the 2023 MIPS payment year is 60 points.

* * * * *

(d) * * *

(6) The additional performance threshold for the 2022 MIPS payment year is 80 points.

(7) The additional performance threshold for the 2023 MIPS payment year is 85 points.

* * * * *

(f) *Exception to application of MIPS payment adjustment factors to model-specific payments under section 1115A APMs.* Beginning with the 2019 MIPS payment year, the payment adjustment factors specified under paragraph (e) of this section are not applicable to payments that meet all of the following conditions:

* * * * *

■ 46. Section 414.1415 is amended by revising paragraph (c)(5) and (6) to read as follows:

§ 414.1415 Advanced APM criteria.

* * * * *

(c) * * *

(5) For the purposes of this section, expected expenditures means the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the Medicare Part A and B expenditures for a participant in the absence of the APM. If the expected expenditures under the APM exceed the Medicare Part A and B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for purposes of Advanced APM determinations.

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this part, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 CFR part 422) are not considered capitation arrangements for purposes of this paragraph (c)(6).

* * * * *

■ 47. Section 414.1420 is amended by revising paragraph (d)(2) introductory text, (d)(2)(ii), (d)(3)(ii)), (d)(4) introductory text, (d)(5), (6), (7) and (8) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(d) * * *

(2) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model financial risk standard.* The APM Entity participates in a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, does one or more of the following:

* * * * *

(ii) Require direct payment by the APM Entity to the payer;

* * * * *

(3) * * *

(ii) Except for risk arrangements described under paragraph (d)(2) of this section, the risk arrangement must have a marginal risk rate of at least 30 percent.

* * * * *

(4) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model nominal amount standard.* For a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model to meet the Medicaid Medical Home Model nominal amount standard, the total annual amount that an APM Entity potentially owes a payer or forgoes must be at least the following amounts:

* * * * *

(5) *Marginal risk rate.* For purposes of this section, the marginal risk rate is defined as the percentage of actual expenditures that exceed expected expenditures for which an APM Entity is responsible under an other payer payment arrangement.

(i) In the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, with exceptions for large losses as described in paragraph (d)(5)(ii) of this section and small losses as described in paragraph (d)(5)(iii) of this section.

(ii) *Allowance for large losses.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the other payer payment arrangement greater than or equal to the total risk requirement under paragraph (d)(3)(i) of this section.

(iii) *Allowance for minimum loss rate.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by less than 4 percent of expected expenditures.

(6) *Expected expenditures.* For the purposes of this section, expected expenditures is defined as the Other Payer APM benchmark. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement. If expected expenditures (that is, benchmarks) under the payment arrangement exceed the expenditures that the participant would be expected to incur in the absence of the payment arrangement, such excess expenditures are not considered when assessing financial risk under the payment arrangement for Other Payer Advanced APM determinations.

(7) *Capitation.* A full capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the payment arrangement for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed for the purposes of reconciling or sharing losses incurred or savings earned by the participant. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 CFR part 422) are not considered capitation arrangements for purposes of this paragraph.

(8) *Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit.* Notwithstanding paragraphs (d)(2) and (4) of this section, if an APM Entity

participating in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model is owned and operated by an organization with 50 or more eligible clinicians whose Medicare billing rights have been reassigned to the TIN(s) of the organization(s) or any of the organization's subsidiary entities, the requirements of paragraphs (d)(1) and (3) of this section apply.

* * * * *

■ 48. Section 414.1425 is amended by—

■ a. Revising paragraph (c)(5) and (6), (d)(3) and (4); and

■ b. Adding paragraph (d)(5).

The revision and addition reads as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(c) * * *

(5) Beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.

(6) Beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.

* * * * *

(d) * * *

(3) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.

(4) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities.

(5) Beginning in the 2020 QP Performance Period, Partial QP status applies only to the TIN/NPI combination(s) through which Partial QP status is attained.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTING

■ 49. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 50. Section 415.172 is amended by revising the section heading and paragraph (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

* * * * *

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

* * * * *

■ 51. Section 415.174 is amended by—

■ a. Revising paragraph (a)(6); and

■ b. Removing and reserving paragraph (b).

The revision reads as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) * * *

(6) The medical records must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary. The extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter to each beneficiary in accordance with the documentation requirements at § 415.172(b).

(b) [Reserved]

PART 416—AMBULATORY SURGICAL CENTERS

■ 52. The authority citation for part 416 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 416.42 [Amended]

■ 53. Section 416.42 is amended in paragraph (a)(1), by removing the phrase ''A physician must'' and by adding in its place the phrase ''A physician or an anesthetist as defined at § 410.69(b) of this chapter must''.

PART 418—HOSPICE CARE

■ 54. The authority citation for part 418 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 55. Section 418.106 is amended by revising paragraph (b)(1) to read as follows:

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

* * * * *

(b) * * *

(1) Drugs may be ordered by any of the following practitioners:

(i) A physician as defined by section 1861(r)(1) of the Act.

(ii) A nurse practitioner in accordance with state scope of practice requirements.

(iii) A physician assistant in accordance with state scope of practice requirements and hospice policy who is:

(A) The patient's attending physician, and

(B) Not an employee of or under arrangement with the hospice.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 56. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 57. Section 424.67 is added to subpart E to read as follows:

§ 424.67 Enrollment requirements for opioid treatment programs (OTP).

(a) *General enrollment requirement.* In order for a program or eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) to receive Medicare payment for the provision of opioid use disorder treatment services, the provider must qualify as an OTP (as that term is defined in § 8.2 of this title) and enroll in the Medicare program under the provisions of subpart P of this part and this section.

(b) *Specific requirements and standards for enrollment.* To enroll in the Medicare program, an OTP must meet all of the following requirements and standards:

(1) Fully complete and submit the Form CMS–855B application (or its successor application) and any applicable supplement or attachment thereto to its applicable Medicare contractor. This includes, but is not limited to, the following:

(i) Maintain and submit to CMS (via the applicable supplement or attachment) a list of all physicians and eligible professionals who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. The list must include the physician's or eligible professional's:

(A) First and last name and middle initial.

(B) Social Security Number.

(C) National Provider Identifier.

(D) License number (if applicable).

(ii) Certifying via the CMS–855B and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in paragraphs (b) and (d) of this section. application) and any applicable supplement thereto to its applicable Medicare contractor.

(2) Comply with the application fee requirements in § 424.514.

(3) Successfully complete the high categorical risk level screening required under § 424.518(c).

(4)(i) Have a current, valid certification by SAMHSA for an opioid treatment program consistent with the provisions and requirements § 8.11 of this title.

(ii) A provisional certification under § 8.11(e) of this title does not meet the requirements of the paragraph (b)(4)(i) of this section.

(5) Report on the Form CMS–855 and/or any applicable supplement all OTP staff that meet the definition of ''managing employee'' in § 424.502. Such individuals include, but are not limited to, the following:

(i) Medical director (as described in § 8.2 of this title).

(ii) Program sponsor (as described in § 8.2 of this title).

(6)(i)(A) Must not employ or contract with a prescribing or ordering physician or eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted (as that term is defined in 42 CFR 1001.2) of a federal or state felony that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries based on the same categories of detrimental felonies, as well as case by case detrimental determinations, found at § 424.535(a)(3).

(B) Paragraph (b)(6)(i)(A) of this section applies regardless of whether the individual in question is:

(*1*) Currently dispensing narcotics at or on behalf of the OTP; or

(*2*) A W–2 employee of the OTP.

(ii) Must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who is revoked from Medicare under § 424.535 or any other applicable section in Title 42, or who is on the preclusion list under § 422.222 or § 423.120(c)(6) of this chapter.

(iii) Must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who has a prior adverse action by a state oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. CMS will consider the factors enumerated at § 424.535(a)(22) in each case of patient harm that potentially applies to this paragraph.

(7)(i) Sign (and adhere to the term of) a provider agreement in accordance with the provisions of 42 CFR part 489.

(ii) An OTP's appeals under 498 of a Medicare revocation (under § 424.535) and a provider agreement termination (under § 489.53(a)(1)) must be filed jointly and, as applicable, considered jointly by CMS under part 498 of this chapter.

(8) Comply with all other applicable requirements for enrollment specified in this section and in subpart P of this part.

(c) *Denial of enrollment.* CMS may deny an OTP's enrollment application on any of the following grounds:

(1) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement in this section.

(2) Any of the denial reasons in § 424.530 applies.

(3) An OTP may appeal the denial of its enrollment application under part 498 of this chapter.

(d) *Continued compliance, standards, and reasons for revocation.* (1) Upon and after enrollment, an OTP—

(i) Must remain validly certified by SAMHSA as required under § 8.11 of this title.

(ii) Remains subject to, and must remain in full compliance with, the provisions of subpart P of this Part and of this section. This includes, but is not limited to, the provisions of paragraph (b)(6) of this section, the revalidation provisions in § 424.515, and the deactivation and reactivation provisions in § 424.540.

(iii) Upon revalidation, successfully complete the moderate categorical risk level screening required under § 424.518(b).

(2) CMS may revoke an OTP's enrollment on any of the following grounds:

(i) The provider does not have a current, valid certification by SAMSHA as required under paragraph (b)(4)(i) or fails to meet any other applicable requirement or standard in this section, including, but not limited to, the OTP standards in paragraph (b)(6) and (d)(1) of this section.

(ii) Any of the revocation reasons in § 424.535 applies.

(3) An OTP may appeal the revocation of its enrollment under part 498 of this title.

(e) *Claim payment.* For an OTP to receive payment for furnished drugs:

(1) The prescribing or medication ordering physician's or other eligible professional's National Provider Identifier must be listed on Field 17 of the Form CMS–1500; and

(2) All other applicable requirements of this section, this part, and part 8 of this title must be met.

(f) *Relation to part 8 of this title.* Nothing in this section shall be construed as:

(1) Supplanting any of the provisions in part 8 of this title; or

(2) Eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8 of this title.

■ 58. Section 424.502 is amended by adding the definition of ''State oversight board'' in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

State oversight board means, for purposes of §§ 424.530(a)(15) and 424.535(a)(22) only, any state administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the State.

* * * * *

■ 59. Section 424.518 is amended by adding paragraphs (b)(1)(xii) and (c)(1)(iv) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(b) * * *

(1) * * *

(xii) Revalidating opioid treatment programs.

* * * * *

(c) * * *

(1) * * *

(iv) Prospective (newly enrolling) opioid treatment programs.

* * * * *

■ 60. Section 424.520 is amended by revising paragraph (d) introductory text to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) *Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs.* The effective date for billing privileges for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs is the later of—

* * * * *

■ 61. Section 424.521 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 424.521 Request for payment by physicians, non-physician practitioners, physician and non-physician organizations, ambulance suppliers, and opioid treatment programs.

(a) Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs may retrospectively bill for services when the physician, non-physician practitioner, physician or non-physician organization, ambulance supplier, or opioid treatment program has met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to —

* * * * *

■ 62. Section 424.530 is amended by reserving paragraphs (a)(12),(13) and (14) and adding paragraph (a)(15) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

* * * * *

(a) * * *

(15) *Patient Harm.* The physician or eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or eligible professional conduct that led to patient harm. In determining whether a denial is appropriate, CMS considers the following factors:

(i) The nature of the patient harm.

(ii) The nature of the physician's or eligible professional's conduct.

(iii) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or eligible professional by the State oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(A) License restriction(s) pertaining to certain procedures or practices.

(B) Required compliance appearances before State oversight board members.

(C) Required participation in rehabilitation or mental/behavioral health programs.

(D) Required abstinence from drugs or alcohol and random drug testing.

(E) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(F) Administrative/monetary penalties.

(G) Formal reprimand(s).

(iv) If applicable, the nature of the IRO determination(s).

(v) The number of patients impacted by the physician's or eligible professional's conduct and the degree of harm thereto or impact upon.

(vi) Any other information that CMS deems relevant to its determination.

* * * * *

■ 63. Section 424.535 is amended by—

■ a. In paragraph (a)(14) introductory text, by removing the phrase ''prescribing Part D drugs'' and adding in its place the phrase ''prescribing Part B or D drugs''; and

■ b. Reserving paragraphs (a)(15) through (21).

■ c. Adding paragraph (a)(22).

The addition reads as follows:

§ 424.535 Revocation of enrollment in the Medicare programs.

(a) * * *

(22) *Patient Harm.* The physician or eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or eligible professional conduct that led to patient harm. In determining whether a revocation is appropriate, CMS considers the following factors:

(i) The nature of the patient harm.

(ii) The nature of the physician's or eligible professional's conduct.

(iii) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or eligible professional by the State oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(A) License restriction(s) pertaining to certain procedures or practices.

(B) Required compliance appearances before State medical board members.

(C) Required participation in rehabilitation or mental/behavioral health programs.

(D) Required abstinence from drugs or alcohol and random drug testing.

(E) License restriction(s) regarding the ability to treat certain types of patients

(for example, cannot be alone with members of a different gender after a sexual offense charge).

(F) Administrative or monetary penalties.

(G) Formal reprimand(s).

(iv) If applicable, the nature of the IRO determination(s).

(v) The number of patients impacted by the physician's or eligible professional's conduct and the degree of harm thereto or impact upon.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 64. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

§ 425.612 [Amended]

■ 65. Section 425.612 is amended in paragraph (a)(1)(v)(E) introductory text by removing the phrase ''paragraph (a)(1)(v)(B)'' and adding in its place the phrase ''paragraph (a)(1)(v)(D)''.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 66. The authority citation for part 489 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

■ 67. Section 489.2 is amended by adding paragraphs (b)(10) and (c)(3) to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) * * *

(10) Opioid treatment programs (OTPs).

(c) * * *

(3) OTPs may enter into provider agreements only to furnish opioid use disorder treatment services.

■ 68. Section 489.10 is amended by revising paragraph (a) to read as follows:

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter. The RNHCIs must meet the conditions for coverage, conditions for participation and the requirements set forth in this section and elsewhere in this chapter. The OTPs must meet the requirements set forth in this section and elsewhere in this chapter.

* * * * *

■ 69. Section 489.13 is amended by revising paragraph (a)(2)(i) to read as follows:

§ 489.13 Effective date of agreement or approval.

(a) * * *

(2) * * *

(i) For an agreement with a community mental health center (CMHC), opioid treatment program (OTP), or a federally qualified health center (FQHC), the effective date is the date on which CMS accepts a signed agreement which assures that the CMHC, OTP or FQHC meets all Federal requirements.

* * * * *

■ 70. Section 489.53 is amended by revising paragraph (a)(3) to read as follows:

§ 489.53 Termination by CMS.

(a) * * *

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter. In the case of an RNHCI, it no longer meets the conditions for coverage, conditions of participation and requirements set forth elsewhere in this chapter. In the case of an OTP, it no longer meets the requirements set forth in this section and elsewhere in this chapter.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 71. The authority citation for part 498 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 72. Section 498.2 is amended in the definition of ''Provider'' by revising the introductory text and adding paragraph (3) to read as follows:

§ 498.2 Definitions.

Provider means any of the following:

* * * * *

(3) An entity that has in effect an agreement to participate in Medicare but only to furnish opioid use disorder treatment services.

* * * * *

Dated: June 21, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 18, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

BILLING CODE 4120–01–P

APPENDIX 1: PROPOSED MIPS QUALITY MEASURES

NOTE: Except as otherwise proposed in this proposed rule, previously finalized measures and specialty measure sets will continue to apply for the 2022 MIPS payment year and future years. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF # / eCQM NQF #.

TABLE Group A: New Quality Measures Proposed for Addition for the 2022 MIPS Payment Year and Future Years

A.1 International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Measure Steward:	Large Urology Group Practice Association and Oregon Urology Institute
Numerator:	Patients with a documented improvement of at least 3 points in their urinary symptom score during the measurement period.
Denominator:	Equals Initial Population. Initial population is: Male patients with an initial diagnosis of benign prostatic hyperplasia, 6 months prior to, or during the measurement period, and a urinary symptom score assessment within 1 month of initial diagnosis and a follow-up urinary symptom score assessment within 6-12 months, who had a qualifying visit during the measurement period.
Exclusions:	Denominator: Patients with urinary retention that starts within 1 year of initial BPH diagnosis; Patients with an initial BPH diagnosis that starts during, or within 30 days of hospitalization; Patients with a diagnosis of morbid obesity, or with a BMI Exam >40 before the follow up urinary symptom score.
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	eCQM Specifications
Rationale:	This measure is being proposed because it represents a patient reported outcome by evaluating the patient's response regarding their symptoms associated with the diagnosis of Benign Prostatic Hyperplasia (BPH). Results can be used by clinicians in evaluating whether the patient's symptoms from BPH have improved during the 6 to 12 months after diagnosis and treatment of this disease. The measure was evaluated by the MAP and it was conditionally supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. Measure information provided by the measure developer indicates IPSS and AUA-SI are statistically valid and reliable symptom scores. The IPSS was adopted by the World Health Organization in 1993. The AUA-SI was developed and validated by the American Urological Association in 1992. The IPSS uses the same questions as the AUA-SI, but also adds a disease-specific quality of life question (OLeary, 2005). It is a reproducible, validated index designed to determine disease severity and response to therapy (DSilva, 2014). Based on the information provided by the measures steward, we believe the measure is evidence-based and represents an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

A.2. Multimodal Pain Management

Category	Description
NQF #: / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.
Measure Steward:	American Society of Anesthesiologists (ASA)
Numerator:	Patients for whom multimodal pain management is administered in the perioperative period from 6 hours prior to anesthesia start time until discharged from the post-anesthesia care unit.
Denominator:	Patients, aged 18 years and older, who undergo selected surgical procedures
Exclusions:	Emergent Cases
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes (Opioid-related)
Collection Type:	MIPS CQMs Specifications
Rationale:	This measure is being proposed because it encourages clinicians to effectively manage patients' pain using multimodal strategies, which in turn can significantly reduce unnecessary opioid use, excessive post-operative prescriptions, and length of stay. We believe there is an urgent need for measures that address the opioid epidemic affecting the nation. It is imperative to include measures in MIPS that support healthy outcomes for patients using opioids. The clinical action being evaluated within this measure supports the reduction in use of opioids for patients in the perioperative treatment of pain. The measure was updated from what was submitted to the MAP following feedback from stakeholders and NCQA's Technical Expert Panel (TEP). The original measure evaluated by the MAP was conditionally supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. The measure steward indicated that testing data from 503 clinicians for 24,728 cases met the denominator criteria during testing of the measure. The mean performance rate calculated from this data was 74.24 percent with a standard deviation of +/- 0.1492 with a performance range of 0.00 to 100.00. Reliability was assessed at the clinician level and based on data from a large, academic medical center and a Veterans Health Administration facility. In May 2018, the ASA conducted a systematic assessment of face validity among members of its Committee on Pain Medicine and Committee on Regional Anesthesia and Acute Pain Medicine. The 33 respondents indicated a substantial level of agreement supporting this measure's value and validity. Based on the information provided by the measures steward, we believe the measure is evidence-based and represents an important clinical process. The measure steward revised the measure by adding an age criteria and removing elective cases as an inclusion criteria. Upon stakeholder feedback, the denominator eligible cases were expanded to make the measure more applicable to ambulatory settings. Due to this denominator expansion, an age of 18 years and older was added to the denominator criteria as many of the pediatric cases captured by the expanded codes do not require multimodal pain management. Additionally, pediatric patients have a different range of appropriate multimodal pain management options. As such, the measure steward limited the patient population to the clinically relevant adult patient population. A denominator exclusion was added for emergent cases to replace the previous elective surgery requirement for denominator eligibility. The measure steward also stated, citing user feedback, when emergent cases are an exclusion criterion compared to using elective cases as an inclusion criterion, the measure produced more reliable results. We agree that these changes result in a more clinically relevant, reliable, and meaningful measure by expanding the denominator eligible code set to capture all applicable adult patients in different settings and refining the patient population to be in alignment with these changes. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

A.3. Adult Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Measure Steward:	National Committee for Quality Assurance
Numerator:	Numerator 1: Members in Denominator 1 (D1) who received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period. Numerator 2: Members in D2 who received at least 1 Td vaccine or 1 Tdap vaccine between 9 years prior to the start of the measurement period and the end of the measurement period. Numerator 3: Members in D3 who received at least 1 dose of the herpes zoster live vaccine or 2 doses of the herpes zoster recombinant vaccine anytime on or after the members 50th birthday. Numerator 4: Members in D4 who were administered both the 13-valent pneumococcal conjugate vaccine and the 23-valent pneumococcal polysaccharide vaccine at least 12 months apart, with the first occurrence after the age of 60. Numerator 5: The actual number of required immunizations administered to members in D5.
Denominator:	Denominator 1: Members age 19 and older at the start of the measurement period. Denominator 2: Members age 19 and older at the start of the measurement period. Denominator 3: Members age 50 and older at the start of the measurement period. Denominator 4: Members age 66 and older at the start of the measurement period. Denominator 5: The total number of possible immunizations required for members age 19 and older determined by their age at the start of the measurement period.
Exclusions:	Denominator: Members with any of the following: • Prior anaphylactic reaction to the vaccine or its components any time during or before the measurement period. • History of encephalopathy within seven days after a previous dose of a Td-containing vaccine. • Active chemotherapy during the measurement period. • Bone marrow transplant during the measurement period. • History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & HB-S disease or cerebrospinal fluid leaks any time during the member's history prior to or during the measurement period. • In hospice or using hospice services during the measurement period.
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(v)of the Act)
High priority measure:	No
Collection Type:	MIPS CQMs Specifications, CMS Web Interface Measure Specifications
Rationale:	We are proposing this preventive immunization measure because it is a comprehensive evaluation for compliance with recommended adult vaccinations and supports the 2019 adult immunization schedule that has been approved by the CDC, which is based on the recommendation from the Advisory Committee on Immunization Practices. NCQA and the HHS National Vaccine Program Office submitted this measure via Call for Measures to be considered for MIPS implementation. This robust composite measure assesses the quality clinical action regarding the administration of the influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. This measure is consistent with Healthy People 2020 goals, developed by the Centers for Disease Control and Prevention, to promote healthy behaviors, for increasing immunization rates. The measure was evaluated by the MAP, but this entity did not support this composite measure since it had not been analytically tested at the clinician level, but clinically it is evidence-based as required by section 1848(q)(2)(D)(v) of the Act. We believe that the health plan level version of the measure can be adapted to the clinician level by revising the measure analytics to assess the proportion of patients who have been administered influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines by MIPS eligible clinicians. Implementing the measure at the clinician level does not change the medical intent or evidence supporting preventive immunizations for patients. Therefore, we believe implementing the measure at the clinician level will be successful. Currently, MIPS includes three of the four composite measure's components as individual measure analytics. Individual measures: Q110: Preventive Care and Screening: Influenza Immunization; and Q111: Pneumococcal Vaccination Status for Older Adults have been implemented in the MIPS and PQRS programs for a combined total of over seven years. Another component of this composite measure, Q474: Zoster (Shingles) Vaccination, was implemented as a new individual measure in 2019 MIPS and was tested at the clinician and group level prior to submission to the Call for Measures. The administration of the vaccination diphtheria toxoids and acellular pertussis (Tdap), contained in Adult Immunization Status, is also present in the MIPS program as a component within measure Q394: Immunizations for Adolescents. We recognize this measure is specified currently for adolescents, but believe the logic this measure represents is adaptable to the adult population. We believe that the individual measures referenced above represent each component of the Adult Immunization Status composite measure. Additionally, measures Q110 and Q111 have been successfully implemented in all MIPS collection types. This accomplishment supports

Category	Description
	the face validity of these measure concepts and demonstrates the ease in which the composite health plan measure can be adapted for MIPS use. As such, we believe the health plan level version of this measure can be adapted accordingly to suit the program requirements of MIPS. Nonetheless, we will continue to work with the measure steward to obtain additional testing results regarding this composite measure's implementation for programs beyond the health plan level. The measure steward provided the following health plan evidence to support the value of proposing this composite measure as a quality measure. The information is based on commercial and Medicaid plan performance rates for members aged 19-64 and Medicare plan rates for members aged 65 and older. Across the plans, performance rates were as follows: influenza (mean=24 percent, min=3 percent, max=73 percent; Td or Tdap (mean=35 percent, min=1 percent, max=94 percent); zoster (mean=28 percent, min=0.1 percent, max=85 percent); pneumococcal (mean=17 percent, min=1 percent, max=62 percent); and composite (mean=28 percent, min=2 percent, max=79 percent). We believe this evidence represents there is a need to improve adult vaccination coverage. Based on the information provided by CDC in conjunction with the ACIP, we believe the measure is clinically evidence-based and represents an important clinical process Therefore, we maintain that this measure provides a comprehensive assessment of quality adult preventive care and would met the meaningful measure initiative. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

A.4. Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Numerator:	The proportion of a provider's (clinic's or clinician's) patient care episodes that met or exceeded the risk-adjusted predicted Residual Change Score. The Residual Change Score is defined as the difference between the Actual and Predicted Change Scores where: 1. The Actual Score is the patient's Functional Status (FS) Score; 2. The Actual Change Score is the change in the patient's FS score from Admission to Discharge; and 3. The Predicted Change Score is the risk-adjusted prediction of FS change. (Please see the Comments section of JIRA submission for details of the Risk-adjustment component.) Calculating the Residual Change Score, Example: • Actual Score at Admission = 45 • Actual Score at Discharge = 60 ○ Actual Change Score (Discharge minus Admission) = +15 ○ Predicted Change Score = +10 • Residual Change Score (Actual Change minus Predicted) = +5 Numerator Options: • Performance Met = The Residual Change Score is equal to or greater than 0 • Performance Not Met = The Residual Change Score is less than 0 Performance may be calculated on 3 levels as follows: 1. Patient Level: For the individual patient episode, the patient's Actual FS scores relative to the risk-adjusted predicted. This level should be used for optimizing care as described below.* 2. Clinician Level: The average of the Residuals for patient care episodes managed by a clinician (individual provider) over a 12 month time period. 3. Clinic Level: The average of the Residuals for patient care episodes managed by a group of clinicians within a clinic over a 12 month time period. * A provider's (clinician's or clinic's) performance must be assessed based on an average all of the provider's patient episodes. On the level of the individual patient, variation is expected. When an individual episode does not result in meeting or exceeding the performance standard, the functional data should be useful to the provider in optimizing the balance of effectiveness/efficiency for that particular care episode. For example, if patient-perceived function is not improving, or has plateaued in progress, that data may be a component of provider-patient communication and care decision-making such as the following examples: 1. Does the provider understand the patient's perception of his/her current level of function? 2. Should the treatment plan be modified? 3. Should the patient be discharged sooner than later? 4. Should the patient be referred to a different care provider?
Denominator:	Patients aged 14+ who initiated rehabilitation therapy, chiropractic, or medical episodes of care for neck impairments including but not limited to cervical (neck) pain, radiculopathy, strain, sprain, stenosis, myelopathy, spondylosis or disc disorders.
Exclusions:	None
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High priority measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications

Category	Description
Rationale:	We are proposing this measure because neck pain is prevalent, impacts functional ability and productivity, and is costly. Measurement results can be used by clinicians in evaluating whether the patient's functional status has improved with initiation of rehabilitation therapy. The measure was evaluated by the MAP conditionally and it was supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required in section 1848(q)(2)(D)(v) of the Act. The measure steward indicated that this measure offers ample room for improvement for performance based on testing data. The results from testing were that for 1378 clinics, 24.24 percent were classified as low performers, 60.01 percent as average, and 15.75 percent as high. The measure steward believed and we agree that having only 15.75 percent classified as high leaves more than adequate room for improvement in eligible clinician performance over time. Based on the information provided by the measures steward, we believe this measure is evidence-based and represents an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

TABLE Group AA: New Quality Measure Proposed for Addition for the 2023 MIPS Payment Year and Future Years

In addition to the new quality measures proposed for addition in Table Group A, we are proposing to add one administrative claims based quality measure for the 2023 MIPS payment year and future years. Quality measures that are specified through the administrative claims collection type do not require separate data submission to CMS. Administrative claims measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims. We are proposing to add this administrative claims-based measure beginning with the 2023 MIPS payment year to allow for time to further refine the measure analytics prior to implementation within the program.

AA.1. All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions

Category	Description
NQF # / eCQM NQF #:	TBD
Quality #:	TBD
Description:	Risk-adjusted outcome measure that uses the outcome of acute, unplanned admissions (per 100 person-years at risk of admission) to assess care quality. Includes Medicare fee-for-service beneficiaries aged 65 years or older who have two or more of the following nine chronic conditions: (1) acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia, (3) atrial fibrillation, (4) chronic kidney disease, (5) chronic obstructive pulmonary disease or asthma, (6) depression, (7) diabetes, (8) heart failure, and (9) stroke or transient ischemic attack. The measure adjusts for: • Demographic variables, clinical comorbidities, and measures of frailty/disability. • Two social risk factors: (1) The Agency for Healthcare Research and Quality Socioeconomic Status Index (AHRQ SES Index) and (2) density of physician specialists. The AHRQ SES Index is a widely used and validated measure of area deprivation derived from the American Community Survey (ACS) census block group-level data and linked to a patient's ZIP code. It summarizes SES measures of employment, income, education, and housing.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Risk-standardized acute admissions per 100 person-years at risk for admission
Denominator:	Medicare fee-for-service beneficiaries ≥ 65 years of age with ≥ 2 of 9 chronic conditions: (1) Acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia (3) Atrial fibrillation (4) Chronic kidney disease (5) Chronic obstructive pulmonary disease or asthma (6) Depression (7) Diabetes (8) Heart failure (9) Stroke or transient ischemic attack
Exclusions:	Denominator Exclusions: (1) Patients without continuous enrollment in Medicare Part A or Part B during the measurement period. (2) Patient was in hospice at any time during the year prior to the measurement year or at start of the measurement year. (3) Patient had no Evaluation and Management visit to a MIPS eligible clinician. Numerator Exclusions: (1) Planned admissions (2) Other admissions that likely do not reflect the quality of ambulatory chronic disease management and primary care provided by the included eligible clinicians: • Complications of procedures or surgeries • Accidents • Injuries • Admissions directly from a skilled nursing facility or acute rehabilitation facility • Admissions that occur within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility • Admissions that occur while patients are enrolled in Medicare's hospice benefit
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Rationale:	We are proposing this risk-adjusted administrative claims measure to assess Medicare aged > 65 patients who have two or more of the following nine chronic conditions: (1) acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia, (3) atrial fibrillation, (4) chronic kidney disease, (5) chronic obstructive pulmonary disease or asthma, (6) depression, (7) diabetes, (8) heart failure, and (9) stroke or transient ischemic attack. More than two-thirds of Medicare beneficiaries have been diagnosed with or treated for two or more chronic conditions. People with multiple chronic conditions (MCCs) are more likely to be admitted to the hospital than those without chronic conditions or with a single chronic condition. Additionally, they are more likely to visit the emergency department, use post-acute care (such as skilled nursing facilities), and require home health assistance based on the CMS Chronic Conditions among Medicare Beneficiaries Chartbook: 2012 Edition (cited in ACO 38 measure information form). This measure promotes improved MCC management and coordinated care by assessing the unplanned hospital admissions for this high-risk population. The measure is specified through the administrative claims collection type that does not require separate data submission to CMS. This administrative claims measure

Category	Description
	is calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims as well as hospital inpatient, outpatient, and physician claims for clinical risk adjustment. It uses the outcome of acute, unplanned admissions (per 100 person-years at risk of admission) to assess care quality. This measure would be added for the 2023 MIPS payment year to allow time to work through operational factors of implementing the measures. This measure is included in the CY 2020 PFS proposed rule for stakeholder comment.

TABLE Group B: New Specialty Measures Sets Proposed for Addition and Previously Finalized Specialty Measure Sets Proposed for Modification for the 2022 MIPS Payment Year and Future Years

We are proposing to add seven new specialty measures sets: Endocrinology, Nutrition/Dietician, Pulmonology, Chiropractic Medicine, Clinical Social Work, Audiology, and Speech Language Pathology. These sets are proposed to be added based in part on the expanded definition of the MIPS eligible clinician for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals. In addition, we have received stakeholder feedback requesting additional specialty sets for clinician types whom did not have an existing specialty measures set. We are soliciting comment on applicable measures for a Clinical Social Work specialty set in the event clinical social workers are proposed for inclusion in the definition of a MIPS eligible clinician in future rulemaking. We are also proposing to modify the previously finalized specialty measures sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), existing measures with substantive changes for the 2019 MIPS performance period described in Table Group DD are noted with a double asterisk (**), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to fully represent the regulatory definition of high priority measures. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table B as follows: NQF # / eCQM NQF #.

The definition of high priority at § 414.1305 includes an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

The following specialty measure set has been excluded from this group because we are not proposing any changes to this specialty measure set: Interventional Radiology. Therefore, we refer readers to the CY 2018 Quality Payment Program final rule for the previously finalized Interventional Radiology specialty measure set (82 FR 54098 through 54099).

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Allergy/Immunology specialty set.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication (2) Percentage of patients who were ordered at least two of the same high-risk medication.	National Committee for Quality Assurance

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Allergy/Immunology specialty set as it is clinically relevant to this clinician type.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ALLERGY/IMMUNOLOGY SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	160	CMS52v 8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis	Health Resources and Services Administration	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale. In addition, we propose to remove this measure from the specialty set because it is not applicable to this specialty as Allergy/Immunology specialists do not diagnose, treat or manage HIV/AIDS patients.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Anesthesiology specialty set.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0236	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	2726	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Outcome)	N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	2681	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A	463	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists

B.2. Anesthesiology

MEASURES PROPOSED FOR **ADDITION** TO THE ANESTHESIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS cCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Opioid)	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Multimodal Pain Management**: Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Anesthesiology specialty set as it is clinically relevant to this clinician type.

B.3a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable.

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	National Committee for Quality Assurance

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Efficiency)	N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology
! (Efficiency)	N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period	American College of Cardiology
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	438	CMS347 v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CARDIOLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.3b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Electrophysiology Cardiac Specialist measure set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Electrophysiology Cardiac Specialist measure set.

B.3b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* !	N/A	348	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.	American College of Cardiology Foundation
* !	2474	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
* !	N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.4. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Gastroenterology specialty set.

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastroenterological Association
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month submission period.	American Gastroenterological Association
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Efficiency)	N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Effective Clinical Care	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	American Gastroenterological Association

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GASTROENTEROLOGY SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0659	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy	American Gastroenterological Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients regardless of age with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the year prior and current year are considered adequately screened to prevent overuse of X-ray assessment	American Gastroenterological Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate**: The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy	American Society for Gastrointestinal Endoscopy	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.5. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dermatology specialty set.

B.5. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
* ** §	0028 / 0028e	226	CMS13 8v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Foundation (PCPI®)

B.5. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A	317	CMS22 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician- or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment	American Academy of Dermatology
* ! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.6. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Family Medicine specialty set.

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS128 v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	/Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
§ * ! (Appropriate Use)	N/A	066	CMS146v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0104e	107	CMS161v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	2372 / N/A	112	CMS125v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
* ! (Opioid)	N/A	305	CMS137 v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	N/A	309	CMS124 v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last IIIV viral load test during the measurement year.	Health Resources and Services Administration
* ! (Outcome)	0209	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710 / 0710e	370	CMS159 v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communica tion and Care Coordinatio n	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A	377	CMS90v 9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermedi ate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	1407	394	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month submission period.	American Gastroenterological Association
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	CMS347 v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16 20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Appropriate Use)	N/A	472	CMS249 v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349 v2	eCQM Specifications	Process	Community /Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.6. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Family Medicine specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	Centers for Disease Control and Prevention	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type.

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.7. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Internal Medicine specialty set.

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS12 8v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS13 1v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS13 4v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Opioid)	N/A	305	CMS13 7v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	N/A	309	CMS12 4v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
*	N/A	317	CMS22 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) •• Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* ! (Outcome)	0209	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A	377	CMS90v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month submission period.	American Gastro-enterological Association
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	CMS347v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	NA	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Appropriate Use)	N/A	472	CMS249v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349v2	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.7. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	Centers for Disease Control and Prevention	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type.

B7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults**: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination**: The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.8. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Emergency Medicine specialty set.

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A	066	CMS146 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis**: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0104e	107	CMS161 v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
	N/A	254	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
* ! (Efficiency)	N/A	415	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care clinician who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A	416	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE EMERGENCY MEDICINE SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	255	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.9. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Obstetrics/Gynecology specialty set.

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
§	N/A	309	CMS124 v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A	310	CMS153 v8	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordinatio n)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communicat ion and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture	National Committee for Quality Assurance
! (Patient Safety)	2063	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecolog ic Society
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining A Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16 20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of women, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A	472	CMS249 v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349 v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.9. Obstetrics/Gynecology

PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type and drives quality of care by assessing the rate of elective deliveries before 39 weeks gestation in the absence of medical indication, following The American College of Obstetrics and Gynecology clinical guidance.
* ! (Care Coordination)	N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, and family and contraceptive planning.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	Centers for Disease Control and Prevention	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type.

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per American College of Obstetrics and Gynecology (ACOG), American Urogynecologic Society, and American Urological Association guidelines.	American Urogynecologic Society	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.10. Ophthalmology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Ophthalmology specialty set.

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0086 / 0086e	012	CMS143v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0087	014	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12 month performance period.	American Academy of Ophthalmology
* ! (Care Coordination)	0089 / 0089e	019	CMS142v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0055 / N/A	117	CMS131v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0563	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12 month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	1536	303	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome) *	N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.10. Ophthalmology

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology	We propose to include this measure in the Ophthalmology specialty set as it is applicable to this clinician type and drives quality of care by assessing patient satisfaction following cataract surgery.

B.10. Ophthalmology

PREVIOSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OPHTHALMOLOGY SET Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0564 / 0564e	192	CMS132 v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures**: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	388	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy):** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.11. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Orthopedic Surgery specialty set.

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421 / 0421e	128	CMS69 v8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v 9	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone $\geq$ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period	National Committee for Quality Assurance
! (Care Coordination)	N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	375	CMS66 v8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	376	CMS56 v8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Discectomy/Laminotomy:** The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Fusion:** The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had a lumbar fusion procedure	Minnesota Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Fusion Surgery:** The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients 18 years of age and older who had a lumbar fusion procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	470	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Total Knee Replacement Surgery:** The average change (preoperative to postoperative) in functional status using the Oxford Knee Score (OKS) for patients age 18 and older who had a primary total knee replacement.	Minnesota Community Measurement

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery:** The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients age 18 and older who had lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Fusion Surgery:** The average change (preoperative to one year postoperative) in leg pain for patients 18 years of age or older who had a lumbar fusion procedure	Minnesota Community Measurement

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MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Orthopedic Surgery specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

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MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

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MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years + with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

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MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Orthopedic Surgery specialty set as it is clinically relevant to this clinician type.

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0097	046	N/A	Medicare Part B Claim Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ORTHOPEDIC SURGERY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	352	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet**: Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	American Association of Hip and Knee Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	353	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.12. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Otolaryngology specialty set.

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Nec Surgery
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ** §	0028 / 0028e	226	CMS13 8v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine

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PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Nec Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Nec Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Nec Surgery
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.12. Otolaryngology

PROPOSED FOR **ADDITION** TO THE OTOLARYNGOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type.

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OTOLARYNGOLOGY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.13. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pathology specialty set.

B.13. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.	College of American Pathologists

B.13. Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology	This measure is proposed for inclusion into the Pathology specialty set as it is applicable to a subset of pathologists and drives care coordination and communication.

B.13. Pathology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PATHOLOGY SET Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
1854	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.14. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pediatrics specialty set.

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A	066	CMS146v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A	239	CMS155v8	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A	240	CMS117v8	eCQM Specifications	Process	Community / Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A	305	CMS137v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	N/A	310	CMS153v8	eCQM Specifications	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	366	CMS136v9	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADIID) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
*	N/A	379	CMS74v9	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
* §	1407	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	NA	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)

B.14. Pediatrics

MEASURES PROPOSED FOR **ADDITION** TO THE PEDIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0710 / 0710e	370	CMS159 v8	eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (−/- 60 days) after an index event date.	Minnesota Community Measurement	We propose to include this measure in the Pediatrics specialty set as the denominator was expanded to include pediatric patients and it drives quality by measuring depression remission.

B.14. Pediatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PEDIATRICS SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	160	CMS52v8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis.	Health Resources and Services Administration	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	467	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Developmental Screening in the First Three Years of Life:** The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the 12 months preceding or on their first, second, or third birthday. This is a composite measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened in the 12 months preceding or on their first, second or third birthday.	Oregon Health & Science University	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.15. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Medicine specialty set.

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421 e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419 e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028 e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PHYSICAL MEDICINE SET

Note: In this this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Ostcoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.16. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Plastic Surgery specialty set.

B.16. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.16. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.17. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Preventive Medicine specialty set.

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	CMS347v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.17. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Preventive Medicine specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Preventive Medicine specialty set as it is clinically relevant to this clinician type.

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v 9	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127v 8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.18. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurology specialty set.

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	268	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.	American Academy of Neurology
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.	American Academy of Neurology
	N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction in the past 12 months.	American Academy of Neurology
! (Care Coordination)	N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed in the past 12 months	American Academy of Neurology
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, (Screener and Opioid Assessment for Patients with Pain, revised) SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
! (Efficiency)	N/A	419	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	435	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12 month measurement period AND whose health related quality of life score stayed the same or improved.	American Academy of Neurology

B.18. Neurology

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Neurology specialty set as a replacement for measure Q282: Dementia: Functional Status Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q282, but is more robust in that it requires more frequent assessment and a plan of care.

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEUROLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.19. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Mental/Behavioral Health specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Mental/Behavioral Health specialty set.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS128 v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
*	0104e	107	CMS161 v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/P opulation Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	366	CMS136v9	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: ● The percentage of discharges for which the patient received follow-up within 30 days after discharge. ● The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	2803	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.19. Mental/Behavioral Health

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Mental/Behavioral Health specialty set as a replacement for measure Q282: Dementia: Functional Status Assessment, which is being proposed for removal. Proposed changes to the measure requested by the measure steward include adding this clinician type to the measure so that measure Q182 will include the patient population in measure Q282. Measure Q182 is more robust in that it requires more frequent assessment and a plan of care.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	325	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table for rationale.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE MENTAL/BEHAVIORAL HEALTH SET Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 60 days) after an index event date.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.20. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Diagnostic Radiology specialty set.

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
! (Care Coordination)	N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
	0507	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology
! (Appropriate Use)	N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology
* ! (Appropriate Use)	N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for abdominal imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended • Liver lesion ≤ 0.5 cm. • Cystic kidney lesion < 1.0 cm. • Adrenal lesion < 1.0 cm.	American College of Radiology
! (Appropriate Use)	N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE DIAGNOSTIC RADIOLOGY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0508	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms:** Percentage of final reports for screening mammograms that are classified as "probably benign."	American College of Radiology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0509	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are submitted to a radiation dose index registry that is capable of collecting at a minimum selected data elements.	American College of Radiology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12 month period after the study.	American College of Radiology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.21. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nephrology specialty set.

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.21. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type.

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEPHROLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale
N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEPHROLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end -stage renal disease (ESRD) who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.22. General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed General Surgery specialty set.

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421 e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419 e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.22. General Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE GENERAL SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons	We propose to include this measure in the General Surgery specialty set as it is clinically relevant to this clinician type.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the General Surgery specialty set as it is clinically relevant to this clinician type.

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GENERAL SURGERY SET Note: In this proposed rule, CMS proposes the removal the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table for rationale.

B.23. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Vascular Surgery specialty set.

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE VASCULAR SURGERY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive**: Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive**: Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale
1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive**: Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.24. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Thoracic Surgery specialty set.

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0129	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	0114	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
* ** §	0028 / 0028 c	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	0119	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE THORACIC SURGERY SET

Note: In this proposed rule, CMS proposes the removal the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.25. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urology specialty set.

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0390	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
*	N/A	462	CMS645 v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.25. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	TBD	CMS771 v1	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-centered Experience and Outcomes	**International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) change 6-12 months after diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association Symptom Index (AUA-SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type.

B.25. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE UROLOGY SET Note: In this proposed rule, CMS proposes the removal the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence**: Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per American College of Obstetrics and Gynecology (ACOG), American Urogynecologic Society, and American Urological Association guidelines	American Urogynecologic Society	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.26a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The Oncology specialty set has been updated to include Hematology and has been renamed as Oncology/Hematology. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Oncology specialty set.

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v8	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	1858	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy:** Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab.	American Society of Clinical Oncology
§	1859	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology
§ ! (Appropriate Use)	1860	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	462	CMS645v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.26a. Oncology/Hematology

MEASURES PROPOSED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	067	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.	American Society of Hematology	We propose to include this measure in the Oncology/Hematology specialty set as this set was updated to include IIematology for the 2020 performance period and this measure is clinically relevant.
	N/A	069	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.	American Society of Hematology	We propose to include this measure in the Oncology/Hematology specialty set as this set was updated to include Hematology for the 2020 performance period and this measure is clinically relevant.
	N/A	070	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry**: Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Oncology/Hematology specialty set as this set was updated to include Hematology for the 2020 performance period and this measure is clinically relevant.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Oncology/Hematology specialty set as it is clinically relevant to this clinician type.

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ONCOLOLGY/HEMATOLOGY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer with more than one emergency department visit in the last 30 days of life.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Not Admitted to Hospice (lower score – better):** Percentage of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ONCOLOLGY/HEMATOLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.26b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Radiation Oncology specialty set.

B.26b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology

B.27. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Infectious Disease specialty set.

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
*	N/A	475	CMS349v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.27. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type.

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE INFECTIOUS DISEASE SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use**: Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)	We agree with specialty society feedback to remove this measure from this specialty set. Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate testing for children with otitis media with effusion, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INFECTIOUS DISEASE SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	474	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Zoster (Shingles) Vaccination**: The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.28. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurosurgical specialty set.

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications fo a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated i all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis t be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests t documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Discectomy/Laminotomy:** The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Fusion:** The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had a lumbar fusion procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Fusion Surgery:** The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients 18 years of ag and older who had a lumbar fusion procedure.	Minnesota Community Measurement

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery:** The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients age 18 and older who had lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Fusion Surgery:** The average change (preoperative to one year postoperative) in leg pain for patients 18 years of age or older who had a lumbar fusion procedure	Minnesota Community Measurement

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEUROSURGICAL SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.29. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Podiatry specialty set.

B.29. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.29. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.30. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Hospitalists specialty set.

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* ! (Patient Safety)	2726	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE HOSPITALISTS SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	407	N/A	Medicare Part B Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.31. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Rheumatology specialty set.

B.31. Rheumatology

PREVIOUSLY FINALISED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	024	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.31. Rheumatology

PREVIOUSLY FINALISED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology
*	N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
*	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* ** §	0028 / 0028e	226	CMS138 v8	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance

B.31. Rheumatology

PREVIOUSLY FINALISED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / cCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.31. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS cCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Rheumatology specialty set as it is clinically relevant to this clinician type.

B.31. Rheumatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE RHEUMATOLOGY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.32. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dentistry specialty set.

B.32. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	378	CMS75v8	eCQM Specifications	Outcome	Community/ Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	379	CMS74v9	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.33. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Therapy/Occupational Therapy specialty set.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association	We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.33. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

B.33. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0428	223	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with General Orthopedic Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.34. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Geriatrics specialty set

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2872e	281	CMS149v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF #/ eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology

B. 34. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older**: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B. 34. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Geriatrics specialty set as a replacement for measure Q282: Dementia: Functional Status Assessment, which is being proposed for removal. Measure Q182 will include the patient population in measure Q282. Measure Q182 is more robust in that it requires more frequent assessment and a plan of care.
! (Outcome)	N/A	TBD	CMS771v1	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-centered Experience and Outcomes	**International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) change 6-12 months after diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association Symptom Index (AUA-SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type.

B. 34. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type.

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GERIATRICS SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization**: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GERIATRICS SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.35. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urgent Care specialty set.

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
§ * ! (Appropriate Use)	N/A	066	CMS146 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population IIealth	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Appropri ate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Appropri ate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropri ate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	2803	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2152	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE URGENT CARE SET Note: In this this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.36. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Skilled Nursing Facility specialty set.

B.36. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance

B.36. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology

B. 36. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type.

B.36. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE SKILLED NURSING FACILITY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.37. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Endocrinology specialty set.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0059 / N/A	001	CMS122v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* §	0055 / N/A	117	CMS131v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0062 / N/A	119	CMS134v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
*	0053	418	N/A	Medicare Part B Claims Measure Specifications , MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	N/A	438	CMS347v3	eCQM Specifications , CMS Web Interface Measure Specifications , MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	N/A	462	CMS645v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD		CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.

B.38. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Nutrition/Dietician specialty set.

B.38. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (IIbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
* §	0421 / 0421c	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
! (Patient Safety)	0419 / 0419c	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.

B.38. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
§	N/A	239	CMS155 v8	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Pulmonology specialty set.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	0102	052	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Chiropractic Medicine specialty set.

B.40. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES PROPOSED FOR ADDITION TO THE CHIROPRACTIC MEDICINE SET									
Indicator	NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Inclusion
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
! (Outcome)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, we are soliciting comment on applicable measures for a Clinical Social Work specialty set, which takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that may be proposed for this new measure set in the event clinical social workers are proposed for inclusion in the definition of a MIPS eligible clinician in future rulemaking. We request comment on the measures available in the Clinical Social Work specialty set.

B.41. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
	2872e	281	CMS149v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
	2803	402	NA	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.42. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Audiology specialty set.

B.42. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.42. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set as it is clinically relevant.
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set as it is clinically relevant and the measure owner is proposing to expand the denominator to include this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.42. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness	Audiology Quality Consortium	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Audiology specialty set as it is clinically relevant.

B.43. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Speech Language Pathology specialty set.

B.43. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Speech Language Pathology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Speech Language Pathology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type. The measure owner is also proposing to add coding for this clinician type for the 2020 performance period.
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Speech Language Pathology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type. The measure owner is also proposing to add coding for this clinician type for the 2020 performance period.

B.43. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Speech Language Pathology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

In this proposed rule, we propose to remove 55 previously finalized quality measures from the MIPS Program for the 2022 MIPS payment year and future years. These measures are discussed in detail below. Our measure removal criteria was discussed in the CY 2019 final rule (83 FR 59763 through 59765).

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), additional criteria that we use for the removal of measures also includes extremely topped out measures, which means measures that are topped-out with an average (mean) performance rate between 98-100 percent.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0097	046	N/A	Medicare Part B Claim Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative of previously finalized measure Q130: Documentation of Current Medications in the Medical Record that also addresses assessment of current medications at the time of a patient and eligible clinician encounter. This measure is not only duplicative but includes measure logic that has demonstrated to be historically challenging for implementation by eligible clinicians. This measure is a legacy measure from the Physician Quality Reporting Initiative that was implemented initially as a Medicare Part B claims only measure. With the expansion of collection methods being used in the program, unforeseen implementation challenges have arisen. We believe measure Q130 is the best measure to support the quality outcome of current medications being documented in the medical record. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty sets as it is clinically relevant to these clinician types: Pulmonology and Clinical Social Work.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0091	051	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry results documented.	American Thoracic Society	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program to ensure measures are not duplicative and present an opportunity to provide a meaningful impact to quality. We prefer the more robust, previously finalized measure Q52: Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy that assesses appropriate management of COPD by prescribing a long-acting inhaled bronchodilator for symptomatic patients based on spirometry test results that demonstrate FEV1/FVC < 70 percent, FEV1 < 60 percent, and patient's assessed COPD symptoms. Measure Q51 represents the process having the spirometry results reviewed and documented which is essentially a component of measure Q52. Therefore, we prefer to have eligible clinicians report the more robust measure Q52 which address spirometry results to provide the best option in pharmacological treatment. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set as it is clinically relevant to this clinician type: Pulmonology.
N/A	068	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy.	American Society of Hematology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because we believe that documentation of iron stores would be considered a standard of care during administration of erythropoietin therapy. We believe this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set as it is clinically relevant to this clinician type: Oncology/ Hematology.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it represents the clinical equivalency of previously finalized measure Q93: Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use. In the circumstance an eligible clinician does not prescribe an antibiotic, most likely a topical therapy would be prescribed. However, the eligible clinician is able to prescribe both an antibiotic and topical and remain numerator compliant for this measure which does not address the overuse of systemic antimicrobial use. Therefore, we believe this measure is not providing a meaningful impact to quality improvement.
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative of previously finalized measure Q182: Functional Outcome Assessment that also addresses functional assessment and possibly pain depending on which standardized tool utilized. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: add coding for physical therapists and occupational therapists to the list of denominator eligible encounters as well as add this measure to the Physical Therapy/ Occupational Therapy specialty set. The measure steward states and we agree that for individuals with osteoarthritis (OA), physical therapists and occupational therapists provide various interventions with the goals of improving muscle performance, activity and participation, and promoting physical activity. Despite these revisions offered by the measure steward, we believe that it is important to reduce duplicity within the program and prefer the more robust measure Q182 which also supports physical and occupation therapist, more frequent functional assessment, and care plan for identified functional deficiencies.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative of measure A.3: Adult Immunization Status proposed in this proposed rule. This new measure, if finalized, is a more robust immunization measure which requires multiple age-appropriate preventive immunizations. We are proposing to remove this measure to be consistent with ensuring measures are not duplicative and present an opportunity to provide a meaningful impact to quality. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: the numerator instructions would be revised to read: "Due to the changing nature of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. If the LAIV is recommended for administration for a particular flu season, an eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting previous receipt, 2) report a denominator exception, either as a patient reason (e.g., for patient preference) or a system reason (e.g., the institution only carries LAIV)." This would allow clinical discretion and alignment with current performance period's CDC/ACIP guidelines without negatively affecting clinicians providing LAIV.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative of measure A.3: Adult Immunization Status proposed in this proposed rule. This new measure, if finalized, is a more robust immunization measure which requires multiple age-appropriate preventive immunizations. In addition, measure Q111 does not align with the current ACIP guidelines, but was retained for certain collection types to provide a measure selection option that addresses an important population health matter. The proposed measure requires patients to receive both the 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal polysaccharide vaccine (PPSV23) at least 12 months apart, with the first occurrence after the age of 60, whereas measure Q111 only requires the patient to receive either PCV13 or PPSV23 vaccine. In the event, we do not finalize the proposal to remove the measure, we would expand the denominator to include nursing home and domiciliary settings as this would be an applicable patient population.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program due to the controversy surrounding the potential correlation between assessment of pain and increase in prescriptions for opioid medications. After consideration of previous stakeholder feedback, we believe this measure may have the unintended consequence of encouraging excessive prescribing of pharmacologic therapies to assist with pain management. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: expand the denominator to include coding for audiology and speech language pathology MIPS eligible clinicians and remove the denominator exception allowing for patients with severe mental and/or physical incapacities to be excluded from the numerator. The measure steward submitted this substantive change based on a literature search the supports the need for improved pain assessment and follow up in patients with dementia. In addition, we propose to add this measure to the following specialty measure sets in the event the measure is retained in the MIPS program based on stakeholder comments as it is clinically relevant to these clinician types: Chiropractic Medicine, Clinical Social Work, Audiology and Speech Language Pathology. Despite these revisions offered by the measure steward, we believe that it is important to ensure that the MIPS quality measures support the safety of patients and have a meaningful impact on quality management of pain by all eligible clinicians.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0508	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms:** Percentage of final reports for screening mammograms that are classified as "probably benign".	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.3 percent for the Medicare Part B Claims specifications collection type and 0.5 percent for the MIPS CQMs specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the Medicare Part B Claims and MIPS CQMs specifications collection types are considered extremely topped out. Average performance rates are based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	160	CMS52v8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis.	Health Resources and Services Administration	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the numerator with addition of Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis and parenteral pentamidine and oral clindamycin with primaquine to Population one. For Population two and three, we would add intravenous pentamidine to the "Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis" value set. In alignment with these updates, the measure steward has proposed to update and create definitions related to CD4 Count Tests to include oral clindamycin and primaquine for population 1 and update logic in all three numerators to allow for 'Medication Active' documentation in addition to 'Medication, Order' documentation for appropriate capture of either an active or ordered medication. Additionally, we would adopt the measure steward's substantive change to remove Leucovoin as a medication option and add oral Clindamycin to align with guideline updates. Additionally, we would update logic for denominator exceptions in population 1 to reflect "3 months or less after". Additionally, if the measure is not finalized for removal from the MIPS program, we propose to remove the measure from the Allergy/ Immunology specialty set since this measure is not applicable to this specialty as Allergy/Immunology specialists do not diagnose, treat or manage HIV/AIDS patients. In addition, if the measure is retained in the MIPS program based on stakeholder comments we propose to add this measure to the following specialty set as it is clinically relevant to this clinician type: Pulmonology. Despite these revisions, we believe this measure is not providing a meaningful impact to quality improvement due to lack of adoption by eligible clinicians.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.5 percent for the MIPS CQMs specifications collection type For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in (83 FR 59761 through 59763). The average performance for this inverse measure is 1.3 percent for the MIPS CQMs specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this is duplicative of previously finalized measure Q182: Functional Outcome Assessment. Measure Q182 does not limit the functional tools utilized for functional assessment, therefore ensuring rheumatologists are able to submit this measure. Additionally, measure Q182 is more robust in quality with inclusion of a follow up plan for identified functional outcome deficiencies. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: revise the numerator statement to: Patients for whom a standardized functional status assessment using an ACR-preferred, patient-reported functional status assessment tool was performed at least once within 12 months. Additionally, we would update the Functional Status Assessment definition to the following: This measure assesses if physicians are using a standardized descriptive or numeric scale, standardized questionnaire, or notation of tool to assessment of the impact of RA on patient activities of daily living. Examples of tools used to assess functional status include but are not limited to: Health Assessment Questionnaire (HAQ), Modified HAQ, HAQ-2, and American College of Rheumatology's Classification of Functional Status in Rheumatoid Arthritis. Functional status should be assessed using a measurement tool assigned preferred status by the ACR. The instruments listed are the ACR-preferred tools that fulfill the measure requirements: PROMIS Physical Function 10-item (PROMIS PF10a), Health Assessment Questionnaire-II (HAQ-II), and Multi-Dimensional Health Assessment Questionnaire (MD-HAQ). Despite these revisions offered by the measure steward, we believe that it is important to reduce duplicity within the program and prefer the more robust measure Q182 which supports more frequent functional assessment and follow up plan for identified functional deficiencies.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because previously finalized measure Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity assesses the same patient population, but requires more frequent assessment in order to be numerator compliant making it a more robust measure.
0659	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association	We propose removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program as it is not consistent with current guidelines. It was previously proposed for removal, but was retained to allow for the measure to be updated to align with newly released guidelines. This measure was not updated to align with new guidelines. The measure steward and a co-owner of this measure, AGA, consulted with other co-owners, the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE), and all agree that measure Q185 should be removed.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0564 / 0564e	192	CMS132 v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The measure steward did propose to update the language to better clarify how the measure is currently implemented. They also requested to update the denominator exclusion data elements/value sets; removing 'Aphakia and Other Disorders of Lens,' 'Cysts of Iris, Ciliary Body and Anterior Chamber,' 'Enophthalmos,' and 'Prior Pars Plana Vitrectomy' and adding 'Glaucoma Associated with Congenital Anomalies, Dystrophies and Systemic Syndromes,' 'Other Endophthalmitis,' and 'Purulent Endophthalmitis'. We do not believe these changes will have an impact on performance rates and will continue to propose its removal due to being extremely topped out. In addition, the measure steward proposed to update the measure to specify the complication should be assessed of the operative eye. This is an inverse measure with extremely high performance rate of 0.9 percent for eCQM specifications collection type and 0.2 percent for MIPS CQMs collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the eCQM and MIPS CQMs specifications collection types are considered extremely topped out. Average performance rates are based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0428	223	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with General Orthopedic Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.	We propose removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program as the measure steward, Focus on Therapeutic Outcomes, Inc. (FOTO) no longer supports the inclusion of the measure. The patient population within this measure is captured in the proposed FOTO measure A.4: Functional Status Change for Patients with Neck Impairments. In the event we do not finalize A.4: Functional Status Change for Patients with Neck Impairments, we would maintain this measure with the following substantive changes: update the numerator to require meeting or exceeding the risk adjusted prediction of the functional status change to be a Performance Met, move the current denominator exclusions to denominator exceptions, add denominator exclusion for patients with diagnosis of a degenerative neurological condition at any time before or during the episode of care, and add denominator exceptions for ongoing care not indicated: patient self-discharged early, patient discharged after only 1-2 visits due medical events, patient seen only 1-2 visits. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
0509	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it represents a structure measure rather than a measure that supports direct patient care. We believe that it is important for eligible clinicians to encourage the development of such systems to track mammography to support patient compliance for adherence of clinical guidelines but systems would likely be implemented by support staff and management. We are striving for more outcome based measures.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1854	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 100 percent for the Medicare Part B Claims specifications collection type and 99.5 percent for the MIPS CQMs specifications collection type. As such, the Medicare Part B Claims and MIPS CQMs specifications collection types are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 99.9 percent for the Medicare Part B Claims specifications collection type and 99.7 percent for the MIPS CQMs specifications collection type. As such, the Medicare Part B Claims and MIPS CQMs specifications collection types are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	255	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure narrows the eligible patient population to the Rh-Negative pregnant women which has not been able to create a benchmark. This is a result of the limited patient population and measure adoption which does not provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. This does not align with the meaningful measure initiative. We encourage measure stewards to develop a measure that expands the patient population to those that had their Rh Status evaluated in the Emergency Department (ED) and received Rh-immunoglobulin (Rhogam) if Rh-negative.
N/A	262	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Image Confirmation of Successful Excision of Image-Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy.	American Society of Breast Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 100 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.0 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients regardless of age with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the year prior and current year are considered adequately screened to prevent overuse of X-ray assessment.	American Gastro-enterological Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the substantive changes submitted by the measure steward would require a less meaningful quality action and extend the prednisone usage from 60 to 90 or greater consecutive days. The revised measure's quality action would be simplified to prescribing supplements such as calcium and/or vitamin D optimization. Additionally, the measure steward proposes to replace the term "Loss Assessment" with "Health Optimization" throughout the measure, define the patient population as 18 and over, as well as updating the numerator definition to "Documentation that calcium and/or Vitamin D optimization has been ordered or performed. This includes, but is not limited to, checking serum levels, documenting use of supplements or prescribing supplements" to better align with the measure's intent. The current measure requires a Central Dual-energy X-Ray Absorptiometry (DXA) and documented review of systems and medication history or pharmacologic therapy (other than minerals/vitamins) for osteoporosis prescribed within the past two years. We agree that patients without risk factors would not be appropriate for frequent DXA scans as the current quality measure requires. The measure steward's substantive changes for the measure do not account for patients with high risk factors, which may warrant additional screening and pharmacologic treatment. The measure would be more robust if it was revised to assess based on multiple clinical criteria such as age, risk factors, etc. We encourage the measure steward to submit a new measure that takes into account risk factors and require the appropriate clinical action.

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N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program. Based on input from the measure steward, we propose the substantive change of expanding the denominator to physical therapy in the circumstance that this measure is not finalized for removal. In addition, we propose to add this measure to the following specialty measure sets in the event the measure is maintained within the program: Physical Therapy/ Occupational Therapy and Clinical Social Work. Although, with the denominator expansion of measure Q282 to physical therapy and the proposed inclusion of behavioral health eligible clinicians to the denominator of measure Q182: Functional Outcome Assessment, this measure would be duplicative to broadly applicable and previously finalized measure Q182. Therefore, we support the removal of measure Q282 due to duplicity. We believe that it is important to reduce duplicative measures within the program and prefer the more robust measure Q182 which supports more frequent functional assessment and care plan for identified functional deficiencies.
N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative and shares a denominator with previously finalized measure Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia which requires screening and provision of mitigation recommendations and referral to resources for patients diagnosed with dementia or their caregivers. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: include physical therapy in the denominator of the measure. In addition, we propose to add this measure to the following specialty measure sets in the event the measure is retained in the MIPS program based on stakeholder comments: Physical Therapy/Occupational Therapy and Clinical Social Work. We believe that it is important to reduce duplicity within the MIPS quality measures and support the removal of measure Q288.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	325	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program as we have reexamined public comments received during last year's rulemaking cycle. Stakeholders commented that it is burdensome for clinicians to retrieve specialists' reports for all patient visits. This insinuates the communication may be happening, but the co-morbid treating physician is not looking for and/or considering the MDD status. Additionally, this measure is duplicative to previously finalized measure Q374: Closing the Referral Loop: Receipt of Specialist Report which specifies numerator compliance as receipt of report from the referring eligible clinician. In the event that the measure is maintained, we propose to add this measure to the following specialty sets: Clinical Social Work.
1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited patient population and adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. There were zero submissions for the 2017 performance period.
N/A	329	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is a catheter at the time maintenance hemodialysis is initiated.	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set based on stakeholder feedback: Nephrology.

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N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians.
N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate:** The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	American Society for Gastrointestinal Endoscopy	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program after review of previous stakeholder feedback, scoring implications, and attribution to the MIPS eligible clinician. The measure does not account for variables which may influence the adenoma detection rate such as geographic location, socioeconomic status of patient population, community compliance of screening, etc. Due to the measure construct, benchmarks calculated from this measure are misrepresented and do not align with the MIPS scoring methodology where 100 percent indicates better clinical care or control. Guidelines and supplemental literature support a performance target for adenoma detection rate of 25 percent for a mixed gender population (20 percent in women and 30 percent in men). In addition, the measure does not account for MIPS eligible clinicians that fail to detect adenomas, but may score higher based on the patient population.
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	We propose the removal of this measure (finalized in (81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients without Major Complications (Discharged to Home by Post-Operative Day #2). Measure Q344 is a more comprehensive measure accounting for the patient population found within measure Q345 as well as assessing for complications and appropriate length of stay. Based on input from the measure steward, we propose the substantive change of replacing the "or" with "and" in the title and the numerator statement in the circumstance that this measure is not finalized for removal. Despite these revisions, this measure is still duplicative in nature and less comprehensive as compared to measure Q344.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q260: Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2). Measure Q260 is a more comprehensive measure accounting for the patient population found within measure Q346 as well as assessing for complications and appropriate length of stay. Based on input from the measure steward, we propose the substantive change of replacing the "or" with "and" in the title and the numerator statement in the circumstance that this measure is not finalized for removal. Despite these revisions, this measure is still duplicative in nature and less comprehensive as compared to measure Q260.
1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive:** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q259: Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged at Home by Post-Operative Day #2). Measure Q259 is a more comprehensive measure accounting for the patient population found within measure Q347 as well as assessing for complications and appropriate length of stay.
N/A	352	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	American Association of Hip and Knee Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.8 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
NA	353	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.6 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are submitted to a radiation dose index registry that is capable of collecting at a minimum selected data elements.	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this is not furthering quality care, but simply submitting to a radiation dose index and does not deter excessive radiation. Despite this structure measure supporting patient care, it does not measure quality care that directly impacts patients. We believe this measure is not providing a meaningful impact to quality improvement to require radiation reduction.
N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12 month period after the study.	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this is not furthering quality care, but simply setting up a database. Despite this structure supporting patient care, it does not measure quality care that directly impacts patients. We believe this measure is not providing a meaningful impact to quality improvement.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0712e	371	CMS160 v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure only captures the process of depression screening and is duplicative of previously finalized measure Q370: Depression Remission at Twelve Months. Measure Q370 is a more robust outcome measure, requiring depression remission for numerator compliance. The screening element found within this process measure is a part of logic for measure Q370. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set as it is clinically relevant to the clinician type: Pediatrics.
N/A	372	CMS82v7	eCQM Specifications	Process	Community/Population Health	**Maternal Depression Screening:** The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because denominator eligibility is determined by the visits to the child's MIPS eligible clinician. The quality action would not be attributed to the child's MIPS eligible clinician, but rather to the obstetrician or primary care provider of the mother. The measure does not account for instances where the mother is not present for the child's visits.
N/A	388	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy):** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.4 percent for the MIPS CQMs specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.9 percent for the Medicare Part B Claims specifications collection type and 98 percent for the MIPS CQMs specifications collection type. As such, the Medicare Part B Claims and MIPS CQMs specifications collection types are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 99.9 percent for the MIPS CQMs specifications collection type. As such, the MIPS CQMs specifications collection types are considered extremely topped out. The Medicare Part B Claims specification has not established a benchmark, but we do not maintain this collection type without a corresponding collection type. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end -stage renal disease (ESRD) who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. This concept would be more inclusive and better represented if the denominator was expanded to include patients with multiple chronic conditions.
N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.7 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: add criteria for denominator eligibility to include Diagnosis for Bacteremia (ICD-10-CM): R78.81 AND Methicillin susceptible Staphylococcus aureus infection as the cause of diseases classified elsewhere (ICD-10-CM): B95.61. Despite these revisions offered by the measures steward, we do not believe this will affect the average performance for this measure.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 60 days) after an index event date.	Minnesota Community Measurement	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this patient population and quality action are duplicative of previously finalized measure Q370: Depression Remission at Twelve Months but vary in timeframe in which depression remission is required. The extended timeframe allows assessment of patient to ensure management and prevention of depression relapse. American Psychiatric Association (2010) states "Continuation therapy is the four-to-nine month period beyond the acute treatment phase during which the patient is treated with antidepressants, psychotherapy, ECT or other somatic therapies to prevent relapse. Relapse is common within the first 6 months following remission from an acute depressive episode; as many as 20-85 percent of patients may relapse." In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator allowing PHQ-9/PHQ9M to be administered during the index encounter or up to 7 days prior to encounter. In addition, we propose to add this measure to the following specialty measure sets in the event the measure is retained in the MIPS program based on stakeholder comments within the program as it is clinically relevant to these clinician types: Pediatrics and Clinical Social Work. Despite these revisions offered by the measures steward, we prefer measure Q370 which supports the quality outcome depression remission at 12 months.
1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	We propose the removal of this measure (finalized in (81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q258: Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7). Measure Q258 is a more comprehensive measure accounting for the patient population found within measure Q417 as well as assessing for complications and appropriate length of stay.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the patient population is captured within previously finalized measure Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%). While the quality action requires persistent beta-blocker treatment, the performance period is narrowed to only include the patients hospitalized and discharged for the first 6 months of the performance period. This does not include patient hospitalized and discharged after July 1, thus missing a substantial portion of the patient population. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator exclusion adding advance illness and frailty. Despite these revisions offered by the measure steward, we maintain that measure Q007 will capture the patient population sampled within this measure and allows for a 12 month performance period.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0733	446	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Operative Mortality Stratified by the Five STS-EACTS Mortality Categories:** Percent of patients undergoing index pediatric and/or congenital heart surgery who die, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, even if after 30 days (including patients transferred to other acute care facilities), and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, stratified by the five STAT Mortality Levels, a multi-institutional validated complexity stratification tool.	Society of Thoracic Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the denominator has a very limited patient population. We believe this measure does not align with the meaningful measure initiative. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set as it is clinically relevant to this clinician type: Thoracic Surgery.
1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies.	American Society of Clinical Oncology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because clinically we believe this to be standard of care. The performance data does not support a meaningful gap. The average performance for this measure is 97.4 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator definition to align with current guidelines as referenced in Table D. 68: Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy of this document.
N/A	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer with more than one emergency department visit in the last 30 days of life.	American Society of Clinical Oncology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this may be outside of the eligible clinician's control. We believe previously finalized measure Q455: Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better) is a related concept that can be a better indicator of compassionate outcomes to the end of life care for oncology patients.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died From Cancer Not Admitted to Hospice (lower score – better):** Percentage of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the concept would be captured in measure Q457: Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better) and is the more robust measure as it requires at least 3 days of hospice prior to death.
N/A	467	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Developmental Screening in the First Three Years of Life:** The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the 12 months preceding or on their first, second, or third birthday. This is a composite measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened in the 12 months preceding or on their first, second or third birthday.	Oregon Health & Science University	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program after review of denominator of this process measure is not able to specifically target a pediatric patients primary clinician for performance of developmental screening. The measure owner submitted a substantive change to revise the denominator eligible coding to include well-child visits. The well-child visit encounters would likely include the attestation of the numerator's quality action and therefore inflate performance of the measure. While we agree that screening pediatric patients for development milestones is indicative of quality interactions with patients, we believe that the complexity of implementing the proposed change creates a less meaningful assessment of MIPS eligible clinicians.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	We propose the removal of this measure (finalized in 83 FR 60108) as a quality measure from the MIPS program because it is duplicative of measure A.3: Adult Immunization Status proposed in this proposed rule. This new measure, if finalized, is a more robust immunization measure which requires multiple age-appropriate preventive immunizations. We are proposing to remove this measure to be consistent with ensuring measures are not duplicative and present an opportunity to provide a meaningful impact to quality.

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2022 MIPS Payment Year and Future Years

NOTE: Electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement period. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might be harmful for patients to receive a particular service when they should prioritize other services. The measure steward also believes that some of the services in this measure are not appropriate for patients 66 years of age and older who are living in a long-term institutional setting. We agree with the measure steward and believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

D.2. Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality #:	005
CMS eCQM ID:	CMS135v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**The measure title is revised to read:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD). **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12- month period when seen in the outpatient setting OR at each hospital discharge **Updated denominator:** For the MIPS CQMs Specifications collection type for Submission Criteria 1 – "At least on additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters. **Updated numerator:** Added language for ARNI therapy. **Updated definition:** Added language for ARNI therapy.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	This measure already includes ARNI therapy in the specifications and coding as well as a statement about the fact that ARNIs are a numerator compliant clinical action. The measure is proposed to be globally updated to include ARNI therapy language in the title, description, numerator, definition, denominator exception, and rate aggregation to align with the intent of the measure. With the inclusion of ARNI therapy, the intent of this measure is aligned with the most current clinical guidelines for ACE/ARB therapies for patient's diagnoses with heart failure. Telehealth visits, for the additional denominator eligible encounters, were added for Submission Criteria 1 in the MIPS CQMs Specifications collection type.

D.3. Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality #:	007
CMS eCQM ID:	CMS145v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI or a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.
Substantive Change:	**Updated calculation method:** For the MIPS CQMs Specifications collection type: To be submitted as a single performance rate. **Updated denominator:** For the MIPS CQMs Specifications collection type, "At least one additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure performance calculation for the MIPS CQMs Specifications collection type so that it is submitted as a single performance rate as opposed to two performance rates. This change allows for better alignment between the collection types. We are also proposing to add telehealth visits for the additional denominator eligible encounters for the MIPS CQMs Specifications collection type. This change is in alignment with the eCQM Specifications collection type. We believe these changes will allow for data congruency between the collection types while also lessening burden for implementation of the measure across these collection types.

D.4. Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality #:	008
CMS eCQM ID:	CMS144v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**For the eCQM Specifications collection type:** The timing for cardiac pacer in situ diagnosis logic has been changed to 'overlaps after'. **Updated denominator: For the MIPS CQMs Specifications collection type**: For Submission Criteria 1, "At least one additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	For the eCQM Specifications collection type: the logic regarding the cardiac pacer in situ diagnosis is being proposed to be updated to change the timing to 'overlaps after' to ensure it is present at the time of the end of the encounter and for harmonization with CMS145v8. For the MIPS CQMs Specifications collection type: we propose to add telehealth encounters for the additional patient encounter as denominator eligible encounters for Submission Criteria 1. This change is in alignment with the eCQM Specifications collection type. We believe these changes will allow for data congruency between the collection types while also lessening burden for implementation of the measure across these collection types.

D.5. Anti-Depressant Medication Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	009
CMS eCQM ID:	CMS128v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**Updated guidance:** Guidance statement updated to reflect the 105 day negative medication history. **Updated denominator:** The required visit needs to be in the 60 days before or after the initial patient population antidepressant medication dispensing event. The initial patient population dispensing period will be from May 1st of the year prior to the measurement period to April 30th of the measurement period. Added nursing home encounters to list of qualifying encounters. **Updated denominator exclusion:** Changed timing to 'overlaps' so that medications that are active in the 105 days prior may count.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to expand the denominator to include nursing home encounters as this measure is applicable to that setting and this will increase the number of MIPS eligible clinicians who can report on the measure. The required visit for the initial patient population is proposed to be in the 60 days before or after the initial patient population antidepressant medication dispensing event as the intent is for a physician who has influence over the medication choice and follow-up to report the measure. The measure steward feels, and we agree, that associating the visit with the medication dispensing event is more in line with the intent of the measure. The initial patient population dispensing period is also being updated. We are proposing to update the denominator exclusion logic so that medications that are active in the 105 days prior will also count as an exclusion. We are proposing to update the guidance as well to reflect the change in the denominator exclusion.

D.6. Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	0089 / 0089e
Quality #:	019
CMS eCQM ID:	CMS142v8
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as the benchmarking data shows that this measure meets the extremely topped out definition, specifically for the Medicare Part B Claims Measure Specification collection type. However, the benchmarking data continues to show a gap for the eCQM Specifications collection type and the MIPS CQMs Specifications collection type, as such, the measure will be retained for these two collection types.

D.7. Appropriate Testing for Children with Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	066
CMS eCQM ID:	CMS146v8
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Removed Ambulatory/ED grouping value set, instead using the individual value sets. **Updated denominator exclusions:** Added exclusion for competing diagnosis at the same encounter as the pharyngitis diagnosis or in the 3 days after the pharyngitis diagnosis.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	For the eCQM Specifications collection type: The Ambulatory/ED grouping value sets are proposed to be removed so that individual value sets will be used in order to increase transparency regarding which encounter value set is being utilized. A denominator exclusion for a competing diagnosis that occurs at the same encounter or 3 days after the pharyngitis diagnosis is proposed to be added to ensure the patient population being assessed is more in alignment with clinical intent of assessing whether or not children diagnosed with pharyngitis were correctly evaluated and subsequently ordered antibiotics.

D.8. Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections

Category	Description
NQF # / eCQM NQF #:	2726
Quality #:	076
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.
Substantive Change:	**Updated numerator definition:** Added definition for Hand Hygiene: Washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR).
Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add the definition for hand hygiene that is found in the Clinical Recommendation Statement as a numerator definition to make it more prominent and add clarity for measure users.

D.9. Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients

Category	Description
NQF # / eCQM NQF #:	0389 / 0389e
Quality #:	102
CMS eCQM ID:	CMS129v9
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer. **Updated denominator:** Removed cryotherapy from denominator statement/header. **Updated denominator definition:** Removed "Note: Patients with multiple adverse factors may be shifted into the high/very high risk category" from definition of Intermediate Risk. **For the eCQM Specifications collection type:** removed SNOMED and CPT codes related to cryotherapy from the SNOMED CT extensional OID and CPT extensional OID "Prostate Cancer Treatment" value set.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to remove cryotherapy from the measure to align with updated clinical guidelines. Current clinical guidelines do not recommend cryotherapy as a routine primary therapy for localized prostate cancer due to the lack of long-term data comparing this to treatments such as radiation or radical prostatectomy. Given that the denominator includes treatments recommended for low/very low-risk prostate cancer patients, the measure steward's technical expert panel (TEP) agreed cryotherapy should be removed from the denominator. All coding related to cryotherapy is being removed in accordance with the updated guidelines. We are proposing to update the denominator definition to align with updated guidelines.

D.10. Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	0104e
Quality #:	107
CMS eCQM ID:	CMS161v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.
Substantive Change:	**Updated denominator:** Added telehealth data element to "Major Depressive Disorder Encounter" definition using "Telehealth Services" value set. **Updated guidance:** Updated to reflect the inclusion of telehealth encounters. **Updated definition:** The specific type and magnitude of the suicide risk assessment is intended to be at the discretion of the individual clinician and should be specific to the needs of the patient. At a minimum, suicide risk assessment should evaluate: (1) Suicidal ideation (2) Patient's intent of initiating a suicide attempt AND, if either is present, (3) Patient plans for a suicide attempt (4) Whether the patient has means for completing suicide Low burden tools to track suicidal ideation and behavior such as the Columbia-Suicide Severity Rating Scale (C-SSRS) and the Suicide Assessment Five-Step Evaluation and Triage (SAFE-T) can also be used. Because no validated assessment tool or instrument fully meets the aforementioned requirements for the suicide risk assessment, individual tools or instruments have not been explicitly included in coding.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure was reviewed by PCPI's technical expert panel and it was recommended to include telehealth encounters. We are proposing to add telehealth data element to "Major Depressive Disorder Encounter" as telehealth encounters are directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We propose to reflect this change in the guidance header for additional clarity. We are proposing to add clarifying language in the definition header regarding suicide risk assessments that could be appropriate to meet the measure. It is still intended that the MIPS eligible clinician use their discretion when choosing the specific type and magnitude of the suicide risk assessment, based upon the patient's specific needs, but the suicide risk assessments should include, at minimum, certain criteria.

D.11. Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.
Substantive Change:	**The measure description is revised to read:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period. **The numerator is revised to read:** Women with one or more mammograms 27 months prior to the end of the measurement period. **Updated denominator exclusions: For eCQM Specifications collection type:** (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator guidance: For the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications collection types**: Added "This measure evaluates primary screening. Do not count biopsies, breast ultrasounds, or MRIs because they are not appropriate methods for primary breast cancer screening. Mammography screening is defined as a bilateral screening (both breasts) of breast tissue. If only one breast is present, unilateral screening (one side) must be performed on the remaining breast."
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add a timing component to the description for better clarity and alignment throughout the measure. The numerator was revised to state the timing in the same manner as the description, however, the timing itself has not been changed only stated differently. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. The measure steward also believes that some of the services in this measure are not appropriate for patients 66 years of age and older who are living in a long-term institutional setting. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. We are proposing to update the numerator guidance for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types to clarify the intent of the measure. The measure logic for the Medicare Part B Claims Measure Specifications will remain the same from prior years to allow a 27-month look back from the denominator eligible visit.

D.12. Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients aged 66 years and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator guidance: For Medicare Part B Claims Measure Specification and MIPS CQMs Specifications collection types:** Do not count DRE, FOBT tests performed in an office setting or performed on a sample collected via DRE.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, or who are living in a long-term institutional setting for more than 90 days. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. The measure steward believes the measure reflects services that may not be appropriate for patients in long-term institutional settings. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. We are also proposing to update guidance for numerator compliance for the Medicare Part B Claims Measure Specification and MIPS CQMs Specifications collection types to align with eCQM Specifications and CMS Web Interface Measure Specifications collection types. The update would not allow fecal occult blood test (FOBT) via tests performed in an office setting or performed on a sample collected via DRE to be numerator compliant. This update aligns with a more effective method as FOBT by stool passed spontaneously (SPS) appears to be statistically superior to FOBT by DRE. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.13. Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period. **Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator:** Allows use of a diagnosis of retinopathy as a proxy for a positive eye exam. • If the patient has a diagnosis of retinopathy that overlaps the measurement period, the patient will be required to have an eye exam in the measurement period. • If the patient does not have a diagnosis of retinopathy that overlaps the measurement period, the patient will be required to have an eye exam in the 24 months prior to the end of the measurement period.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure description to better align with proposed changes to logic. We agree with this update as it clarifies the intent of the measure. We are proposing to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, and for patients who are living in a long-term institutional setting, such as a nursing home. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services and that services within this measure may not be appropriate for older patients living in a long-term institutional setting for longer than 90 days during the measurement period. In response to reports from EHR vendors that the measure was not reportable due to the results from an eye exam not being in structured data, we are proposing to use the diagnosis of retinopathy as a proxy for a positive eye exam. Patients with a diagnosis of retinopathy are required to have an eye exam yearly while patients without that diagnosis are required to have an eye exam once every 24 months. We believe that by removing these two patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

D.14. Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality #:	119
CMS eCQM ID:	CMS134v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, and for patients who are living in a long-term institutional setting, such as a nursing home. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services and that services within this measure may not be appropriate for older patients living in a long-term institutional setting for longer than 90 days during the measurement period. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

D.15. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0421 / 0421e
Quality #:	128
CMS eCQM ID:	CMS69v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.
Substantive Change:	**Updated denominator exclusions:** Added patients in hospice care. Removed "or refuse follow-up" language from denominator exclusion. **For the eCQM Specifications collection type:** Added a 'union' operator of 'Intervention, Performed' for each 'Intervention, Order' for Above and Below Normal Follow-Up Interventions, and a 'union' operator of 'Intervention, Not Performed' for each 'Intervention, Not Ordered' for Above and Below Normal Follow-up Interventions not done due to a medical reason.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward convened an expert work group (EWG) and it was recommended that patients receiving hospice care should be removed from this measure. We agree with the EWG that this patient population should be removed as patients in hospice care would not benefit from this clinical service. Since assessment of BMI is not a valuable clinical assessment for hospice patients we believe that by removing this patient population it will reduce the burden of submission for these MIPS eligible clinicians providing care to these patients. We are proposing to remove "or refuse follow-up" from the denominator exclusion for clarity. We are proposing to add a union operator to the eCQM Specifications collection type to allow the intervention to be either completed or ordered, creating a new numerator option. We propose to update the eCQM Specifications collection type by adding a 'union' operator to allow intervention to be either completed or ordered for numerator compliance. This allows for better alignment with measure intent.

D.16. Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0418 / 0418e
Quality #:	134
CMS eCQM ID:	CMS2v9
National Quality Strategy Domain:	Community/ Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **Updated denominator:** Added speech language pathology MIPS eligible clinician type. **For the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications:** Added physical therapy MIPS eligible clinician type. **Updated denominator exception:** Updated language to situations where the patient's cognitive capacity, functional capacity or motivation to improve may impact the accuracy of results of standardized depression assessment. **The numerator is revised to read:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **For the eCQM Specifications collection type:** Updated the "Depression medications – adolescent" and the "Additional evaluation for depression – adolescent" value sets to include additional medications.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure description for better alignment with the measure intent and clinical practices, therefore the measure, will reflect those changes within the guidance and logic. This change will not affect the denominator population, but may expand the numerator population and provides a better opportunity for compliance. Based upon requests from stakeholders physical therapy evaluation codes are proposed to be add to the denominator eligible encounters to allow for this measure to be used in an additional setting. We agree that this is a clinically relevant measure to the physical therapy setting. We are proposing to update the denominator exception for better clarity to allow MIPS eligible clinicians to use cognitive capacity as a denominator exception. The measure steward based this decision on feedback from clinical subject matter experts. We agree that this is not a new denominator exception, but rather clarifies what is deemed a denominator exception for this measure. The eCQM Specifications collection type's adolescent medication value sets is proposed to be updated to include additional medications based upon recommendations from clinical subject matter experts. The additions will provide an opportunity for better compliance by expanding the list of appropriate medication codes while also improving alignment with measure intent.

D.17. Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384/0384e
Quality #:	143
CMS eCQM ID:	CMS157v8
National Quality Strategy Domain:	Person and Caregiver Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated Guidance: For the eCQM Specifications collection type:** This measure is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter where the patient and physician have a face-to-face interaction. Due to the nature of some applicable coding related to the radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face encounter during the series of treatments. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy within 30 days prior to the encounter AND administered chemotherapy within 30 days after the date of the encounter.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the guidance within the eCQM Specifications collection type to address the limitations of the radiation treatment management code 77427 and to provide clarification about the variation in how this code is applied versus how the measure performance is assessed.

D.18. Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain

Category	Description
NQF # / eCQM NQF #:	0383
Quality #:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.
Substantive Change:	**Updated the description to read**: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain. **Updated the denominator to read:** All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **Updated the numerator to read:** Patient visits that included a documented plan of care to address pain
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revert this measure to the 2018 performance period measure specification. The 2019 measure narrows the patient population to those who report moderate to severe pain and require the plan of care before or on the data of the second visit with the clinician. The measure steward has submitted this version to NQF for re-endorsement where the measure steward received feedback to further test the updated analytics. As such, we agree with reverting to the NQF-endorsed measure. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.19. Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).
Substantive Change:	**Updated definition:** Biologic DMARD Therapy- Includes Abatacept (Orencia), Adalimumab (Humira), Adalimumab-adbm (Cyltezo), Adalimumab-atto (Amjevita), Anakinra (Kineret), Baricitinib (Olumiant), Certolizumab pegol (Cimzia), Etanercept (Enbrel), Etanercept-szzs (Erelzi), Golimumab (Simponi), Infliximab (Remicade), Infliximab-abda (Renflexis), Infliximab-dyyb (Inflectra), Infliximab-qbtx (Ixifi), Sarilumab (Kevzara), Tocilizumab (Actemra), Tofacitinib (Xeljanz).
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add Baricitinib (olumiant) and remove Rituximab (Rituxan) to the definition of "Biologic DMARD Therapy" as it was approved in 2018 by the FDA for the treatment of rheumatoid arthritis. We agree with the inclusion of Baricitinib in order to capture the relevant patient population. This revision allows eligible clinicians to achieve performance with use of a new pharmacological therapy to treat RA.

D.20. Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	177
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50% of encounters for RA for each patient during the measurement year.
Substantive Change:	**Updated description:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year. **Updated definition:** Removed Patient Activity Scale (PAS) from definition of "Assessment of Disease Activity".
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward recently conducted an assessment of available RA disease activity tools and is updating the list of tools they will endorse. The Patient Activity Scale (PAS) will no longer be an ACR-preferred rheumatoid arthritis disease activity measurement tool and as such, we are proposing to remove this scale as an acceptable assessment tool within this measure and update the description to align with this revision.

D.21. Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	180
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months. **The numerator is revised to read:** Patients who have been assessed for glucocorticoid use and for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of a glucocorticoid management plan within 12 months.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that this measure be revised to expand the numerator population being assessed for improvement or no change in disease activity by dropping the prolonged doses of prednisone from ≥ 10 mg daily (or equivalent) to > 5 mg daily (or equivalent). The measure steward conducted literature review that found a nearly 2-fold greater serious infection at 5-10 mg of prednisone in RA. This change takes into consideration the dangers to patients associated with being on 5-10 mg doses of prednisone. We agree with the decision to drop the dosage of prednisone to > 5 mg daily (or equivalent) given it aligns more closely to dosing associated with patient risk and it is important to include these patients in the population being assessed for improvement or no change.

D.22. Elder Maltreatment Screen and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	181
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**Updated denominator:** Added physical and occupational therapy, ophthalmology, audiology and speech language pathology MIPS eligible clinician types.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing, based upon requests from stakeholders, that coding be added to the denominator eligible encounters to include physical/occupational therapy, ophthalmology, audiology and speech language pathology MIPS eligible clinician types. This expansion of the numerator allows this measure to be used in an additional setting. We agree that this measure is clinically relevant for the physical therapy setting.

D.23. Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	2624
Quality #:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**Updated denominator:** Added mental/behavioral health, audiology, and speech language pathology MIPS eligible clinicians.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing that the denominator be expanded to include coding for more MIPS eligible clinicians. We agree with the decision to expand the MIPS eligible clinician types as it is clinically relevant to this clinician type and allows for the removal of duplicative quality measures promoting functional assessment.

D.24. Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality #:	191
CMS eCQM ID:	CMS133v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.
Substantive Change:	**The measure description is revised to read:** Percentage of cataract surgeries for patients aged 18 and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery. **The initial population is revised to read: For the eCQM Specifications collection type:** All cataract surgeries for patients aged 18 years and older who did not meet any exclusion criteria. **The denominator is revised to read: For the MIPS CQMs Specifications collection type:** All cataract surgeries for patients aged 18 years and older who did not meet any exclusion criteria. **The denominator exclusion is revised to read:** Cataract surgeries in patients with significant ocular conditions impacting the visual outcome of surgery. **Update denominator exclusions:** Removed the following data elements/value sets: 'Chorioretinal Scars,' 'Moderate or Severe Impairment, Better Eye, Profound Impairment, Lesser Eye,' 'Other Corneal Deformities,' 'Other Disorders of Sclera,' 'Other Retinal Disorders,' and 'Profound Impairment, Both Eyes'. Add the following data elements/value sets: 'Cataract, Congenital,' 'Cataract, Mature or Hypermature,' 'Cataract, Posterior Polar,' 'Hypotony of Eye,' 'Macular Scar of Posterior Polar' (new value set), 'Morgagnian Cataract,' 'Posterior Lenticonus,' 'Retrolental Fibroplasias,' 'Traumatic Cataract,' and 'Vascular Disorders of Iris and Ciliary Body'. **The numerator is revised to read:** Cataract surgeries with best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following cataract surgery.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Outcome
Rationale:	We are proposing that the measure language be updated to reflect that it is not a patient-based measure, but rather a measure that assesses cataract surgeries. The measure steward believes and we agree this update in language better aligns to the measure intent and implementation and also aligns with the current measure guidance. The measure steward convened an Eye Care technical expert panel (TEP) who also agreed that these language updates would provide more clarity around the intent, and be more explicit. The Eye Care TEP also reviewed and evaluated the denominator exclusions resulting in removal and addition of data elements/value sets outlined above.

D.25. Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	0422
Quality #:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the knee impairment successfully calculated and the score was less than zero (< 0)" will become Performance Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the knee and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a knee impairment, who has had an interruption of a Treatment Episode for the same functional knee deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1009) identifying the close of a Treatment Episode for the same knee deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional knee deficit, progressing through treatment without interruption (for example a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a knee deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with knee impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. The numerator is revised to read: Patients who were presented with the Knee FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.26. Functional Status Change for Patients with Hip Impairments

Category	Description
NQF # / eCQM NQF #:	0423
Quality #:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the hip impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the hip and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a hip impairment, who has had an interruption of a Treatment Episode for the same functional hip deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1010) identifying the close of a Treatment Episode for the same hip deficit identified at Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional hip deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a hip deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with hip impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care no indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.). (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read**: Patients who were presented with the Hip FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.27. Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / ECQM NQF #:	0424
Quality #:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the lower leg, foot, or ankle impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the lower leg, foot or ankle and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a lower leg, foot or ankle impairment, who has had an interruption of a Treatment Episode for the same functional lower leg, foot or ankle deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1011) identifying the close of a Treatment Episode for the same lower leg, foot or ankle deficit identified at the Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional lower leg, foot or ankle deficit, progressing through treatment, without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a foot, ankle or lower leg deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with foot, ankle or lower leg impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care no indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Foot/Ankle FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

Category	Description
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.28. Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF # / ECQM NQF #:	0425
Quality #:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the low back impairment successfully calculated and the score was less than zero (< 0)" will become Performance Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the low back and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a low back impairment, who has had an interruption of a Treatment Episode for the same functional low back deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1012) identifying the close of a Treatment Episode for the same low back deficit identified at Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a Discharge from the current Treatment Episode Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional low back deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for a low back functional deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with a low back impairment who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. The numerator is revised to read: Patients who were presented with the Low Back FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.29. Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF # / ECQM NQF #:	0426
Quality #:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the shoulder impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the shoulder and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a shoulder impairment, who has had an interruption of a Treatment Episode for the same functional shoulder deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1013) identifying the close of a Treatment Episode for the same shoulder deficit identified at the Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional shoulder deficit, progressing through treatment, without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for a shoulder functional deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with shoulder impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Shoulder FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.30. Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF # / ECQM NQF #:	0427
Quality #:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the elbow, wrist, or hand impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the elbow, wrist, or hand and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with an elbow, wrist, or hand impairment, who has had an interruption of a Treatment Episode for the same functional knee deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1014) for identifying the close of a Treatment Episode for the same elbow, wrist or hand deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional elbow, wrist or hand deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for an elbow, wrist or hand deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with elbow, wrist or hand impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Elbow/Wrist/Hand FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

Category	Description
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We are proposing the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it will create a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.31. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / ECQM NQF #:	0028 / 0028e
Quality #:	226
CMS eCQM ID:	CMS138v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. **Updated denominator: For the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types:** Added physical therapy MIPS eligible clinician type. **Updated Guidance: For the Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types:** Added: (1) The denominator of population criteria 2 is a subset of the resulting numerator for population criteria 1, as population criteria 2 is limited to assessing if patients identified as tobacco users received an appropriate tobacco cessation intervention. For all patients, population criteria 1 and 3 are applicable, but population criteria 2 will only be applicable for those patients who are identified as tobacco users. Therefore, data for every patient that meets the initial population criteria will only be submitted for population 1 and 3, whereas data submitted for population 2 will be for a subset of patients who meet the initial population criteria, as the denominator has been further limited to those who were identified as tobacco users. (2) To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the 24-month period. If a patient has multiple tobacco use screenings during the 24-month period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. **Updated instructions: For the MIPS CQM Specifications collection types:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. For this implementation of the measure, the 24 month look back period includes the program year and the year prior. For Quality Payment Program (QPP) 2020, the 24 month period would be from 1/1/2019-12/31/2020. **Updated guidance: For the CMS Web Interface Measure Specifications collection types:** • If there is more than 1 patient query regarding tobacco use, use the most recent query during the 24-month period to determine tobacco status. • "Within 24 months" is defined as the 24-month look-back from the measurement period end date (1/1/2019 - 12/31/2020). • Screening for tobacco use may be completed during a telehealth encounter. • Tobacco cessation intervention can be performed by another healthcare provider; therefore, the tobacco use screening and tobacco cessation intervention do not need to be performed by the same provider or clinician. • Screening for tobacco use and cessation intervention do not have to occur on the same encounter, but both must occur during the 24-month look-back period. • Screening for tobacco use and cessation intervention may be completed during a telehealth encounter. • Tobacco cessation intervention may be completed during a telehealth encounter.

Category	Description
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that the measure description be revised to clarify the summarized intent for population criteria 2. Based upon requests from stakeholders, physical therapy evaluation codes are also being proposed for addition in the denominator eligible encounters for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types to allow for this measure to be used in an additional setting. We agree that this preventive assessment is a clinically relevant measure for clinicians in the physical therapy setting. We are proposing refinements to the guidance for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications collection types in response to stakeholder feedback regarding the timing for which tobacco cessation intervention must occur. In response to our determination and stakeholder feedback for the CMS Web Interface Measure Specifications, Medicare Part B Claims Measure Specifications, and MIPS CQMs Specifications collection types, we are proposing to allow a 24-month period to assess for tobacco cessation intervention. These refinements are in alignment with the clinical guidelines and will decrease burden for eligible clinicians performing tobacco screening and tobacco cessation intervention. The timing refinement proposed will maintain the balance of clinical guideline and measure alignment, and support our effort to reduce burden for measure submission. Additionally, this timing refinement allows the clinician to create personalized, patient-centered care while still maintaining the clinical integrity of the measure and clinical guidelines. The CMS Web Interface Measure Specifications collection type was updated with additional guidance in order to add clarity regarding how this measure is implemented using that collection type. We are also proposing updates to the instructions for MIPS CQMs Specifications collection types to further clarify the timing of the tobacco cessation intervention in alignment with the updated numerator guidance. We agree this proposal will maintain clinical intent, provide clarity, reduce clinician burden, and allow for personalized patient care. We are also proposing updates to guidance for the Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications collection types based upon stakeholder feedback requesting clarification regarding interpretation of the three rates included in this measure.

D.32. Controlling High Blood Pressure

Category	Description
NQF # / ECQM NQF #:	0018 / N/A
Quality #:	236
CMS eCQM ID:	CMS165v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period. **Updated denominator: For the eCQM Specifications collection type:** Removed Blood Pressure Visit grouping value set and added in the individual value sets. **Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. (2) Patients 66 year of age and older with advanced illness and frailty. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Updated: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. Added: (1) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (3) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator/guidance:** Updated to allow blood pressures taken by a clinician from remote monitoring devices in a medical setting or in an offsite setting (i.e. patient's domicile) to count towards the measure with additional clarification regarding usable blood pressure readings: -Not requiring the numerator blood pressure reading to be during a visit or overlap with a diagnosis of hypertension. (Applicable to eCQM only). -If the day of the last blood pressure reading there are multiple blood pressure readings on that day, use the lowest systolic and diastolic on that day. -The blood pressure reading that is being used should not come from an ED or inpatient visit. -Do not include blood pressure readings reported by or taken by the patient.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome

Rationale:	We are proposing for the eCQM specifications collection type: In order to increase transparency of which value set is being used for encounters, the "Blood Pressure Visit" grouping value set is being removed so that individual value sets will be used. We are proposing to update the allowable denominator exclusions to include patients 66 years of age and older with advanced illness and frailty, patients with dementia taking the listed medications, and patients who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement period. The measure steward believes and we agree it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might be harmful for patients to receive a particular service when they should prioritize other services. Additionally, we believe that some of the services in this measure are not appropriate for patients who are living in a long-term institutional setting for more than 90 days during the measurement period. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. Additionally, we propose the measure guidance be updated to align with the 2018 measure guideline updates making it so that a visit is no longer required for the numerator blood pressure reading with additional guidance that blood pressure should not be taken during major events as this can artificially elevate blood pressure. In alignment with this, blood pressure readings from an ED or inpatient visit should not be used as a numerator blood pressure reading. The guidance is also being updated to allow blood pressure readings taken by a clinician from remote monitoring devices in a medical setting or in an offsite setting (i.e. patient's domicile) to be numerator compliant. Patient reported blood pressure readings cannot be used for numerator compliance.

D.33. Use of High-Risk Medications in the Elderly

Category	**Description**
NQF # / ECQM NQF #:	0022 / N/A
Quality #:	238
CMS eCQM ID:	CMS156v8
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.
Substantive Change:	**Updated numerator statement for submission criteria 2:** Percentage of patients who were ordered at least two of the same high-risk medications on different days. **Updated guidance:** Added 'on different days' to align with update to numerator submission criteria 2.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The numerator statement for submission criteria 2 is proposed to be updated to clarify that the assessment is looking for high-risk medications that are prescribed on different days, which is in alignment with the intent of the assessment being captured. This update is also reflected in the guidance.

D.34. Childhood Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	240
CMS eCQM ID:	CMS117v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday
Substantive Change:	**The measure description is revised to read:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. **Updated numerator:** Added value set for Hepatitis B carriers to allow Hepatitis B carriers to meet this part of the numerator. **Updated definition:** Removed 'Three HiB Vaccinations' and added new definition statements 'HiB 3 Dose Immunizations or Procedures,' 'HiB 4 Dose Immunizations or Procedures,' 'HiB 3 or 4 Dose Immunizations,' 'All HiB Vaccinations,' and 'Has Appropriate Number of HiB Immunizations.' Revised logic to include the correct number of HiB doses depending on the manufacturer of the vaccine given to align with current guidelines. Updated the logic for the HiB vaccine to require the correct amount of doses depending on the manufacturer of the vaccine given. Create a 3 dose and a 4 dose HiB vaccine.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that the numerator be updated to include a value set for Hepatitis B carriers in order to allow this patient population to meet Hep B vaccine numerator compliance piece. We agree that this would suffice for the "had documented history of the illness" piece of numerator compliance. Additionally, we propose that the measure logic be updated for the HiB vaccine to ensure the correct dosing is administered as instructed by the drug manufacturer's instructions and alignment with the current guidelines. The description is also being updated to align with this. We agree the logic should match the dosing of the vaccine given to ensure that the patient is receiving the correct and full dosage.

D.35. Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
NQF # / eCQM NQF #:	0643
Quality #:	243
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.
Substantive Change:	**Updated denominator exceptions:** Added (1) Documentation of patient reason(s) for not referring to an outpatient CR program (for example, no traditional CR program available to the patient, within 60 min [travel time] from the patient's home, patient does not have access to an alternative model of CR delivery that meets all criteria for a CR program, patient refused or other patient reasons).
Steward:	American Heart Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing a new denominator exception be added to allow for documentation of patient reason(s) for not having a CR referral. The measure stewards believes denominator exceptions are used in select cases to allow for a fairer measurement of quality for those providers with higher risk populations. Exceptions are also used to defer to the clinical judgment of the provider. A MIPS eligible clinician who recommends CR referral to an eligible patient whom then refuses at the time of referral for one or more reasons (for example, lack of transportation, patient preference), will now be able to exclude this patient from the numerator population. In such a case, the MIPS eligible clinician will not be penalized based upon patient reason(s) for not having a CR referral. If the patient has told the physician that he/she does not wish to enroll in a CR program, the MIPS eligible clinician can document in the medical record that he/she has recommended referral but that the patient has refused CR. The measure steward believes this is important because, in this scenario, the MIPS eligible clinician should not be penalized for the lack of a completed CR program referral as long as the CR referral recommendation and the patient refusal are documented. By adding this exception, reasons for patient non-compliance can be better tracked to correspond with implementing practices that may improve compliance and thereby overall clinical care.

D.36. Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	268
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.
Substantive Change:	**The measure description is revised to read:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy. **Updated denominator:** All females aged 12 years and older with a diagnosis of epilepsy. **Updated numerator:** Female patients or caregivers counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy **Updated denominator exceptions:** Removed (1) Documentation of medical reason(s) why counseling was not performed for women of childbearing potential with epilepsy (4340F with 1P) **Updated definition of "Counseling"** - Counseling must include a discussion of at least two of the following three counseling topics: • Need for folic acid supplementation, • Drug to drug interactions with contraception medication, • Potential anti-seizure medications effect(s) on fetal/child development and/or pregnancy.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that the denominator be expanded to include all females aged 12 years and older and that the denominator exception of "Documentation of medical reason(s) why counseling was not performed for women of childbearing potential with epilepsy" be removed as there is no longer an exception for patients with a diagnosis of neurodevelopmental disorder, encephalopathy, hydrocephalus, brain injury, cerebral palsy, severe cognitive impairment, or severe intellectual disability. The description is being updated to reflect the changes made to the denominator. The numerator action was updated to require counseling for both contraception and pregnancy in relation to epilepsy and how its treatment may affect. We agree with this requirement as both clinical aspects are important to the patient. The measure steward has requested, and we agree with, the denominator expansion and the removal of the denominator exception as they believe all women diagnosed with epilepsy at risk for pregnancy and/or pregnancy complications should be counseled.

D.37. Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	283
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.
Substantive Change:	**Update denominator:** Added physical therapy MIPS eligible clinician type.
Steward:	American Psychiatric Association and American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that the denominator coding be expanded to include physical therapy as a denominator eligible encounter. We agree with the decision to expand this measure to physical therapy MIPS eligible clinicians as it is clinically relevant to this clinician type.

D.38. Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	286
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.
Substantive Change:	**Updated denominator:** Added physical therapy MIPS eligible clinician type.
Steward:	American Psychiatric Association and American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing that the denominator coding be expanded to include physical therapy as a denominator eligible encounter. We agree with the decision to expand this measure to physical therapy MIPS eligible clinicians as it is clinically relevant to this clinician type.

D.39. Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	290
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.
Substantive Change:	**Updated numerator options:** Performance Met: Psychosis, depression, anxiety, apathy, AND impulse control disorder assessed Performance Not Met: Psychosis, depression, anxiety, apathy, AND impulse control disorder not assessed
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the numerator options to better align with the intent of the measure, which requires assessment of five individual components of psychiatric symptoms. We agree with the measure steward that this update to the numerator options aligns with the intent of the measure.

D.40. Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	305
CMS eCQM ID:	CMS137v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis b. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention. **Updated initial population:** Changed intake period for the initial population to January 1 to November 14. Added telehealth services to initial population encounter value sets. **Updated numerator:** Added telehealth services to the numerator encounter value sets. Added Opiate Antagonists for numerator compliance **Numerator 1 is revised to read:** Initiation of treatment includes either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. **Numerator 2 is revised to read:** Engagement in ongoing treatment includes two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention (i.e., engagement for these members cannot be satisfied with medication treatment alone).
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing that the initial population and numerator value sets be updated to include telehealth services. We agree with including telehealth services as they are appropriate for this measure and patients using these services should be included in the initial population as well as be considered for numerator compliance. Both numerators are being updated to add pharmacotherapy as a numerator compliant clinical quality action. Numerator 2 is also being updated to reflect the change in the time period for follow-up, which is increasing to 34 days from 30 days and to align with pharmacotherapy addition; patients who initiated treatment with a medication need two or more engagement events where only one can be a medication treatment event.

D.41. Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	317
CMS eCQM ID:	CMS22v8
National Quality Strategy Domain:	Community /Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Updated logic to allow for the documentation of a reason (finding of elevated blood pressure or hypertension) for scheduling a follow up visit and added value set "Finding of Elevated Blood Pressure or Hypertension". Added Potassium and Sodium codes to the Dietary Recommendation value set. **Updated numerator definition:** Added potassium and sodium for dietary/lifestyle recommendations.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the logic to allow for the documentation of a reason (finding of elevated blood pressure or hypertension) for scheduling a follow up visit which improves alignment with measure intent. This logic change will include the addition of a new values set "Finding of Elevated Blood Pressure or Hypertension" strengthening alignment with measure intent. We also propose to add clinically relevant potassium and sodium codes to expand documentation options that align with the measure intent. This will also be reflected in the numerator definition.

D.42. Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525
Quality #:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Updated denominator:** Removed emergency medicine setting.
Steward:	American College of Cardiology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose and agree with the measure steward's request to remove the emergency department setting. Chronic anticoagulation therapy would be managed by a clinician providing continuous medical care which would not be applicable to the emergency medicine specialty.

D.43. Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	332
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
Substantive Change:	**Updated denominator:** Changed requirements for denominator eligibility Patients aged ≥ 18 years on date of encounter AND **Diagnosis for bacterial and infectious agent** **OR** **Sinusitis caused by, or presumed to be caused by, bacterial infection** AND Patient encounter WITHOUT Telehealth Modifier AND Antibiotic regiment prescribed
Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing the measure no longer requires a diagnosis for bacterial and infectious agent to be denominator eligible as long as the sinusitis is caused by, or presumed to be caused by, bacterial infection. We agree that this change will not change the intent of the measure, but could lessen the burden to MIPS eligible clinicians by removing the requirement for a diagnosis.

D.44. Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	335
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.
Substantive Change:	**The measure title is revised from Elective Delivery or Early Induction Without Medical Indication ≥ 37 and < 39 Weeks (Overuse) to read:** Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse). **The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication. **Updated denominator:** Changed to include all deliveries at < 39 weeks of gestation. **Updated numerator:** Numerator options will be updated to reflect the measure now including all deliveries at < 39 weeks gestation.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing the measure population be expanded to include all deliveries at < 39 weeks of gestation. We agree with this change as delivery prior to 39 weeks of gestation increases risk to both the mother and baby. Induction prior to 39 weeks of gestation should only be performed when clinically indicated. It is important to have a complete population to ensure that all instances of early induction are being captured and assessed for proper clinical action.

D.45. Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	336
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, and family and contraceptive planning.
Substantive Change:	**Updated description to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth and who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. **Updated numerator:** Added clinical actions necessary for numerator compliance (1) Tobacco use screening and cessation education (2) Healthy lifestyle behavioral advice to bring the BMI within healthy limits (3) Immunization review and education
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	Three more components have been added to the list of clinical actions needed at a post-partum visit in order to be numerator compliant. The measure steward convened an expert work group (EWG) who, upon literature review, recommended adding these three clinical activities. The description was updated to align with the additional clinical actions. We agree and propose that that these clinical actions should be included in a post-partum visit as they will positively impact patient health and are clinically valuable in supporting post-partum patients.

D.46. Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	337
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.
Substantive Change:	**The description is revised to read:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test. **The numerator is revised to read:** Patients who have a documented negative TB screening or have documentation of the management of a positive TB screening test with no evidence of active tuberculosis, confirmed through use of radiographic imaging (i.e., chest x-ray, CT) prior to treatment with a biologic immune response modifier.
Steward:	American Academy of Dermatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	Newly published psoriasis clinical guidelines recommend that tuberculosis (TB) screening tests be completed prior to treatment. Numerator compliance for this measure will now have a timing component associated with the TB screening tests and imaging as they need to be completed prior to treatment with a biologic immune response modifier. We agree and propose this change as it follows the current clinical guidelines.

D.47. Pain Brought Under Control Within 48 Hours

Category	Description
NQF # / eCQM NQF #:	0209
Quality #:	342
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.
Substantive Change:	**Updated denominator:** Added the outpatient setting.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing that the denominator coding be expanded to include the outpatient setting as an applicable setting. We received prior stakeholder feedback with this request and agree with the decision to expand this measure to the outpatient MIPS eligible clinicians as it is clinically relevant to this setting.

D.48. HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	348
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.
Substantive Change:	**The measure title is revised from HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate to read:** Implantable Cardioverter-Defibrillator (ICD) Complications Rate.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.

D.49. Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality #:	370
CMS eCQM ID:	CMS159v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Updated denominator:** Allow PHQ-9/PHQ9M to be administered during the index encounter or up to 7 days prior to encounter.
Steward:	Minnesota Community Measurement
High Priority Measure:	No
Measure Type:	Outcome
Rationale:	The measure steward believes that allowing flexibility for the timeframe in which a PHQ-9/PHQ-9M can be obtained will accommodate pre-visit planning or distribution of a PHQ-9/PHQ-9M tool prior to the encounter (office visit, psychiatry or psychotherapy visit, telephone or online encounter). The intent of this change includes the following principles: (1) The patient must have the corresponding diagnosis at the time of the index encounter. (2) The patient must have completed the PHQ-9/PHQ-9M and have a score greater than 9. (3) That same PHQ-9/PHQ-9M is directly tied to and used during the index encounter. We agree and propose this change as it will allow for pre-visit planning and administration of the tool while also accounting for clinical workflow. Additionally, this revision may lessen the burden of completing the PHQ-9/PHQ-9M tool during the health visit.

D.50. Functional Status Assessments for Congestive Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	377
CMS eCQM ID:	CMS90v9
National Quality Strategy Domain:	Person and Caregiver- Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**Updated numerator:** Added the Minnesota Living with Heart Failure Questionnaire (MLHQF) tool and the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) tool to the list of acceptable FSAs.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The Minnesota Living with Heart Failure Questionnaire (MLHQF) tool and the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) tool are proposed to be added to the list of numerator compliant tools that may be used to complete the measure's clinical action. The MLHQF tool has previously been approved by the measure steward's expert work group for inclusion in this measure and the KCCQ-12 tool is being included based upon expert feedback and stakeholder requests, as the measure already contains the KCCQ tool. We agree and are proposing that both of these tools are relevant and appropriate for inclusion in this measure and, potentially, will capture an increased number of instances that meet numerator requirements.

D.51. Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	378
CMS eCQM ID:	CMS75v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The numerator is revised to read:** Children who had cavities or decayed teeth overlapping the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the numerator statement to include a timing component for better alignment with numerator logic.

D.52. Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	379
CMS eCQM ID:	CMS74v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The numerator is revised to read:** Children who receive a fluoride varnish application during the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the numerator header to align with the numerator logic.

D.53. Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	1365e
Quality #:	382
CMS eCQM ID:	CMS177v8
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.
Substantive Change:	**Updated numerator:** Added telehealth data element to "Major Depressive Disorder Encounter" definition using "Telehealth Services" value set (OID: 2.16.840.1.113883.3.464.1003.101.12.1031). **Updated guidance:** A suicide risk assessment should be performed at every visit for major depressive disorder during the measurement period. This measure is an episode-of-care measure; the level of analysis for this measure is every visit for major depressive disorder during the measurement period. For example, at every visit for MDD, the patient should have a suicide risk assessment. Use of a standardized tool(s) or instrument(s) to assess suicide risk will meet numerator performance, so long as the minimum criteria noted above is evaluated. Standardized tools can be mapped to the concept "Intervention, Performed": "Suicide risk assessment (procedure)" included in the numerator logic below, as no individual suicide risk assessment tool or instrument would satisfy the requirements alone. **Updated numerator definition:** The specific type and magnitude of the suicide risk assessment is intended to be at the discretion of the individual clinician and should be specific to the needs of the patient. At a minimum, suicide risk assessment should evaluate: (1) Risk (for example, age, sex, stressors, comorbid conditions, hopelessness, impulsivity) and protective factors (for example, religious belief, concern not to hurt family) that may influence the desire to attempt suicide. (2) Current severity of suicidality. (3) Most severe point of suicidality in episode and lifetime. Low burden tools to track suicidal ideation and behavior such as the Columbia-Suicidal Severity Rating Scale can also be used. Because no validated assessment tool or instrument fully meets the aforementioned requirements for the suicide risk assessment, individual tools or instruments have not been explicitly included in coding.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The measure steward's Technical Expert Panel (TEP) recommended adding telehealth services to the numerator eligible encounters. We agree and propose that performing suicide risk assessments is a clinically relevant action that should be completed by MIPS eligible clinicians providing telehealth services for patients diagnosed with major depressive disorder. It is important for patient safety that this clinical action is being performed on all patients with this diagnosis regardless of setting. The guidance and numerator definition are being updated per TEP recommendations to clarify that while sample assessments are listed, they are not reflected in the coding of this measure because the assessments do not meet all of the requirements for the suicide risk assessment.

D.54. Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	385
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.
Substantive Change:	**Updated denominator exclusion:** Added an exclusion to remove patients with a pre-operative visual acuity of better than 20/40.
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to revise this measure to include a denominator exclusion to account for patients with a pre-operative visual acuity better than 20/40, as these patients would not be expected to show an improvement in visual acuity following surgical intervention. We believe these patients should be excluded based upon expected visual acuity outcomes. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.55. Follow-up After Hospitalization for Mental Illness (FUH)

Category	Description
NQF # / eCQM NQF #:	0576
Quality #:	391
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication/Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Substantive Change:	**Updated denominator:** Added self-harm as a denominator eligible diagnosis. **The measure description is revised to read:** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose the denominator be expanded to include patients diagnosed with self-harm. We agree that this patient population is relevant to this measure and follow-up after hospitalization for patients with a self-harm diagnosis is directly applicable to patient safety.

D.56. HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation

Category	Description
NQF # / eCQM NQF #:	2474
Quality #:	392
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older
Substantive Change:	**The measure title is revised from HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation to read:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.

D.57. HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	393
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Infection rate following CIED device implantation, replacement, or revision.
Substantive Change:	**The measure title is revised from HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision to read:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.

D.58. Immunizations for Adolescents

Category	Description
NQF # / eCQM NQF #:	1407
Quality #:	394
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/ Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.
Substantive Change:	**Updated denominator exclusions:** Added exclusion for encephalopathy due to Tdap vaccine. **Updated numerator to specify compliant serogroups:** Serogroups A, C, W, Y
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose the denominator exclusion be expanded to include encephalopathy as an eligible reason to exclude the patient from the Tdap vaccine clinical action. Both Adacel® and Boostrix® list progressive or unstable neurologic conditions, which would include encephalopathy, as reasons to defer their administration. The numerator was updated to specify the required serogroup. According to the Centers for Disease Control, all 11 to 12 year olds should be vaccinated with a meningococcal conjugate vaccine (Serogroups A, C, W, Y), with a booster dose given at 16 years old. All teens may also be vaccinated with a serogroup B meningococcal vaccine, preferably at 16 through 18 years old. This measure is assessing a younger patient population. We agree with adding specificity to the numerator to align with the current guidelines.

D.59. Appropriate Follow-up Imaging for Incidental Abdominal Lesions

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	405
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for abdominal imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended • Liver lesion ≤ 0.5 cm. • Cystic kidney lesion < 1.0 cm. • Adrenal lesion ≤ 1.0 cm.
Substantive Change:	**Updated measure assessment:** The measure analytic is being updated and will no longer be inverse. **The measure description is revised to read:** Percentage of final reports for abdominal imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow□up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion ≤ 1.0 cm • Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **The denominator is revised to read:** All final reports for imaging studies for patients aged 18 years and older with one or more of the following incidentally noted: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion ≤ 1.0 cm • Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated denominator note: For the MIPS CQMs Specifications collection type:** Updated to include changes in the denominator and to include: *Other "simple-appearing criteria": • Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) Radiologists may choose not to include in the radiology report benign-appearing renal cysts (Bosniak I or II or equivalent*) or cystic lesions that are too small to characterize (TSTC) but likely benign (a lesion is too small to characterize (TSTC) when the lesion size is less than twice reconstructed slice thickness (ACR, 2017). **Updated denominator: For the MIPS CQMs Specifications collection type:** Updated criteria: Incidental finding: Cystic renal lesion that is simple appearing* (Bosniak I or II), or Adrenal lesion ≤ 1.0 cm or Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** Updated to include changes in the denominator and to include: *Other "simple-appearing criteria": • Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) Radiologists may choose not to include in the radiology report benign-appearing renal cysts (Bosniak I or II or equivalent*) or cystic lesions that are too small to characterize (TSTC) but likely benign (a lesion is too small to characterize (TSTC) when the lesion size is less than twice reconstructed slice thickness (ACR, 2017). **Updated numerator instructions:** Removed inverse measure instructions. Added: A short note can be made in the final report, such as: "No follow-up imaging is recommended as incidental lesions are likely benign " or "No follow-up imaging is recommended per consensus recommendations based on imaging criteria. Further lab evaluation could be pursued based on clinical findings" **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications collection type:** Updated to reflect the changes to what is considered an incidental lesion.

Category	Description
	The numerator is revised to read: Final reports for imaging studies that include a description of incidental cystic renal lesion or adrenal lesion stating follow-up imaging is not recommended. **Updated numerator options:** Updated to reflect changes to the analytics of the measure and what is considered an incidental lesion. **Updated denominator exception:** Updated to read: Documentation of medical reason(s) that follow-up imaging is indicated (e.g., patient has lymphadenopathy, signs of metastasis or an active diagnosis or history of cancer, and other medical reason(s).
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update all aspects of this measure based upon the American College of Radiology's Technical Expert Panel (TEP) recommendations in order to bring the measure into alignment with current guidelines. The measure analytic is also being updated so that it is no longer an inverse measure. In addition, liver lesions have been removed from the denominator and the denominator exception has been updated to reflect the intent of the measure. We agree with these changes as they will bring the measure in better alignment with current clinical guidelines. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.60. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	415
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care clinician who have an indication for a head CT.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **Update description:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT. **Update denominator exclusions:** Removed pregnancy and revised list of antiplatelets applicable to the exclusion.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type. The benchmarking data shows that this measure is meets the extremely topped out definition for the Medicare Part B Claims Measure Specification collection type. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type. Additionally, we propose the denominator exclusions be updated to remove pregnancy as an eligible exclusion due to the low count of exclusion instances, and the list of antiplatelets was revised based upon an in depth review by the quality measures committee and measure leads and now aligns more closely with the current clinical workflow. The description was updated to align with the measure language throughout the specification.

D.61. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Updated denominator exclusions:** Removed thrombocytopenia.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We are proposing, due to the low count of exclusion instances, to remove thrombocytopenia from the list of eligible denominator exclusions.

D.62. Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053
Quality #:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator exclusions**: Updated: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. Added: (1) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (3) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose and agree with the measure steward that the denominator exclusions be updated because it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. We are also proposing to update the exclusion for living long term in an institution to include the criteria for more than 90 days during the measurement period. We agree with the measure steward as this would ensure the correct patient population is being removed from the eligible population and will lessen the burden to submit data for these MIPS eligible clinicians.

D.63. Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	438
CMS eCQM ID:	CMS347v3
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.
Substantive Change:	**Updated denominator exception:** Added hospice care.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward proposes to add patients receiving hospice care to the eligible denominator exceptions to align with the intent of the measure. We agree with the measure steward that this patient population should be removed as patients in hospice care would not benefit from this clinical service and we believe that by removing this patient population it will reduce the burden of submission for these MIPS eligible clinicians providing care to these patients.

D.64. Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.
Substantive Change:	**Updated denominator:** Removed exclusion for modifiers 52, 53, 73, and 74.
Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We are proposing that the denominator be expanded to include coded colonoscopy procedures that are indicated as incomplete or discontinued with modifiers 52, 53, 73, or 74 as denominator eligible. We agree that these procedures should be included in the denominator as the measure is looking to assess whether a colonoscopy was clinically indicated for the patient. Even if the colonoscopy was indicated as incomplete or discontinued, we would want that instance included in the denominator to determine if there was a valid medical reason for it to be performed.

D.65. Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	440
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.
Substantive Change:	**The measure title is revised from Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician to read:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician. **The measure description is revised to read:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC), Squamous Cell Carcinoma (SCC) (including in situ disease), or melanoma in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist. **Updated denominator:** Added melanoma diagnosis codes. **Updated numerator:** Included language to reflect the addition of melanoma to the denominator.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing that the denominator be expanded to include melanoma diagnosis codes. The measure steward believes this will allow for a broader patient population to reflect communication and care coordination of skin cancers, not just non-melanoma skin cancer. The measure title, description, denominator, and numerator language is being updated to align with the inclusion of a melanoma diagnosis.

D.66. Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	441
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated
Substantive Change:	**Updated denominator exceptions:** Added Procedure-Related BP's not taken during an outpatient visit. Examples of Procedure-related BP Locations: Same Day Surgery, Ambulatory Service Center, G.I. Lab, Dialysis, Infusion Center, Chemotherapy.
Steward:	Wisconsin Collaborative for Healthcare Quality (WCHQ)
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We are proposing and agree with the WCHQ Measurement Advisory Committee that procedure-related blood pressures should be excluded from this measure. We agree with the inclusion of the denominator exception as procedure-related blood pressures can be artificially elevated. This change also aligns with other blood pressure related measure exclusions.

D.67. Appropriate Workup Prior to Endometrial Ablation

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	448
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of women, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results documented before undergoing an endometrial ablation.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation. **Updated denominator:** Replace the word "women" with "patients". **Updated numerator:** Replace the word "women" with "patients".
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to update the measure description to read "percentage of patients" in order to be gender inclusive. This change will also be reflected throughout the measure for consistency.

D.68. Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy

Category	Description
NQF # / eCQM NQF #:	1858
Quality #:	450
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab.
Substantive Change:	**Updated denominator definition:** Use the 2018 ASCO/CAP guideline definitions to determine HER2 status- HER2 Positive: • If result is IHC 3+ based on circumferential membrane staining that is complete, intense and in >10% of the invasive tumor cells • If result is ISH positive based on: • Single-probe average HER2 copy number ≥= 6. 0 signals/cell • Dual-probe HER2/CEP17 ratio ≥= 2. 0 with an average HER2 copy number ≥= 4. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number = 6. 0 signals/cell HER2 Equivocal: • If result is IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within > 10% of the invasive tumor cells • If result is ISH equivocal based on: • Single-probe ISH average HER2 copy number ≥= 4. 0 and < 6. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number ≥= 4. 0 and < 6. 0 signals/cell HER2 Negative: • If result is IHC 1+ based on incomplete membrane staining that is faint/barely perceptible and within > 10% of the invasive tumor cells • If result is IHC 0 based on no staining observed or membrane staining that is incomplete and is faint/barely perceptible and ≤= 10% of the invasive tumor cells • ISH negative based on: • Single-probe average HER2 copy number < 4. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number < 4. 0 signals/cell HER2 Indeterminate: Report HER2 test result as indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal. Conditions may include: • Inadequate specimen handling • Artifacts (crush or edge artifacts) that make interpretation difficult • Analytic testing failure.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to update the denominator definition so that it aligns with the 2018 ASCO/CAP guidelines.

D.69. Average Change in Back Pain Following Lumbar Discectomy / Laminotomy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had a lumbar discectomy /laminotomy procedure.
Substantive Change:	**The measure title is revised from Average Change in Back Pain Following Lumbar Discectomy / Laminotomy to read:** Back Pain After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. Removed diagnosis of disc herniation. **Updated denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op pain assessment is greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being back pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at 3 months postoperatively (6 to 20 weeks). **Updated definitions:** Added: (1) Back Pain Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure who rates their back pain as less than or equal to 3.0. (2) Back Pain Target #2 - A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9943 is submitted. • VAS Pain Scale is not administered postoperatively at three months (6 to 20 weeks) • Back pain is measured using a different patient reported tool or via telephone screening • Postoperative VAS Pain Scale is administered less than six weeks or more than 20 weeks (3 month window) • Postoperative VAS value is greater than 3.0 and no valid preoperative to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward chose the targets based on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.70. Average Change in Back Pain Following Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had a lumbar fusion procedure.
Substantive Change:	**The measure title is revised from Average Change in Back Pain Following Lumbar Fusion to read:** Back Pain After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being back pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at one year postoperatively (9 to 15 months). **Updated definitions:** Added: (1) Back Pain Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their back pain as less than or equal to 3.0. (2) Back Pain Target #2 – A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note;** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9946 is submitted. • VAS Pain Scale is not administered postoperatively at one year (9 to 15 months) • Back pain is measured using a different patient reported tool or via telephone screening • Postop VAS Pain Scale is administered less than nine months or more than 15 months (1 year window) • Postoperative VAS value is greater than 3.0 and no valid preop to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward base the target on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is ≤2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.71. Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.
Substantive Change:	**The measure title is revised from Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy to read:** Leg Pain After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added the following discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. Removed diagnosis of disc herniation. **Updated denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being leg pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at 3 months postoperatively (6 to 20 weeks). **Updated definitions:** Added: (1) Leg Pain Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure who rates their leg pain as less than or equal to 3.0. (2) Leg Pain Target #2 - A patient who does not meet Leg Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9949 is submitted. • VAS Pain Scale is not administered postoperatively at three months (6 to 20 weeks) • Leg pain is measured using a different patient reported tool or via telephone screening • Postoperative VAS Pain Scale is administered less than six weeks or more than 20 weeks (3 month window) • Postoperative VAS value is greater than 3.0 and no valid preop to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0.We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.72. Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	462
CMS eCQM ID:	CMS645v3
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**The measure description is revised to read:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure description to align with the removal of the custom HCPCS, J code J1950, which previously denoted the practitioner's intent of androgen deprivation therapy (ADT) for a period of 12 months or greater. The intent of the measure remains intact, but no longer requires the HCPCS to identify the intended patient population.

D.73. Average Change in Functional Status Following Lumbar Fusion Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients 18 years of age and older who had a lumbar fusion procedure.
Substantive Change:	**The measure title is revised from Average Change in Functional Status Following Lumbar Fusion Surgery to read:** Functional Status After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 22, need a pre and post-op assessment to hit the change target of 30 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being functional status is less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI) at one year postoperatively (9 to 15 months). **Added numerator definition:** Functional Status Target #1 - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status as less than or equal to 22. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the change is greater than or equal to 30 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative tool be administered to the patient to increase the chance that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1043 is submitted. • ODI is not administered postoperatively at one year (9 to 15 months) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 9 months or greater than 15 months (1 year window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure change • Preoperative ODI (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure.) NQF endorsement removed until the measure can be evaluated with the new analytics.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target on a study Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registry-based study. vanHooff, ML et al Spine J. 2016 Oct;16 (10):1221-1230. Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op ODI to determine an equivalent ODI threshold. ODI score less than or equal to 22 indicates the achievement of an acceptable symptom state and can be used as a criterion for treatment success. [AUC]: 0.89 [sensitivity: 78.3%, specificity: 82.1%] for 1 year follow-up]. The OR benchmark of change (30) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 22. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.74. Average Change in Functional Status Following Total Knee Replacement Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	470
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oxford Knee Score (OKS) for patients age 18 and older who had a primary total knee replacement
Substantive Change:	**The measure title is revised to read:** Functional Status After Primary Total Knee Replacement. **The measure description is revised:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need a post-op OKS assessment. The measure will now be target-based with performance met being functional status is greater than or equal to 37 on the Oxford Knee Score (OKS) at one year postoperatively (9 to 15 months). Patients who are missing an assessment will be considered numerator non-compliant. **Added numerator definition:** OKS Target - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status score as greater than or equal to 37. **Updated numerator note:** The following situations are those in which the numerator targets cannot be reached and Performance Not Met (M1046) is submitted: • Oxford Knee Score (OKS) is not administered postoperatively at one year (9 to 15 Months) • Functional status is measured using a different patient-reported functional status tool or Oxford Knee Score (OKS) version • Postoperative Oxford Knee Score (OKS) is administered less than 9 Months or greater than 15 Months • Postoperative Oxford Knee Score (OKS) score is less than 37 NQF endorsement removed until the measure can be evaluated with the new analytics.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed that this measure assessment will be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward derived the target from a study "Patient acceptable symptom states after total hip or knee replacement at mid-term follow-up" [Kuerentjes JC, Van Tol FR Bone Joint Res 2014; 3:7–13]. Receiver operating characteristic (ROC) curves identified a PASS threshold of 42 for the OHS after THR and 37 for the OKS after TKR. THR patients with an OHS greater than or equal to 42 and TKR patients with an OKS greater than or equal to 37 had a higher NRS for satisfaction and a greater likelihood of being willing to undergo surgery again. The Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op OKS to determine an equivalent OKS threshold. OKS score greater than or equal to 37 indicates the achievement of an acceptable symptom state and correlates with a higher numeric rating scale for satisfaction [ROC curves PASS threshold of 37 with sensitivity of 76.3% and specificity of 76.5%]. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.75. Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients age 18 and older who had lumbar discectomy/laminotomy procedure
Substantive Change:	**The measure title is revised from Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery to read:** Functional Status After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added the following discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. **Update denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. Removed diagnosis of disc herniation. **Updated numerator:** For numerator compliance patients need either a post-op functional assessment (to meet the target portion) or if post-op greater than 22, need a pre and post-op assessment to hit the change target of 30 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being functional status is less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI) at 3 months postoperatively (6 to 20 weeks). **Added numerator definition:** Functional Status Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure rates their functional status as less than or equal to 22. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 30 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1049 is submitted. • ODI is not administered postoperatively at three months (6 to 20 weeks) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 6 weeks or greater than 20 weeks (3 month window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure change Preoperative ODI (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward derived the target from a study Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registry-based study. vanHooff, ML et al Spine J. 2016 Oct;16(10):1221-1230. Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op ODI to determine an equivalent ODI threshold. ODI score less than or equal to 22 indicates the achievement of an acceptable symptom state and can be used as a criterion for treatment success. [AUC]: 0.89 [sensitivity: 78.3%, specificity: 82.1%] for 1 year follow-up]. The OR benchmark of change (30) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 22. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.76. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	472
CMS eCQM ID:	CMS249v2
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.

Category	Description
Substantive Change:	**Updated guidance:** There are two ways that a patient can be excluded from the measure: 1. The patient has a specific number of "combination" risk factors (the number of risk factors varies by age). 2. The patient has one or more of the "independent" risk factors, including a 10-year probability of major osteoporotic fracture of 8.4 percent or higher as determined by the FRAX. Denominator exclusions statement: Exclude patients with a combination of risk factors (as determined by age) or one of the independent risk factors Ages: 50-54 (>=4 combination risk factors) or 1 independent risk factor Ages: 55-59 (>=3 combination risk factors) or 1 independent risk factor Ages: 60-64 (>=2 combination risk factors) or 1 independent risk factor COMBINATION RISK FACTORS [The following risk factors are all combination risk factors; they are grouped by when they occur in relation to the measurement period]: The following risk factors may occur any time in the patient's history but must be active during the measurement period: White (race) BMI <= 20 kg/m2 (must be the first BMI of the measurement period) Smoker (current during the measurement period) Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) The following risk factor may occur any time in the patient's history and must not start during the measurement period: Osteopenia The following risk factors may occur at any time in the patient's history or during the measurement period: Rheumatoid arthritis Hyperthyroidism Malabsorption Syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption Chronic liver disease Chronic malnutrition The following risk factors may occur any time in the patient's history and do not need to be active at the start of the measurement period: Documentation of history of hip fracture in parent Osteoporotic fracture Glucocorticoids (>= 5 mg/per day) [cumulative medication duration >= 90 days] INDEPENDENT RISK FACTORS (The following risk factors are all independent risk factors; they are grouped by when they occur in relation to the measurement period): The following risk factors may occur at any time in the patient's history and must not start during the measurement period: Osteoporosis The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period: Gastric bypass FRAX[R] ten-year probability of all major osteoporosis related fracture >= 8.4 percent Aromatase inhibitors The following risk factors may occur at any time in the patient's history or during the measurement period: Type I Diabetes End stage renal disease Osteogenesis imperfecta Ankylosing spondylitis Psoriatic arthritis Ehlers-Danlos syndrome Cushing's syndrome Hyperparathyroidism Marfan syndrome Lupus **Updated denominator exclusions:** Changed FRAX[R] ten-year probability of all major osteoporosis related fracture result from 9.3% to 8.4%.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process

Category	Description
Rationale:	We are proposing that the denominator exclusion for the Fracture Risk Assessment Tool FRAX® ten-year probability of all major osteoporosis related fracture result be changed from 9.3% to 8.4% to align with the US Preventive Services Task Force (USPSTF) recommendations. We agree with this change as it keeps the measure in alignment with the current clinical guidelines. The guidance is being updated for better alignment with the measure and to align with the updated denominator exclusion.

D.77. Average Change in Leg Pain Following Lumbar Fusion Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to one year postoperative) in leg pain for patients 18 years of age or older who had a lumbar fusion procedure
Substantive Change:	**The measure title is revised from Average Change in Leg Pain Following Lumbar Fusion Surgery to read:** Leg Pain After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance Patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at one year postoperatively (9 to 15 months).
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target score on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of improvement (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.78. HIV Screening

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	475
CMS eCQM ID:	CMS349v2
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 15-65 years of age who have been tested for HIV within that age range.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV. **The numerator is revised to read:** Patients with documentation of an HIV test performed on or after their 15th birthday and before their 66th birthday.
Steward:	Centers for Disease Control and Prevention
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure description to better align the measure specification. We agree with this update as it clarifies the intent of the measure. We propose that the numerator be revised to add clarity and to align the wording with logic used. Neither the intent of the measure nor the numerator action will be changed.

TABLE Group DD: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years

NOTE: Electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table DD as follows: NQF # / eCQM NQF #.

DD.1. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / ECQM NQF #:	0028 / 0028e
Quality #:	226
CMS eCQM ID:	CMS138v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Substantive Change:	**Updated numerator guidance: for the 2019 performance period: For the CMS Web Interface Measure Specification collection type:** Removed "and the cessation intervention must occur during or after the most recent tobacco user status is documented" language from the guidance.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the numerator guidance in the CMS Web Interface Measure Specifications collection type for the 2019 performance period to remove the guidance given regarding the timing of the tobacco cessation intervention as this does not align with the intent of the measure. The refinements are in alignment with the clinical guidelines and will decrease burden for eligible clinicians performing tobacco screening and tobacco cessation intervention. The timing refinement proposed will maintain the balance of clinical guideline and measure alignment and support our effort to reduce burden for measure submission. Additionally, this timing refinement allows the clinician to create personalized, patient-centered care while still maintaining the clinical integrity of the measure and clinical guidelines. To the extent this proposed change constitutes a change in methodology after the start of the 2019 MIPS performance period, we believe that consistent with section 1871(E)(1)(A)(ii) of the Social Security Act, it would be contrary to the public interest not to modify the measure because the current guidance is inconsistent with the intent of the CMS Web Interface version of this measure and unduly burdensome for clinicians. The proposal is to update the CMS Web Interface Measure Specifications collection type numerator guidance previously stated in the current posted 2019 measure specification for PREV-10 (NQF 0028): Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, available at https://qpp.cms.gov/about/resource-library, in response to extensive stakeholder feedback regarding the timeframe during which the tobacco cessation intervention must occur. Specifically, stakeholders expressed concern that this additional language would not be comparable to the historic benchmark as it changed how the quality action of tobacco cessation intervention was abstracted in terms of numerator compliance. Additionally, stakeholders voiced concern regarding how this change would fit into the current clinical workflow as patients are asked about tobacco use on most if not all encounters, but clinicians do not feel it is necessary to provide tobacco cessation intervention at all encounters especially if it was already completed earlier in the year. Based on this feedback and our review, we have determined that the previously stated guidance is inconsistent with the intent of the CMS Web Interface Measure Specifications collection type version of this measure and unduly burdensome for clinicians. In response to our determination and stakeholder feedback, we are proposing to update the CMS Web Interface Measure Specifications collection type numerator guidance to clarify that screening for tobacco use and tobacco cessation intervention do not have to occur on the same encounter, but must occur during the 24-month look-back period. We agree this proposal will maintain clinical intent, provide clarity, reduce clinician burden, and allow for personalized care.

Appendix 2: Improvement Activities

NOTE: In this proposed rule, for the CY 2020 performance period and future years, we are proposing to: (1) add two new improvement activities; (2) modify seven existing improvement activities; and (3) remove 15 improvement activities from the Inventory. These are discussed in greater detail below.

Table A: Proposed New Improvement Activities for the MIPS CY 2020 Performance Period and Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_BE_XX**
Proposed Subcategory:	Beneficiary Engagement
Proposed Activity Title:	Drug Cost Transparency
Proposed Activity Description:	To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s).[1])
Proposed Weighting:	High
Rationale:	The costs of prescription drugs is a driving cost of overall health care spending in the United States and of out-of-pocket health care expenses for patients. As we consider broader efforts to increase transparency for patients, payers, provider organizations, and clinicians, as well as begin to drive down drug prices, this activity serves as a mechanism for drug price transparency at the clinician-patient level and may protect patients from unforeseen costs. By discussing drug pricing with patients, clinicians may better prescribe medications patients can afford, which could have the effect of increasing patient medication compliance and adherence. Thus, we believe this proposed activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, per the improvement activity definition which has been codified at § 414.1305. This activity is weighted as high due to difficulties clinicians may have in identifying drug costs and out-of-pocket costs of drugs for individual patients as costs and reimbursement amounts vary by drug and payer, as well as challenges with identifying the appropriateness of patient assistance programs.[2 3] As stated previously, we have given certain improvement activities high-weighting due to the intensity of the activity (81 FR 77194). To summarize, we believe that an activity that requires significant investment of time and resources should be high-weighted.
Proposed Activity ID:	**IA_CC_XX**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes.
Proposed Activity	To receive credit for this improvement activity, a MIPS eligible clinician must attest

Description:	that they reported MACRA patient relationship codes (PRC) using the applicable HCPCS modifiers on 50 percent or more of their Medicare claims for a minimum of a continuous 90-day period within the performance period. Reporting the PRC modifiers enables the identification of a clinician's relationship with, and responsibility for, a patient at the time of furnishing an item or service. See the CY 2018 PFS final rule (82 FR 53232 through 53234) for more details on these codes.
Proposed Weighting:	High
Rationale:	The patient relationship categories and codes define and distinguish the relationship and responsibilities of a clinician with a patient at the point of furnishing an item or service. These codes provide insight into clinician interactions with patients and identify the clinician's relationship to and responsibility for the patient at the time of furnishing an item or service. These codes were developed, as required under section 1848(r)(3) of the Act, to facilitate the attribution of patients and episodes to one or more clinicians. Beginning in 2018, clinicians started voluntarily reporting the patient relationship codes using the applicable HCPCS modifiers (82 FR 53232 through 53234). To properly report the code modifiers, clinicians must add one of the modifiers to each claim line. We propose that, for the CY 2020 performance period and beyond, clinicians who choose to report the modifiers on 50 percent or more of their Medicare claims for a minimum of a continuous 90-day period within the performance period would earn one (1) high-weighted improvement activity. We believe reporting these modifiers would provide the minimum sample of data necessary to access the modifiers' ability to capture the clinician's relationship with the patient and whether the clinician is appropriately reporting the modifiers. This improvement activity is weighted as high due to the intensity of the activity. We believe reporting the modifiers to each claim line for 50 percent or more of Medicare claims continuously for 90 days requires significant investment of time and resources and should be weighted high. For the initial and current period of voluntary reporting the PRC modifiers, where clinicians gain familiarity, data collected will be used to provide aggregate feedback on the performance of clinicians in using the codes within different clinical scenarios and specialties. Data collected from this activity will be used to test the reliability and validity of the modifiers in measuring the clinician's relationship to and responsibility for the Medicare patient before we consider whether to propose in future rulemaking to require the reporting of the PRC modifiers on claims. In the event that we do decide to require such reporting, we would likely propose to remove this improvement activity from MIPS.

1/ See the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses, Final Rule, 84 FR 23832, 23883 (May 23, 2019).

2/Allan GM, Lexchin J, Wiebe N. *Physician awareness of drug cost: a systematic review*. PLoS Med. 2007 Sep;4(9):e283. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/17896856

3/ Arora V, Moriates C, Shah N. *The challenge of understanding health care costs and charges*. AMA Journal of Ethics. 2015;17(11): 1046. doi: 10.1001/journalofethics.2015.17.11.stas1-1511.

TABLE B: Proposed Changes to Previously Adopted Improvement Activities for the MIPS CY 2020 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_28**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Completion of an Accredited Safety or Quality Improvement Program
Current Activity Description:	Completion of an accredited performance improvement continuing medical education program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information.
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain)" as an example of an accredited continuing medical education (CME) program that could meet this improvement activity. Due to the importance of safe prescribing to prevent opioid misuse and opioid use disorder, CME programs related to opioid analgesic REMS may be especially useful to MIPS eligible clinicians in their attempts to prevent opioid misuse among their patients and combat the opioid epidemic.
Proposed Revised Activity Description:	Completion of an accredited performance improvement continuing medical education (CME) program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information. An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain).
Current Improvement Activity	
Current Activity ID:	**IA_PM_2**
Current Subcategory:	Population Management
Current Activity Title:	Anticoagulant Management Improvements
Current Activity Description:	Individual MIPS eligible clinicians and groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, their ambulatory care patients receiving warfarin are being managed by one or more of the following improvement activities: • Patients are being managed by an anticoagulant management service, that involves

	systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up; and patient communication of results and dosing decisions; and/or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Current Weighting:	High
Proposed Change and Rationale:	Addition of "anti-coagulation medications (oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors)"; and "Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program)." This language was consolidated from IA_PM_1, proposed for removal in Table C. We believe IA_PM_1 is duplicative in content to, but less robust than IA_PM_2, with overall fewer examples of actions that can be undertaken to satisfy the intent of the improvement activity. However, IA_PM_1 contained more detail about the type of anti-coagulation medication that could be prescribed to satisfy this activity and an additional example of an action that can be undertaken to satisfy the intent of IA_PM_2, participation in systematic anticoagulation program; so these elements of IA_PM_IA were added to IA_PM_2. Removal of ", for 60 percent of practice patients in the transition year … in Quality Payment Program Year 2 and future years". These time references to transition year and Quality Payment Program Year 2 are now irrelevant because they are in the past. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposal to remove IA_PM_1 as discussed in Table C.
Proposed Revised Activity Description:	Individual MIPS eligible clinicians and groups who prescribe anti-coagulation medications (including, but not limited to oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors) must attest that for 75 percent of their ambulatory care patients receiving these medications are being managed with support from one or more of the following improvement activities: • Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program); • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM)

	program.
Current Improvement Activity	
Current Activity ID:	**IA_EPA_4**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Additional improvements in access as a result of QIN/QIO TA
Current Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services (for example, investment of on-site diabetes educator).
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "or improve care coordination". We are proposing to consolidate this language from activity IA_CC_3, which is being proposed for removal in Table C. IA_CC_3 is duplicative to IA_EPA_4 in content related to Quality Innovation Network-Quality Improvement Organization technical assistance, but referred to improving care coordination. We believe the Quality Innovation Network-Quality Improvement Organization technical assistance can support both access to services and care coordination[1] and, furthermore, that care coordination and access to services are inherently related and can logically be combined into one improvement activity. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposal to remove IA_CC_3 as discussed in Table C.
Proposed Revised Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_19**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Current Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following such as: • Multi-Source Feedback; • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data.
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program". This language was added to consolidate it from IA_PSPA_14 proposed for removal in Table B. We believe IA_PSPA_14 is duplicative in content, but less robust than IA_PSPA_19 related to adopting a model for quality improvement. However, IA_PSPA_14 contains a unique relevant example that we wish to preserve under IA_PSPA_19. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposal to remove IA_PSPA_14 as discussed in Table C.
Proposed Revised Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following, such as: • Participation in multisource feedback; [2] • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties;

	• Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence;[3] • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.[4]
Current Improvement Activity	
Current Activity ID:	**IA_BE_7**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Activity Description:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing the addition of activity description language from four other improvement activities related to participation in QCDR; IA_BE_11. Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan; IA_BE_2 Use of QCDR to support clinical decision making; IA_BE_9 Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement; and IA_BE_10 Participation in a QCDR, that promotes implementation of patient self-action plans. The activity description will include the current (IA_BE_7) activity description with the addition of "Participation in a Qualified Clinical Data Registry and"…, including: • "The use of processes and tools that engage patients for adherence to treatment plans" (from IA_BE_11); • "Activities that promote implementation of shared clinical decision making capabilities" (from IA_BE_2); • "Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" (from IA_BE_9); • "Activities that promote implementation of patient self-action plans" (from IA_BE_10). This language was added to consolidate activity description language from improvement activities being proposed for removal in Table C (IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10). The activities we propose to remove are duplicative to IA_BE_7. We are also proposing to remove the language "use of…tools" to better capture the content of the consolidated improvement activity regarding promoting patient engagement more broadly. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposals to remove IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10 as discussed in Table C.
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR), that promotes patient engagement, including: • Use of processes and tools that engage patients for adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision making capabilities; or • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Current Improvement Activity	

Current Activity ID:	**IA_PSPA_7**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Current Activity Description:	Use of QCDR data, for ongoing practice assessment and improvements in patient safety.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing the addition of activity description language from four other improvement activities related to participation in QCDR; IA_CC_6 Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination; IA_AHE_4 Leveraging a QCDR for use of standard questionnaires; IA_AHE_2 Leveraging a QCDR to standardize processes for screening; and IA_PM_10 Use of QCDR data for quality improvement such as comparative analysis reports across patient populations. The activity description will include the current (IA_PSPA_7) activity description with the addition of "Participation in a Qualified Clinical Data Registry and"… including: • "Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups)" (from IA_CC_6); • "Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment)" (from IA_AHE_4); • "Use of standardized processes for screening for social determinants of health such as food security, employment and housing" from (from IA_AHE_2); • "Use of supporting QCDR modules that can be incorporated into the certified EHR technology" (This language adapted from IA_AHE_2 and updated to replace "tools" with "QCDR modules" to add additional specificity to the action that can be taken in the QCDR to promote ongoing practice assessment and patient safety.); or • "Use of QCDR data for quality improvement (such as) comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes" (from IA_PM_10). This language was added to consolidate improvement activity description language from activities (IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10) proposed for removal in Table C. The activities we propose to remove are duplicative to IA_PSPA_7. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposals to remove IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10 as discussed in Table C.
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire[5], MD Anderson Symptom Inventory[6], and/or SF-12/VR-12 functional health status assessment[7]; • Use of standardized processes for screening for social determinants of health such as food security, employment, and housing; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement such as comparative analysis across

	specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_10**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Completion of Collaborative Care Management Training Program
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI), available to the public, in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing to remove reference of the CMS Transforming Clinical Practice Initiative (TCPI) in the activity description. This initiative is ending on September 28, 2019,[9] and therefore, will no longer be applicable to this improvement activity description after said date. The example training program referenced, the APA Collaborative Care Model, continues to be available to the public. The revised activity description only proposes to remove reference to TCPI.
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available to the public[8], in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.

1/ Quality Improvement Organizations. About QIN-QIO. Available at https://qioprogram.org/about/why-cms-has-qios.

2/ Multisource feedback (MSF), or 360-degree employee evaluation, is a questionnaire-based assessment method in which rates are evaluated by peers, patients, and coworkers on key performance behaviors. More information available at https://www.ncbi.nlm.nih.gov/pubmed/12739254.

3/ Bridges to Excellence program. More information available at http://www.bridgestoexcellence.org/.

4/ American Board of Medical Specialties Portfolio Program. More information available at https://mocportfolioprogram.org/about-us/.

5/ The Seattle Angina Questionnaire is a self-assessed health-related quality of life instrument for coronary artery disease. See: Spertus JA et al. *Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease.* J Am Coll Cardiol. 1995 Feb;25(2):333-41. Available at https://www.ncbi.nlm.nih.gov/pubmed/7829785.

6/ The MD Anderson Symptom Inventory (MDASI) is a multi-symptom patient-reported outcome (PRO) measure for clinical and research use. Available at https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/md-anderson-symptom-inventory.html.

7/ The Optum SF Health Surveys are patient-reported outcome (PRO) surveys across eight health domains. Available at https://www.optum.com/solutions/life-sciences/answer-research/patient-insights/sf-health-surveys.html?s=PPC&pstc=optum:ppc:LS_4.1_2018:g:ls:Frm:18wd1fk01rr23&ppcid=sf12&adid=323753202402&adgroupid=52618954298&campaignid=1036340767&o=optum:ppc:LS_4.1_2018:frm:ls:Frm:18wd1fk01rr23&gclid=Cj0KCQjwg73kBRDVARIsAF-kEH_sDfonepf7U7tsZzzLcHc15b_DxREHpFu0kNGwu2ANu-33WiGoSBIaAgIdEALw_wcB.

8/ The American Psychiatric Association (APA) Collaborative Care Model has been shown to be an effective and efficient model in delivering integrated care. More information on this model and the training program is available at https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/learn.

9/ Transforming Clinical Practice Initiative. Available at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

TABLE C: Improvement Activities Proposed for Removal for the MIPS CY 2020 MIPS Performance Period and Future Years

In this rule, we are proposing to remove 14 previously finalized improvement activities from the MIPS Program for the MIPS CY 2020 performance period and future years. These improvement activities are discussed in detail below. Improvement activity proposed removal factors are discussed in section III.K.3.c.(3) of this proposed rule.

Current Improvement Activity	
Current Activity ID:	**IA_PM_1**
Current Subcategory:	Population Management
Current Activity Title:	Participation in Systematic Anticoagulation Program
Current Activity Description:	Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program) for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, who receive anti-coagulation medications (warfarin or other coagulation cascade inhibitors).
Current Weighting:	High
Removal Rationale:	We are proposing to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PM_2. We are proposing to consolidate the unique language from IA_PM_1 into IA_PM_2 per the proposed change in Table B. The proposed revised IA_PM_2 adds additional detail from IA_PM_1. We note that this proposed removal is made in conjunction with our proposal to change IA_PM_2 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_CC_3**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of additional activity as a result of TA for improving care coordination
Current Activity Description:	Implementation of at least one additional recommended activity from the Quality Innovation Network-Quality Improvement Organization after technical assistance has been provided related to improving care coordination.
Current Weighting:	Medium
Removal Rationale:	We are proposing to remove IA_CC_3 under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_EPA_4. We are proposing to consolidate the unique language from IA_CC_3 into IA_EPA_4 per the proposed change in Table B. The proposed modified language to IA_EPA_4 adds the outcome of "improve care coordination" from the proposed removed activity to make IA_EPA_4 more robust. We note that this proposed removal is made in conjunction with our proposal to change IA_EPA_4 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_14**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in Quality Improvement Initiatives
Current Activity Description:	Participation in other quality improvement programs such as Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Current Weighting:	Medium

Removal Rationale:	We are proposing to remove this IA_PSPA_14 under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of the activities included in IA_PSPA_19. We are proposing to consolidate the unique language in IA_PSPA_14 with IA_PSPA_19 per the proposed change in Table B. The proposed modified language to IA_PSPA_19 adds the examples "Bridges to Excellence" and "American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program" as additional actions that an eligible clinician or group can take to participate in a quality improvement program. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_19 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_5**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Annual Registration in the Prescription Drug Monitoring Program
Current Activity Description:	Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must participate for a minimum of 6 months.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar in content but less robust than the currently adopted IA_PSPA_6. IA_PSPA_6 requires consultation of and specific thresholds of use for a prescription drug monitoring program instead of simply registering in a prescription drug monitoring program as described in IA_PSPA_5. Because of this, we believe IA_PSPA_6 already captures the essence of IA_PSPA_5 and would directly fall into that improvement activity. We note that this proposed removal is made in conjunction with our proposal to adopt removal factors in section III.K.3c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of this referenced proposal.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_24**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Initiate CDC Training on Antibiotic Stewardship
Current Activity Description:	Completion of greater than 50 percent of the modules of the Centers for Disease Control and Prevention antibiotic stewardship course. Note: This activity may be selected once every 4 years, to avoid duplicative information given that some of the modules may change on a year by year basis, but over 4 years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is less robust than IA_PSPA_23. IA_PSPA_23 requires completion of all modules of a Centers for Disease Control and Prevention antibiotic stewardship course, instead of 50 percent of modules of a Centers for Disease Control and Prevention antibiotic stewardship course. Because of this, we believe IA_PSPA_23 already captures the essence of IA_PSPA_24 and would directly fall into that improvement activity. We note that this proposed removal is made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of this referenced proposal.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_3**
Current Subcategory:	Behavioral and Mental Health

Current Activity Title:	Unhealthy alcohol use
Current Activity Description:	Unhealthy alcohol use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including screening and brief counseling (refer to NQF #2152) for patients with co-occurring conditions of behavioral or mental health conditions.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to the currently adopted IA_BMH_9. We believe IA_BMH_9 is more robust because it requires a threshold of patients for which this unhealthy alcohol use screening must be completed, whereas IA_BMH_3 simply requires engagement, screening and counseling without such a threshold. Because of this, we believe IA_BMH_9 already captures the essence of IA_BMH_3 and would directly fall into that improvement activity. We note that this proposed removal is made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of this referenced proposal.
Current Improvement Activity	
Current Activity ID:	**IA_BE_11**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan
Current Activity Description:	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposing changes to IA_BE_7 that add "…the use of processes and tools that engage patients for adherence to treatment plan" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the proposed changes to IA_BE_7 would capture the essence of IA_BE_11. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_BE_2**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of QCDR to support clinical decision making
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposing changes to IA_BE_7 that add "activities that promote implementation of shared clinical decision making capabilities" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the proposed changes to IA_BE_7 would capture the essence of IA_BE_2. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_BE_9**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of QCDR patient experience data to inform and advance improvements in

	beneficiary
Current Activity Description:	Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposing changes to IA_BE_7 that add "use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the proposed changes to IA_BE_7 would capture the essence of IA_BE_9. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_BE_10**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes implementation of patient self-action plans.
Current Activity Description:	Participation in a QCDR, that promotes implementation of patient self-action plans.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposing changes to IA_BE_7 to add "[activities that] promote implementation of patient self-action plans" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the proposed changes to IA_BE_7 would capture the essence of IA_BE_10. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_CC_6**
Current Subcategory:	Care Coordination
Current Activity Title:	Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination
Current Activity Description:	Participation in a Qualified Clinical Data Registry, demonstrating performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we are proposing changes to IA_PSPA_7 to add "performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups);" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the proposed changes to IA_PSPA_7 would capture the essence of IA_CC_6. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_4**

Current Subcategory:	Achieving Health Equity
Current Activity Title:	Leveraging a QCDR for use of standard questionnaires
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities for use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment).
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we are proposing changes to IA_PSPA_7 to add "use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment);" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the proposed changes to IA_PSPA_7 would capture the essence of IA_AHE_4. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_2**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Leveraging a QCDR to standardize processes for screening
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology is also suggested.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we are proposing changes to IA_PSPA_7 to add "use of standardized processes for screening for social determinants of health such as food security, employment and housing…use of supporting tools that can be incorporated into the certified EHR technology" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the proposed changes to IA_PSPA_7 would capture the essence of IA_AHE_2. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_PM_10**
Current Subcategory:	Population Management
Current Activity Title:	Use of QCDR data for quality improvement such as comparative analysis reports across patient populations
Current Activity Description:	Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (for example, comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we are proposing changes

	to IA_PSPA_7 to add "use of QCDR data for quality improvement such as comparative analysis reports across patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the proposed changes to IA_PSPA_7 would capture the essence of IA_PM_10. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_CC_4**
Current Subcategory:	Care Coordination
Current Activity Title:	TCPI Participation
Current Activity Description:	Participation in CMS Transforming Clinical Practice Initiative
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 7, improvement activity is obsolete. The Transforming Clinical Practice Initiative is ending on September 28, 2019[1] and therefore, clinicians will no longer be able to attest to this improvement activity after that date. We note that this proposed removal is made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of this proposal.

1/ Transforming Clinical Practice Initiative. Available at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

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Part III

Department of Homeland Security

8 CFR Parts 103, 212, 213, et al.
Inadmissibility on Public Charge Grounds; Final Rule

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 103, 212, 213, 214, 245 and 248

[CIS No. 2637–19; DHS Docket No. USCIS–2010–0012]

RIN 1615–AA22

Inadmissibility on Public Charge Grounds

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Final rule.

SUMMARY: This final rule amends DHS regulations by prescribing how DHS will determine whether an alien applying for admission or adjustment of status is inadmissible to the United States under section 212(a)(4) of the Immigration and Nationality Act (INA or the Act), because he or she is likely at any time to become a public charge. The final rule includes definitions of certain terms critical to the public charge determination, such as ''public charge'' and ''public benefit,'' which are not defined in the statute, and explains the factors DHS will consider in the totality of the circumstances when making a public charge inadmissibility determination. The final rule also addresses USCIS' authority to issue public charge bonds under section 213 of the Act in the context of applications for adjustment of status. Finally, this rule includes a requirement that aliens seeking an extension of stay or change of status demonstrate that they have not, since obtaining the nonimmigrant status they seek to extend or change, received public benefits over the designated threshold, as defined in this rule.

This rule does not create any penalty or disincentive for past, current, or future receipt of public benefits by U.S. citizens or aliens whom Congress has exempted from the public charge ground of inadmissibility. This rule does not apply to U.S. citizens, even if the U.S. citizen is related to an alien subject to the public charge ground of inadmissibility. The rule also does not apply to aliens whom Congress exempted from the public charge ground of inadmissibility (such as asylees, refugees, or other vulnerable populations listed as exempt in this final rule). Nor does this rule apply to aliens for whom DHS has statutory discretion to waive this ground of inadmissibility, if DHS has exercised such discretion.

In addition, this includes special provisions for how DHS will consider the receipt of public benefits, as defined in this rule, by certain members of the U.S. Armed Forces and their families; certain international adoptees; and receipt of Medicaid in certain contexts, especially by aliens under the age of 21, pregnant women (and women for up to 60 days after giving birth), and for certain services funded by Medicaid under the Individuals with Disabilities Education Act (IDEA) or in a school setting. Aliens who might qualify for these exemptions should study the rule carefully to understand how the exemptions work.

This final rule also clarifies that DHS will only consider public benefits received directly by the alien for the alien's own benefit, or where the alien is a listed beneficiary of the public benefit. DHS will not consider public benefits received on behalf of another. DHS also will not attribute receipt of a public benefit by one or more members of the alien's household to the alien unless the alien is also a listed beneficiary of the public benefit.

This final rule supersedes the 1999 Interim Field Guidance on Deportability and Inadmissibility on Public Charge Grounds.

DATES: This final rule is effective at 12:00 a.m. Eastern Time on October 15, 2019. DHS will apply this rule only to applications and petitions postmarked (or, if applicable, submitted electronically) on or after the effective date. Applications and petitions already pending with USCIS on the effective date of the rule (*i.e.,* were postmarked before the effective date of the rule and were accepted by USCIS) will not be subject to the rule.

FOR FURTHER INFORMATION CONTACT: Mark Phillips, Residence and Naturalization Division Chief, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts NW, Washington, DC 20529–2140; telephone 202–272–8377.

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Table of Abbreviations

AAO—Administrative Appeals Office
ACA—Affordable Care Act
ACTC—Additional Child Tax Credit
AFM—Adjudicator's Field Manual
ASEC—Annual Social and Economic Supplement of the Current Population Survey
BIA—Board of Immigration Appeals
BLS—U.S. Bureau of Labor Statistics
CDC—Centers for Disease Control and Prevention
CBP—U.S. Customs and Border Protection

CFR—Code of Federal Regulations
CHIP—Children's Health Insurance Program
CNMI—Commonwealth of the Northern Mariana Islands
DACA—Deferred Action for Childhood Arrivals
DD Act—The Developmental Disabilities Assistance and Bill of Rights Act of 2000
DHS—U.S. Department of Homeland Security
DOJ—U.S. Department of Justice
DOS—U.S. Department of State
EITC—Earned Income Tax Credit
E.O.—Executive Order
EOIR—Executive Office for Immigration Review
FAM—Foreign Affairs Manual FCRA—Fair Credit Reporting Act
FPG—Federal Poverty Guidelines
FPL—Federal Poverty Level
Form DS–2054—Medical Examination for Immigrant or Refugee Applicant
Form I–129—Petition for a Nonimmigrant Worker
Form I–129CW—Petition for a CNMI-Only Nonimmigrant Transitional Worker
Form I–130—Petition for Alien Relative
Form I–140—Immigrant Petition for Alien Workers
Form I–290B—Notice of Appeal or Motion
Form I–356—Request for Cancellation of Public Charge Bond
Form I–407—Record of Abandonment of Lawful Permanent Resident Status
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Form I–539—Application to Extend/Change Nonimmigrant Status
Form I–539A—Supplemental Information for Application to Extend/Change Nonimmigrant Status
Form I–600—Petition to Classify Orphan as an Immediate Relative
Form I–601—Application for Waiver of Grounds of Inadmissibility
Form I–693—Report of Medical Examination and Vaccination Record Form
I–800—Petition to Classify Convention Adoptee as an Immediate Relative
Form I–864—Affidavit of Support Under Section 213A of the INA
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Form I–864W—Request for Exemption for Intending Immigrant's Affidavit of Support
Form I–912—Request for Fee Waiver
Form I–94—Arrival/Departure Record
Form I–944—Declaration of Self-Sufficiency
Form I–945—Public Charge Bond
Form N–600—Application for Certificate of Citizenship
Form N–600K—Application for Citizenship and Issuance of Certificate Under Section 322
GA—General Assistance
GAO—U.S. Government Accountability Office
HHS—U.S. Department of Health and Human Services
HOPWA—Housing Opportunities for Persons with AIDS
HCV—Housing Choice Voucher
ICE—U.S. Immigration and Customs Enforcement
IEFA—Immigration Examinations Fee Account
IIRIRA—Illegal Immigration Reform and Immigrant Responsibility Act of 1996
INA—Immigration and Nationality Act
INS—Immigration and Naturalization Service
IRCA—Immigration Reform and Control Act of 1986
IRS—Internal Revenue Service
LIHEAP—Low Income Home Energy Assistance Program
LIS—Medicare Part D Low Income Subsidy
LPR—Lawful Permanent Resident
NEPA—National Environmental Policy Act of 1969
NHE—National Health Expenditure
NOID—Notice of Intent to Deny
NPRM—Notice of Proposed Rulemaking
PRA—Paperwork Reduction Act
PTC—Premium Tax Credit
PRWORA—Personal Responsibility and Work Opportunity Reconciliation Act of 1996
RFE—Request for Evidence
RFRA—Religious Freedom Restoration Act
SAVE—Systematic Alien Verification for Entitlements Secretary—Secretary of Homeland Security
SIPP—Survey of Income and Program Participation
SNAP—Supplemental Nutrition Assistance Program
SORN—System of Records Notice
SSA—Social Security Administration
SSI—Supplemental Security Income
TANF—Temporary Assistance for Needy Families
TPS—Temporary Protected Status
USDA—U.S. Department of Agriculture
U.S.C.—United States Code
USCIS—U.S. Citizenship and Immigration Services
VAWA—Violence Against Women Act
VAWA 2013—Violence Against Women Reauthorization Act of 2013
WAP—Weatherization Assistance Program
WIC—Special Supplemental Nutrition Program for Women, Infants, and Children

I. Executive Summary

A. Purpose of the Regulatory Action

This rule changes how the Department of Homeland Security (DHS) interprets and implements the public charge ground of inadmissibility.[1] The Immigration and Nationality Act (INA or the Act) renders inadmissible and therefore (1) ineligible for a visa, (2) ineligible for admission and (3) ineligible for adjustment of status, any alien [2] who, in the opinion of the DHS (or the Departments of State (DOS) or Justice (DOJ), as applicable),[3] is likely at any time to become a public charge.[4] The statute does not define the term ''public charge,'' but in a related statute, Congress has articulated a national policy that (1) ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations,'' and (2) ''the availability of public benefits not constitute an incentive for immigration to the United States.'' [5] In addition, the public charge statute provides that in making the inadmissibility determination, administering agencies must ''at a minimum consider the alien's age; health; family status; assets, resources, and financial status; and education and skills.'' [6] The agencies may also consider any affidavit of support under section 213A of the Act, 8 U.S.C. 1183a, *i.e.,* Form I–864, Affidavit of Support Under Section 213A of the INA, submitted on the alien's behalf.[7]

Since 1999, the prevailing approach to public charge inadmissibility has been dictated primarily by the May 26, 1999, *Field Guidance on Deportability and Inadmissibility on Public Charge Grounds* (1999 Interim Field Guidance), issued by the former Immigration and Naturalization Service (INS).[8] Under

[1] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[2] Congress has by statute exempted certain categories of aliens, such as asylees and refugees, from the public charge ground of inadmissibility. *See, e.g.,* INA sections 207(c)(3) and 209(c), 8 U.S.C. 1157(c)(3), 1159(c). A full list of exemptions is included in this rule.

[3] Three different agencies are responsible for applying the public charge ground of inadmissibility, each in a different context or contexts. DHS primarily applies the public charge ground of inadmissibility at ports of entry and when adjudicating certain applications for adjustment of status. This rule amends the standards applicable to those contexts, and also sets forth evidentiary requirements applicable to the adjustment of status context.

DOS Consular officers are responsible for applying the public charge ground of inadmissibility as part of the visa application process and for determining whether a visa applicant is ineligible for a visa on public charge grounds. This rule does not directly revise DOS standards or processes. DHS is working with DOS to ensure that the Foreign Affairs Manual appropriately reflects the standards in this rule.

DOJ is responsible for applying the public charge ground of inadmissibility in immigration court, where DHS may bring and prosecute the charge against certain inadmissible aliens. Immigration judges adjudicate matters in removal proceedings, and the Board of Immigration Appeals and in some cases the Attorney General adjudicate appeals arising from such proceedings. This rule does not directly revise DOJ standards or processes. DHS understands that the DOJ plans to conduct rulemaking to ensure that the standards applied in immigration court are consistent with the standards in this rule.

[4] *See* INA section 212(a)(4)(A), 8 U.S.C. 1182(a)(4)(A).

[5] *See* 8 U.S.C. 1601(2).

[6] *See* INA section 212(a)(4)(B)(i), 8 U.S.C. 1182(a)(4)(B)(i).

[7] *See* INA section 212(a)(4)(B)(ii), 8 U.S.C. 1182(a)(4)(B)(ii).

[8] *See* Field Guidance on Deportability and Inadmissibility on Public Charge Grounds, 64 FR 28689 (May 26, 1999). Due to a printing error, the **Federal Register** version of the field guidance

that approach, ''public charge'' has been interpreted to mean a person who is ''primarily dependent on the Government for subsistence, as demonstrated by either the receipt of public cash assistance for income maintenance or institutionalization for long-term care at Government expense.'' [9] As a consequence, an alien's reliance on or receipt of non-cash benefits such as the Supplemental Nutrition Assistance Program (SNAP), or food stamps; Medicaid; and housing vouchers and other housing subsidies are not currently considered by DHS in determining whether an alien is deemed likely at any time to become a public charge.

DHS is revising its interpretation of ''public charge'' to incorporate consideration of such benefits, and to better ensure that aliens subject to the public charge inadmissibility ground are self-sufficient, *i.e.,* do not depend on public resources to meet their needs, but rather rely on their own capabilities, as well as the resources of family members, sponsors, and private organizations.[10] This rule redefines the term ''public charge'' to mean an alien who receives one or more designated public benefits for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months). This rule defines the term ''public benefit'' to include cash benefits for income maintenance, SNAP, most forms of Medicaid, Section 8 Housing Assistance under the Housing Choice Voucher (HCV) Program, Section 8 Project-Based Rental Assistance, and certain other forms of subsidized housing. DHS has tailored the rule to limit its effects in certain ways, such as for active duty military members and their families, and children in certain contexts.

This rule also explains how DHS will interpret the minimum statutory factors for determining whether ''in the opinion of'' [11] the officer, the alien is likely at any time to become a public charge. Specifically, the rule contains a list of negative and positive factors that DHS will consider as part of this determination, and directs officers to consider these factors in the totality of the alien's circumstances. For instance, with respect to the statutory factor for the alien's age, DHS would generally consider it to be a negative factor if the alien is younger than 18 or older than 61, and a positive factor if the alien is between the ages of 18 and 61. These positive or negative factors operate as guidelines to help the officer determine whether the alien is likely at any time to become a public charge, *i.e.,* is more likely than not at any time in the future to receive one or more designated public benefits for more than 12 months in the aggregate within any 36-month period. The rule also contains lists of heavily weighted negative factors and heavily weighted positive factors. For example, the rule includes a heavily weighted negative factor for an alien who is not a full-time student and is authorized to work, but is unable to demonstrate current employment, recent employment history, or a reasonable prospect of future employment. DHS believes that these circumstances should be accorded heavy negative weight in a public charge inadmissibility determination because, as discussed in the preamble to the NPRM and in the preamble to this final rule, the presence of these circumstances suggests a greater likelihood that the alien will become a public charge than other negative factors suggest. The presence of a single positive or negative factor, or heavily weighted negative or positive factor, will never, on its own, create a presumption that an applicant is inadmissible as likely to become a public charge or determine the outcome of the public charge inadmissibility determination. Rather, a public charge inadmissibility determination must be based on the totality of the circumstances presented in an applicant's case.

With respect to applications for adjustment of status in particular, this rule also provides a more comprehensive evidentiary framework under which U.S. Citizenship and Immigration Services (USCIS) will consider public charge inadmissibility. Under this rule, applicants for adjustment of status who are subject to the public charge ground of inadmissibility must file a Declaration of Self-Sufficiency (Form I–944) with their Application to Register Permanent Residence or Adjust Status (Form I–485) to demonstrate they are not likely to become a public charge. The Form I–944 only applies to adjustment applicants and not applicants for admission at a port of entry.

In addition, applicants required to submit Form I–864, Affidavit of Support Under Section 213A of the INA, in accordance with section 212(a)(4)(C) or (D), must generally submit Form I–944 with the Form I–485. Failure to submit each form, where required, may result in a rejection or a denial of the Form I–485 without a prior issuance of a Request for Evidence or Notice of Intent to Deny.[12]

This rule also revises DHS regulations governing the discretion of the Secretary of Homeland Security (Secretary) to accept a public charge bond under section 213 of the Act, 8 U.S.C. 1183, for those seeking adjustment of status. Additionally, this rule contains additional provisions that will render certain nonimmigrants ineligible for extension of stay or change of status if she or he received one or more public benefits for more than 12 months in the aggregate within any 36-month period since obtaining the status he or she wishes to extend or change.

Finally, DHS notes that the INA also contains a separate public charge ground of deportability.[13] This rule does not interpret or change DHS's implementation of the public charge ground of deportability.

B. Legal Authority

DHS's authority for making public charge inadmissibility determinations and related decisions is found in several statutory provisions. Section 102 of the Homeland Security Act of 2002,[14] 6 U.S.C. 112, and section 103 of the Act, 8 U.S.C. 1103, charge the Secretary with the administration and enforcement of the immigration and naturalization laws of the United States. In addition to establishing the Secretary's general authority for the administration and enforcement of immigration laws, section 103 of the Act, 8 U.S.C. 1103, enumerates various related authorities, including the Secretary's authority to establish regulations and prescribe such forms of bond as are necessary for carrying out such authority. Section 212 of the Act, 8 U.S.C. 1182, establishes classes of aliens that are ineligible for visas, admission, or adjustment of status; paragraph (a)(4) of that section establishes the public charge ground of inadmissibility, including the minimum factors the Secretary must consider in making a determination that an alien is likely to become a public charge. Section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), also establishes the enforceable affidavit of support requirement, as applicable, to certain family-based and employment-based

appears to be dated ''March 26, 1999'' even though the guidance was actually signed May 20, 1999, became effective May 21, 1999 and was published in the **Federal Register** on May 26, 1999.

[9] *See* Field Guidance on Deportability and Inadmissibility on Public Charge Grounds, 64 FR 28689, 28692 (May 26, 1999).

[10] *See* 8 U.S.C. 1601(1), (2)(A).

[11] *See* INA section 212(a)(4)(A), 8 U.S.C. 1182(a)(4)(A).

[12] *See* 8 CFR 103.2(a)(7), (b)(8)(ii).

[13] *See* INA section 237(a)(5), 8 U.S.C. 1227(a)(5).

[14] Public Law 107–296, 116 Stat. 2135, 2142–44 (Nov. 25, 2002).

immigrants, and exempts certain aliens from both the public charge ground of inadmissibility and the affidavit of support requirement. Section 213 of the Act, 8 U.S.C. 1183, provides the Secretary with discretion to admit into the United States an alien who is determined to be inadmissible as a public charge under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), but is otherwise admissible, upon the giving of a proper and suitable bond. That section authorizes the Secretary to establish the amount and conditions of such bond. Section 213A of the Act, 8 U.S.C. 1183a, sets out requirements for the sponsor's affidavit of support, including reimbursement of government expenses where the sponsored alien received means-tested public benefits. Section 214 of the Act, 8 U.S.C. 1184, addresses requirements for the admission of nonimmigrants, including authorizing the Secretary to prescribe the conditions of such admission through regulations and when necessary, establish a bond to ensure that those admitted as nonimmigrants or who change their nonimmigrant status under section 248 of the Act, 8 U.S.C. 1258, depart if they violate their nonimmigrant status or after such status expires. Section 245 of the Act, 8 U.S.C. 1255, generally establishes eligibility criteria for adjustment of status to lawful permanent residence. Section 248 of the Act, 8 U.S.C. 1258, authorizes the Secretary to prescribe conditions under which an alien may change his or her status from one nonimmigrant classification to another. The Secretary promulgates the changes in this rule under all of these authorities.

C. Summary of the Proposed Rule

On October 10, 2018, DHS published a Notice of Proposed Rulemaking (NPRM) entitled Inadmissibility on Public Charge Grounds.[15] The NPRM identified the groups of individuals generally subject to, or exempt from, the public charge inadmissibility ground. Further, DHS proposed definitions for the terms ''public charge,'' ''likely at any time to become a public charge,'' ''public benefit,'' and ''alien's household.''

As part of the definition of public benefit, DHS proposed to designate an exhaustive list of public benefits that would be considered for purposes of a public charge inadmissibility determination, as well as for purposes of extension of stay and change of nonimmigrant status applications. DHS recognized that the universe of public benefits is quite large, and that some benefits are more commonly used, at greater taxpayer expense, than others. In seeking to provide clear notice of the effects of the rule, and to limit certain indirect costs that may be associated with the rule, DHS elected to limit the number and types of non-cash public benefits that it would designate. DHS therefore proposed to designate just a few means-tested non-cash benefits related to food and nutrition, housing, and healthcare, which bear directly on the recipient's self-sufficiency and together account for significant federal expenditures on low-income individuals. DHS's proposed list of public benefits included cash benefits for income maintenance, institutionalization for long-term care at government expense, SNAP, most forms of Medicaid, Premium and Cost Sharing Subsidies for Medicare Part D (Medicare Part D LIS), Section 8 Housing Assistance under the HCV Program, Section 8 Project-Based Rental Assistance, and certain other forms of subsidized housing. DHS also sought comment on the potential inclusion of other public benefits programs. As noted below, this final rule designates each of the above-referenced public benefits, except for institutionalization for long-term care at government expense and Medicare Part D LIS. DHS is not designating any additional programs.

DHS proposed to limit its consideration of an alien's receipt of these designated public benefits in two main ways, each of which DHS incorporated into the definition of public benefit. First, DHS proposed to establish ''thresholds'' for the amount or duration of public benefits that the alien must receive, before DHS will consider the alien to have received a public benefit. In other words, DHS proposed that it would not consider an alien's receipt of a given public benefit at all, unless the alien received the benefit in an amount, or for a duration, that met an applicable threshold. Specifically, DHS proposed the following thresholds:

- For public benefits that are ''monetizable'' (such as cash benefits, SNAP, and housing vouchers and rental assistance), DHS proposed a threshold of 15 percent of the Federal Poverty Guidelines (FPG) for a household of one within a period of 12 consecutive months.
- For public benefits that cannot be monetized (such as Medicaid, Medicare Part D LIS, subsidized housing, and institutionalization for long-term care at government expense), DHS proposed a threshold of receipt during more than 12 months in the aggregate within a 36-month period.
- DHS also proposed a threshold to address circumstances where an alien receives a combination of monetizable benefits equal to or below the 15 percent threshold, together with one or more benefits that cannot be monetized. In such cases, DHS proposed that the threshold for duration of receipt of the non-monetizable benefits would be more than 9 months in the aggregate within a 36-month period.

DHS expressly sought comment on these proposed thresholds, including whether DHS should consider an alien's receipt of benefits below any given threshold, as part of DHS's totality of the circumstances determination. As noted below, this final rule adopts a single threshold for all designated public benefits (including those that were considered ''monetizable'' under the proposed rule): More than 12 months in the aggregate within a 36-month period. And this final rule authorizes officers to consider receipt of benefits below that threshold, to the extent relevant in the totality of the circumstances.

Second, DHS proposed to tailor its rule to limit its effects in certain ways, for a range of reasons. For instance, DHS proposed to not consider the receipt of public benefits by certain aliens who, at the time of receipt, filing, or adjudication, are enlisted in the U.S. Armed Forces, serving in active duty or in the Ready Reserve, or if received by such an individual's spouse or children. DHS also proposed to not consider emergency Medicaid or Medicaid received for services provided under the Individuals with Disabilities Education Act (IDEA), and to not consider any school-based benefits provided to individuals who are at or below the maximum eligible age for secondary education, as determined under State law. Lastly, DHS proposed to exempt from consideration Medicaid benefits received by children of U.S. citizens whose lawful admission for permanent residence and subsequent residence in the custody of U.S. citizen parents will result automatically in the child's acquisition of citizenship, or upon finalization of adoption in the United States by the U.S. citizen parents (or upon meeting eligibility criteria) or children entering the United States for the prime purpose of attending a citizenship interview under the Child Citizenship Act of 2000.[16] As noted below, this final rule revises these

[15] Inadmissibility on Public Charge Grounds, 83 FR 51114 (proposed Oct. 10, 2018).

[16] *See* Public Law 106–395, 114 Stat. 1631, 1631–33 (Oct. 30, 2000) (codified at INA 320(a)–(b), 8 U.S.C. 1431(a)–(b)).

provisions in certain ways, and also includes an additional provision exempting Medicaid receipt by aliens under the age of 21 and pregnant women (including women for 60 days after the last day of pregnancy).

In addition to proposing new definitions, DHS proposed a regulatory framework for analyzing the aforementioned statutory factors that must be considered for purposes of the public charge inadmissibility determination. DHS also proposed to amend its existing regulations addressing public charge bonds. In addition, DHS proposed to require applicants seeking an extension of stay or change of nonimmigrant status to demonstrate that they have not received and are not currently receiving, nor are they likely to receive public benefits, as defined in the regulation, for the duration of their stay. Again, as noted below, this final rule revises these provisions in certain ways.

DHS received 266,077 comments on the proposed rule, the vast majority of which opposed the rule. The preamble to this final rule includes summaries of the significant issues raised by the comments, and includes responsive explanations, and policy changes.

D. Summary of Changes in the Final Rule

Following careful consideration of public comments received and relevant data provided by stakeholders, DHS has made several changes to the regulatory text proposed in the NPRM.[17] As discussed in detail elsewhere in this preamble, the changes in this final rule include the following:

1. Definitions

• *Definitions of ''Public Charge'' and ''Public Benefit.''* DHS has revised the definition of ''public charge'' and ''public benefit'' to clarify the threshold of public benefit receipt that renders an alien a public charge. As noted above, the proposed rule defined a public charge as an alien who receives one or more public benefits as defined in the proposed rule. The proposed rule incorporated the threshold concept into the definition of public benefit, and proposed different thresholds for ''monetizable'' and ''non-monetizable'' benefits. Following receipt of public comments regarding a variety of issues, including the complexity of the proposed standard for monetizing certain public benefits, DHS has revised the definitions for public charge and public benefits, and will now evaluate all benefits with a single duration-based standard (*i.e.,* the proposed standard for non-monetizable benefits). DHS has also incorporated the single duration standard into the definition of ''public charge,'' rather than the definition of ''public benefit.'' Consequently, under this simplified duration standard, a public charge is an alien who receives one or more public benefit for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two public benefits in one month counts as two months).

• *Consideration of Receipt of Public Benefits below the Threshold, in the Totality of the Circumstances.* Under the proposed rule, DHS would not have considered the receipt of benefits below the applicable threshold in the totality of the circumstances. As a consequence, USCIS would have been unable to consider an alien's past receipt of public benefits below the threshold *at all,* even if such receipt was indicative, to some degree, of the alien's likelihood of becoming a public charge at any time in the future. Under this final rule, adjudicators will consider and give appropriate weight to past receipt of public benefits below the single durational threshold described above in the totality of the circumstances.[18]

• *Receipt of Public Benefits.* DHS has added a definition of ''receipt'' of public benefits, consistent with the explanation in the proposed rule preamble. The new definition clarifies that an application or certification for benefits does not constitute receipt, although it may serve as evidence of the alien's likelihood of receiving public benefits in the future. It also clarifies that when an alien receives, applies for, or obtains a certification for public benefits solely on behalf of another person, DHS does not consider the alien to have received the benefit.

• *Likely at Any Time to Become a Public Charge.* DHS has amended the definition of ''likely at any time to become a public charge'' to clarify that an alien is likely at any time to become a public charge if the alien is more likely than not at any time in the future to become a public charge, as determined based on the totality of the alien's circumstances.

• *Primary Caregiver.* DHS has included a new definition of ''primary caregiver'' to account for a new consideration in the totality of the circumstances for aliens who may not be currently employed or have employment history but are nonetheless contributing to their households by caring for others. DHS defines primary caregiver as an alien who is 18 years of age or older and has significant responsibility for actively caring for and managing the well-being of a child or an elderly, ill, or disabled person in the alien's household.

2. Public Benefits

• *Medicaid Received by Aliens Under Age 21 and Pregnant Women.* Following receipt of public comments addressing the nature of the Medicaid benefit for children and pregnant women. DHS has revised provisions under which DHS would have considered an alien's receipt of Medicaid, regardless of the alien's age. For purposes of this final rule, DHS has excluded consideration of the receipt of Medicaid by aliens under the age of 21 and pregnant women during pregnancy and during the 60-day period after pregnancy.

• *Medicare Part D Low-Income Subsidy.* The NPRM's definition for public benefit included Medicare Part D LIS. Following receipt of public comment regarding the nature of the Medicare Part D LIS, which is part of an overall benefit scheme that contains extensive work requirements, DHS has decided to exclude an alien's receipt of such subsidies from the public benefit definition for purposes of the public charge inadmissibility determination.

• *Benefits Received by Military Servicemembers and their Spouses and Children.* The NPRM's definition for public benefit excluded the consideration of public benefits received by an alien who at the time of receipt of the public benefit, filing, or adjudication, is enlisted in the U.S. Armed Forces, serving in the active duty or in the Ready Reserve component of the U.S. Armed Forces, or is the spouse or child of such servicemember. The NPRM did not make clear what immigration benefit types this provision applies to. DHS has revised the public benefit definition to clarify that this provision applies with respect to applications for admission, adjustment of status, and extension of stay or change of status.

• *Benefits Received while in a Status that is Exempt from the Public Charge Ground of Inadmissibility.* DHS has revised the public benefit definition to clarify that DHS will not consider any public benefits received by an alien during periods in which the alien was present in the United States in a classification that is exempt from the public charge ground of inadmissibility or for which the alien received a waiver

[17] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114 (proposed Oct. 10, 2018).

[18] As stated in the Benefits Received Before Effective Date and Previously Excluded Benefits section of this rule, DHS will not apply this rule to benefits received before the effective date of the rule, except for those benefits that would have been considered under the 1999 Interim Field Guidance.

of the public charge inadmissibility ground.

• *Public Benefits Received by Children Eligible for Acquisition of Citizenship.* DHS has revised the proposed definition of public benefit that excluded from consideration Medicaid received by children of U.S. citizens whose lawful admission for permanent residence and subsequent residence in the legal and physical custody of their U.S. citizen parent will result automatically in the child's acquisition of citizenship, or whose lawful admission for permanent residence will result automatically in the child's acquisition of citizenship upon finalization of adoption in the United States by the U.S. citizen parent(s) or, upon meeting other eligibility criteria as required.[19] DHS has changed this provision to clarify that public benefits, as defined in the rule, do not include any public benefits that were or will be received by such children.

• *Benefits Provided for Institutionalization.* The NPRM's definition of public benefit included benefits for long-term institutionalization at government expense. Following receipt of public comment regarding specific benefits considered to provide for institutionalization, DHS has removed the reference to long-term institutionalization within the definition of public benefit, as the long-term institutionalization benefits that DHS has in the past considered, and intends to consider under this rule, are already part of the public benefit definition, *i.e.,* Temporary Assistance for Needy Families (TANF), Supplemental Security Income (SSI), and Medicaid.

3. Applicability to Nonimmigrants

• *''Likely to Receive'' Public Benefits and ''Currently Receiving'' Public Benefits Condition.* Following receipt of public comments addressing the public benefit condition for nonimmigrants seeking extension of stay or change of status, DHS has revised this provision. Under the proposal, DHS would have considered whether such an alien has received, is currently receiving, or is likely to receive public benefits in excess of the designated thresholds since obtaining the nonimmigrant status the alien seeks to attend or from which the alien seeks to change. DHS has modified the provision by removing the future-looking requirement. DHS will only consider whether the alien has received designated benefits for more than 12 months in the aggregate within a 36-month period since obtaining the nonimmigrant status they wish to extend or change, up until the time of adjudication of the extension of stay or change of status request.

• *Victim of Severe Form of Trafficking in Persons (T) Nonimmigrants Exemption.* DHS has revised several regulatory provisions relating to individuals who have a pending application setting forth a prima facie case for eligibility for T nonimmigrant status, or who are present in the United States in valid T nonimmigrant status. In the proposed rule, DHS provided that T nonimmigrants applying for adjustment of status were subject to the public charge inadmissibility ground and could request a waiver of inadmissibility. DHS has modified the provisions with respect to T nonimmigrants to accurately reflect changes codified by Congress in the Violence Against Women Reauthorization Act of 2013 (VAWA 2013).[20] DHS has revised the public charge inadmissibility exemption provision proposed in the NPRM and created new provisions to align these regulations with the changes to the law made by VAWA 2013. T nonimmigrants applying for adjustment of status will no longer need to submit a waiver of inadmissibility for public charge purposes.

• *Victims of Criminal Activity (U) Nonimmigrants Exemption.* DHS has revised the regulatory provisions relating to the exemption from public charge inadmissibility for individuals who have a pending application for U nonimmigrant status, or who are granted U nonimmigrant status, to align these regulations with the changes to the law made by VAWA 2013. In the proposed rule, U nonimmigrant petitioners or those granted U nonimmigrant status were exempted from the public charge inadmissibility ground for purposes of U nonimmigrant status or for purposes of adjustment of status under section 245(m) of the Act, 8 U.S.C. 1255(m). DHS has clarified that, in general, U visa petitioners and those granted U nonimmigrant status are exempt from a public charge inadmissibility determination in any future immigration benefit request that requires a finding of admissibility, not only adjustment of status under section 245(m) of the Act, 8 U.S.C. 1255(m).

• *VAWA 2013 Public Charge Exemptions and the Affidavit of Support Requirement for Certain Employment-Based Petitions.* DHS has revised several regulatory provisions relating to T nonimmigrants, U nonimmigrants, VAWA self-petitioners, and qualified aliens as described in 8 U.S.C. 1641(c). The proposed rule was silent on the applicability of section 212(a)(4)(D) of the INA, 8 U.S.C. 1182(a)(4)(D), which requires an affidavit of support as described in section 213A of the INA, 8 U.S.C. 1183a, for certain employment-based immigrant petitions. DHS has modified the exemption provisions at 8 CFR 212.23(a) with respect to T nonimmigrants, U nonimmigrants, VAWA self-petitions, and certain qualified aliens to accurately reflect changes codified by Congress in VAWA 2013.[21] An alien who falls under one of the VAWA 2013 exemptions from public charge inadmissibility would not need to demonstrate that he or she is not likely at any time to become a public charge, but would need to submit a sufficient affidavit of support described in 213A of the INA, 8 U.S.C. 1183a, if adjusting under an employed-based category that requires one by statute.

4. Totality of the Circumstances Determination

• *The Alien is a Primary Caregiver for Household Member as a Consideration in the Education and Skills Factor:* DHS has added a provision that would take into consideration whether an alien is a primary caregiver of another in the alien's household, for example a child or elderly relative. This factor is intended to take into consideration difficult-to-monetize contributions by aliens who may lack current employment or an employment history due to their full time, unpaid care of household members.

• *Heavily Weighted Negative Factor for Receipt of Public Benefits above the Threshold.* Under the proposed rule, in conducting the public charge inadmissibility determination, there were two separate heavily weighted factors related to the receipt of public benefits: (1) The alien is currently receiving or is currently certified or approved to receive one or more public benefits and (2) an alien has received one or more public benefits above the applicable threshold within the 36-months immediately preceding the alien's application for a visa, admission or adjustment of status. DHS has consolidated these factors within one

[19] *See* Child Citizenship Act of 2000, Public Law 106–395, 114 Stat. 1631, 1631–33 (Oct. 30, 2000) (codified at section 320(a)–(b) of the Act, 8 U.S.C. 1431(a)–(b)), in accordance with 8 CFR part 320.

[20] *See* Public Law 113–4, 127 Stat. 54 (Mar. 7, 2013).

[21] *See* Public Law 113–4, 127 Stat. 54 (Mar. 7, 2013).

heavily weighted negative factor. The factor will apply in cases where the alien has received or has been certified or approved to receive one or more public benefits for more than 12 months within any 36-month period, beginning no earlier than 36 months prior to the alien's application for admission or adjustment of status.

• *Heavily Weighted Positive Factor for Private Health Insurance.* In this final rule DHS added a new heavily weighted positive factor for when the alien has private health insurance appropriate for the expected period of admission, and for which the alien does not receive subsidies in the form of premium tax credits (including advance premium tax credits) under the ACA. This heavily weighted positive factor is in addition to the positive factor that would apply in circumstances where an alien has sufficient household assets and resources (including health insurance not considered to be a public benefit under 8 CFR 212.22(b)) to cover reasonably foreseeable medical costs, including costs related to a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide care for himself or herself, to attend school, or to work.

• *Evidence of the Alien's Health.* In response to concerns regarding the qualifications of USCIS adjudicators to evaluate the alien's health, DHS has revised the rule to clarify that, if the alien is required to undergo an immigration medical examination from a civil surgeon or panel physician, DHS will generally defer to the immigration medical examination report when assessing whether the alien is more likely than not at any time in the future to become a public charge on account of a diagnosed medical condition unless there is evidence that the report is incomplete. DHS, however, continues to permit the use of other documentation regarding the alien's medical conditions, as proposed in the NPRM, to assess whether the alien's health makes the alien more likely than not to become a public charge at any time in the future.

• *Household Assets.* DHS has revised the rule to clarify that DHS considers an alien's ownership of significant assets similar to the standards in the affidavit of support regulations under 8 CFR 213a.2(c)(2)(iii)(B).

• *Household Income and Servicemembers of the Armed Forces.* DHS has revised the rule to clarify that if the applicant is on active duty, other than training, in the Armed Forces of the United States, the applicant's gross household income may be 100 percent of the most recent FPG for the alien's household size, and not 125 percent of the FPG for the alien's household size, as proposed in the NPRM, in order to serve as a positive factor in the public charge inadmissibility determination.

• *Household Income and Public Benefits.* DHS has revised the rule to clarify that the applicant's gross household income does not include any household income from public benefits, as defined in this rule.

• *Household Income from Illegal Activities.* DHS has revised the rule to clarify that household income from illegal activity or sources will not be considered as part of the income, assets, or resources factor in the public charge inadmissibility determination. DHS has also consolidated the consideration of income from sources other than household members into a single provision.

• *Household Income and Evidentiary Considerations.* DHS amended the rule to clarify that when assessing the alien's annual gross household income, DHS considers the most recent federal tax-year transcripts from the United States Internal Revenue Service (IRS) for each household member whose income will be considered. Additionally, DHS also clarified that if the most recent tax-year transcripts from the IRS are unavailable, DHS will consider other credible and probative evidence of the household member's income, including an explanation why the evidence is not available.

• *Fee Waivers and Categories Excluded from Public Charge.* DHS has revised the rule to state that a fee waiver request or receipt would not be considered for purposes of determining public charge inadmissibility if the fee waiver was applied for, or granted, as part of an application for which a public charge inadmissibility determination was not required.

• *Public Benefit Disenrollment and Eligibility.* DHS has clarified in the rule how USCIS will consider past public benefits receipt, in the totality of the circumstances. USCIS will consider whether an alien has disenrolled or requested to be disenrolled from the public benefit(s). USCIS will also consider, as part of the totality of the circumstances, any evidence that the alien submits from a Federal, State, local, or tribal agency administering a public benefit, that the alien has specifically identified as showing that the alien does not qualify or would not qualify for such public benefit by virtue of, for instance, the alien's annual gross household income or prospective immigration status, or length of stay. While an alien's prospective ineligibility for a given benefit would not be outcome-determinative, USCIS will consider the information in the totality of the circumstances.

• *Education and Skills.* To clarify additional types of documentation that establish a steady employment history, DHS has revised the evidentiary considerations for the education and skills factor, to require that applicants submit, with their adjustment of status applications, federal tax return transcripts for the previous three years or, if such transcripts are unavailable, other credible and probative evidence, including an explanation of the unavailability of such transcripts.

5. Public Charge Bond for Adjustment of Status Applicants

• *Breach of Bonds and Threshold of Public Benefit Receipt.* In the NPRM, DHS proposed that a public charge bond is considered breached if the bonded alien had used public benefits in the amount or for the duration established as the threshold in the proposed public benefits definition. In this final rule, DHS has modified the threshold to a single duration-based threshold and has moved that threshold from the proposed public benefits definition into the public charge definition. To ensure that the bond breach conditions remain the same in this final rule, DHS has revised the rule, and incorporated the single duration threshold ''for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months)'' in the bond breach determination.

• *Substitution.* DHS has revised proposed 8 CFR 213.1 to indicate that DHS will only offer public charge bonds of unlimited duration. Correspondingly, DHS has removed text that references bonds of limited durations or provisions that addressed the substitution of a bond of limited duration. DHS has retained, however, the general bond substitution provision.

• *Cancellation on the basis of Permanent Departure from the United States.* DHS has clarified that an alien is only considered to have voluntarily lost lawful permanent resident status for the purposes of bond cancellation based on a permanent departure when the alien has submitted a record of abandonment of lawful permanent resident status on the form prescribed by DHS and in accordance with the form's instructions, while the alien is outside of the United States.

• *Discretionary Cancellation.* DHS has added language to this final rule to clarify that DHS retains discretion to cancel a public charge bond,

notwithstanding an absence of a written request from the obligor or alien, if DHS determines that an alien otherwise meets the applicable eligibility requirements.

• *Bond Amount.* In response to public comment, DHS has revised proposed 8 CFR 213.1 to reduce the minimum amount in which a public charge bond may be offered to $8,100, annually adjusted for inflation based on the Consumer Price Index for All Urban Consumers (CPI–U), and rounded up to the nearest dollar.

• *Bond Breach and Public Benefits Received while in a Status that is Exempt from the Public Charge Ground of Inadmissibility.* DHS has revised this rule to clarify that DHS will not consider, as part of a public charge bond breach determination, any public benefits received by an alien during periods for which the alien received a waiver of the public charge inadmissibility ground. In the NPRM, DHS had already proposed that public benefits received while in a public charge exempt status following the initial grant of status as a lawful permanent resident, and any public benefits received after the alien obtained U.S. citizenship, would not be counted towards the bond breach determination. These exemptions remain unchanged in this final rule.

6. Other Changes

• *Prospective Application of the Rule.* DHS clarified in 8 CFR 212.20, 214.1, and 248.1 that this final rule applies prospectively to applications and petitions postmarked (or, if applicable, submitted electronically) on or after the effective date. (DHS retained and further refined provisions addressing how it will consider receipt of public benefits before the effective date of this rule.)

• *Technical Changes.* DHS has also made miscellaneous technical edits to reduce redundancy and improve readability and clarity.

• *Changes to Form I–539A.* DHS has made non-substantive changes to Supplemental Information for Application to Extend/Change Nonimmigrant Status (Form I–539A), which collects biographical information about derivative beneficiaries named on an applicant's Application to Extend/Change Nonimmigrant Status (Form I–539). Form I–539A was published as a new form on March 8, 2019, to replace Supplement A of Form I–539. In light of the creation of Form I–539A, DHS has moved the information collection regarding public benefits received by the derivative beneficiaries from Form I–539 to Form I–539A. Each derivative beneficiary of a Form I–539 will need to complete a separate Form I–539A, and provide information regarding the derivative beneficiary's applications for, or receipt of, public benefits, except where the nonimmigrant classification that the derivative beneficiary seeks to extend, or to which the alien seeks to change, is exempted from the public charge ground of inadmissibility.

E. Summary of Costs and Benefits

This rule will impose new costs on the population applying to adjust status using Form I–485 that are subject to the public charge ground of inadmissibility. DHS will now require any adjustment applicants subject to the public charge ground of inadmissibility and who are applying for adjustment of status on or after the effective date of this final rule to submit a Form I–944 with their Form I–485 to demonstrate they are not likely to become a public charge. Failure to submit the form, where required, may result in a rejection or a denial of the Form I–485 without a prior issuance of a Request for Evidence or Notice of Intent to Deny.[22] Additionally, the associated time burden estimate for completing Form I–485 will increase.

The rule will also impose additional costs for those seeking extension of stay or change of status by filing a Petition for a Nonimmigrant Worker (Form I–129); Petition for a CNMI-Only Nonimmigrant Transitional Worker (Form I–129CW); or Form I–539 and Form I–539A, as applicable. The associated time burden estimate for completing these forms will increase because these applicants will be required to demonstrate that they have not received, since obtaining the nonimmigrant status that they seek to extend or from which they seek to change, and through the adjudication, public benefits as described in final 8 CFR 212.21(b) for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months). Moreover, the rule will impose new costs associated with the new public charge bond process, including new costs for completing and filing a Public Charge Bond (Form I–945), and Request for Cancellation of Public Charge Bond (Form I–356).

DHS estimates that the additional total cost of the rule will be approximately $35,202,698 annually. This cost includes the population applying to adjust status who are also required to file Form I–944, the opportunity costs of time associated with such filings, as well the increased time burden estimates for completing Forms I–485, I–129, I–129CW, and I–539, and for requesting or cancelling a public charge bond using Form I–945 and Form I–356, respectively.

Over the first 10 years of implementation, DHS estimates the total quantified new direct costs of the final rule will be about $352,026,980 (undiscounted). In addition, DHS estimates that the 10-year discounted total direct costs of this final rule will be about $300,286,154 at a 3 percent discount rate and about $247,249,020 at a 7 percent discount rate.

Simultaneously, DHS is eliminating the use and consideration of the Request for Exemption for Intending Immigrant's Affidavit of Support (Form I–864W), currently applicable to certain classes of aliens. In lieu of Form I–864W, the alien will indicate eligibility for the exemption of the affidavit of support requirement on Form I–485.

The final rule will also potentially impose new costs on obligors (individuals or companies) if an alien has been determined to be likely at any time in the future to become a public charge and will be permitted to submit a public charge bond, for which USCIS will use the new Form I–945. DHS estimates the total cost to file Form I–945 will be, at minimum, about $34,166 annually.[23]

Moreover, the final rule will potentially impose new costs on aliens or obligors who submit Form I–356 as part of a request to cancel the public charge bond. DHS estimates the total cost to file Form I–356 would be approximately $824 annually.[24]

The final rule will also result in a reduction in transfer payments from the Federal Government to individuals who may choose to disenroll from or forego enrollment in a public benefits program. Individuals who might choose to disenroll from or forego future enrollment in a public benefits program include foreign-born non-citizens, as well as U.S. citizens who are members of mixed-status households,[25] who may otherwise be eligible for public benefits. DHS estimates that the total reduction in transfer payments from the Federal and State governments will be

[22] *See* 8 CFR 103.2(a)(7), (b)(8)(ii).

[23] Calculation: $35.59 (cost per obligor to file Form I–945) * 960 (estimated annual population who would file Form I–945) = $34,166.40 = $34,166 (rounded) annual total cost to file Form I–945.

[24] Calculation: $33.00 (cost per obligor to file Form I–356) * 25 (estimated annual population who would file Form I–356) = $825.00 annual total cost to file Form I–356.

[25] DHS uses the term ''foreign-born non-citizen'' since it is the term the Census Bureau uses. DHS generally interprets this term to mean alien in this analysis. In addition, DHS notes that the Census Bureau publishes much of the data used in this analysis.

approximately $2.47 billion annually due to disenrollment or foregone enrollment in public benefits programs by foreign-born non-citizens who may be receiving public benefits. DHS estimates that the 10-year discounted federal and state transfer payments reduction of this final rule will be approximately $21.0 billion at a 3 percent discount rate and about $17.3 billion at a 7 percent discount rate. However, DHS notes there may be additional reductions in transfer payments that we are unable to quantify.

There also may be additional reductions in transfer payments from states to individuals who may choose to disenroll from or forego enrollment in public benefits program. For example, the Federal Government funds all SNAP food expenses, but only 50 percent of allowable administrative costs for regular operating expenses.[26] Similarly, Federal Medical Assistance Percentages (FMAP) in some U.S. Department of Health and Human Services (HHS) programs, like Medicaid, can vary from between 50 percent to an enhanced rate of 100 percent in some cases.[27] Since the state share of federal financial participation (FFP) varies from state to state, DHS uses the average FMAP across all states and U.S. territories of 59 percent to estimate the amount of state transfer payments. Therefore, the 10-year undiscounted amount of state transfer payments of the provisions of this final rule is about $1.01 billion annually. The 10-year discounted amount of state transfer payments of the provisions of this final rule would be approximately $8.63 billion at a 3 percent discount rate, and about $7.12 billion at a 7 percent discount rate. Finally, DHS recognizes that reductions in federal and state transfers under federal benefit programs may have impacts on state and local economies, large and small businesses, and individuals. For example, the rule might result in reduced revenues for healthcare providers participating in Medicaid, companies that manufacture medical supplies or pharmaceuticals, grocery retailers participating in SNAP, agricultural producers who grow foods that are eligible for purchase using SNAP benefits, or landlords participating in federally funded housing programs.

Additionally, the final rule will have new direct and indirect impacts on various entities and individuals associated with regulatory familiarization with the provisions of the rule. Familiarization costs involve the time spent reading the details of a rule to understand its changes. A foreign-born non-citizen (such as those contemplating disenrollment or foregoing enrollment in a public benefits program) might review the rule to determine whether he or she is subject to the provisions of the final rule and may incur familiarization costs. To the extent that an individual or entity directly regulated by the rule incurs familiarization costs, those familiarization costs are a direct cost of the rule. In addition to those individuals or entities the rule directly regulates, a wide variety of other entities would likely choose to read and understand the rule and, therefore, would incur familiarization costs. For example, immigration lawyers, immigration advocacy groups, health care providers of all types, non-profit organizations, non-governmental organizations, and religious organizations, among others, may need or want to become familiar with the provisions of this final rule. DHS believes such non-profit organizations and other advocacy groups might choose to read the rule to provide information to those foreign-born non-citizens that might be affected by a reduction in federal and state transfer payments. Familiarization costs incurred by those not directly regulated are indirect costs.

DHS estimates the time that would be necessary to read this final rule would be approximately 16 to 20 hours per person depending on an individual's average reading speed and level of review, resulting in opportunity costs of time. An entity, such as a non-profit or advocacy group, may have more than one person that reads the rule. Using the average total rate of compensation as $36.47 per hour for all occupations, DHS estimates that the opportunity cost of time will range from about $583.52 to $729.40 per individual who must read and review the final rule.

The final rule will produce some quantified benefits due to the regulatory changes DHS is making. The final rule will produce some benefits for T nonimmigrants applying for adjustment of status based on their T nonimmigrant status, as this population will no longer need to submit Application for Waiver of Grounds of Inadmissibility (Form I–601) seeking a waiver of the public charge ground of inadmissibility. DHS estimates the total benefit for this population is $15,176 annually.[28]

The primary benefit of the final rule would be to better ensure that aliens who are admitted to the United States, seek extension of stay or change of status, or apply for adjustment of status will be self-sufficient, *i.e.,* will rely on their own financial resources, as well as the financial resources of the family, sponsors, and private organizations.[29] DHS also anticipates that the final rule will produce some benefits from the elimination of Form I–864W. The elimination of this form will potentially reduce the number of forms USCIS would have to process. DHS estimates the amount of cost savings that will accrue from eliminating Form I–864W would be about $36.47 per petitioner.[30] However, DHS is unable to determine the annual number of filings of Form I–864W and, therefore, currently is unable to estimate the total annual cost savings of this change. Additionally, a public charge bond process will also provide benefits to applicants as they potentially will be given the opportunity for adjustment if otherwise admissible, at the discretion of DHS, after a determination that he or she is likely to become a public charge.

Table 1 provides a more detailed summary of the final provisions and their impacts.

[26] Per section 16(a) of the Food and Nutrition Act of 2008, Public Law 110–234, tit. IV, 122 Stat. 923, 1092 (May 22, 2008) (codified as amended at 7 U.S.C. 2025). *See also* USDA, *FNS Handbook 901,* at p. 41 (2017). Available at: *https://fns-prod.azureedge.net/sites/default/files/apd/FNS_HB901_v2.2_internet_Ready_Format.pdf*, (last visited July 26, 2019).

[27] *See* Dep't of Health and Human Servs. Notice, Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2016 through September 30, 2017, 80 FR 73779 (Nov. 25, 2015).

[28] Calculation: $14,880 (Filing fees for Form I–601) + $296.48 (Opportunity cost of time for Form I–601) = $15,176.48 = $15,176 (rounded) total current estimated annual cost for filing T nonimmigrants filing Form I–601 seeking a waiver of grounds of inadmissibility. Therefore, the estimated total benefits of the final rule for T nonimmigrants applying for adjustment of status using Form I–601 seeking a waiver on grounds of inadmissibility will equal the current cost to file Form I–601 for this population.

[29] *See* 8 U.S.C. 1601(1), (2)(A).

[30] Calculation of savings from opportunity cost of time for no longer having to complete and submit Form I–864W: ($36.47 per hour * 1.0 hours) = $36.47.

TABLE 1—SUMMARY OF MAJOR PROVISIONS AND ECONOMIC IMPACTS OF THE FINAL RULE

Provision	Purpose	Expected impact of final rule
Revising 8 CFR 212.18. Application for Waivers of Inadmissibility in connection with an application for adjustment of status by T nonimmigrant status holders. Revising 8 CFR 245.23. Adjustment of aliens in T nonimmigrant classification.	To clarify that T nonimmigrants seeking adjustment of status are not subject to public charge ground of inadmissibility.	**Quantitative:** *Benefits:* • Benefits of $15,176 annually to T nonimmigrants applying for adjustment of status who will no longer need to submit Form I–601 seeking a waiver on public charge grounds of inadmissibility. *Costs:* • None.
Adding 8 CFR 212.20. Purpose and applicability of public charge inadmissibility. Adding 8 CFR 212.21. Definitions ..... Adding 8 CFR 212.22. Public charge determination.	To define the categories of aliens that are subject to the public charge determination. To establish key definitions, including ''public charge,'' ''public benefit,'' ''likely to become a public charge,'' ''household,'' and ''receipt of public benefits.'' Clarifies that evaluating public charge is a prospective determination based on the totality of the circumstances. Outlines minimum and additional factors considered when evaluating whether an alien immigrant is inadmissible based on the public charge ground. Positive and negative factors are weighed to determine an individual's likelihood of becoming a public charge at any time in the future.	**Quantitative:** *Benefits:* • Benefits of $36.47 per applicant from no longer having to complete and file Form I–864W. *Costs:* • DHS anticipates a likely increase in the number of denials for adjustment of status applicants based on public charge inadmissibility determinations due to formalizing and standardizing the criteria and process for inadmissibility determinations. **Quantitative:** *Benefits:* • Better ensure that aliens who are seeking admission to the United States or apply for adjustment of status are self-sufficient through an improved review process of the mandatory statutory factors.
Adding 8 CFR 212.23. Exemptions and waivers for public charge ground of inadmissibility.	Outlines exemptions and waivers for inadmissibility based on the public charge ground.	
Adding 8 CFR 214.1(a)(3)(iv) and amending 8 CFR 214.1(c)(4)(iv). Nonimmigrant general requirements. Amending 8 CFR 248.1(a) and adding 8 CFR 248.1(c)(4). Change of nonimmigrant classification eligibility.	To provide, with limited exceptions, that an application for extension of stay or change of nonimmigrant status will be denied unless the applicant demonstrates that he or she has not received public benefits since obtaining the nonimmigrant status that he or she is seeking to extend or change, as defined in final 8 CFR 212.21(b), for 12 months, in the aggregate, within a 36 month period.	**Quantitative:** *Costs:* • $6.1 million annually for an increased time burden for completing and filing Form I–129; • $0.12 million annually for an increased time burden for completing and filing Form I–129CW; • $2.4 million annually for an increased time burden for completing and filing Form I–539. **Quantitative:** *Benefits:* • Better ensures that aliens who are seeking to extend or change to a status that is not exempt from the section 212(a)(4) inadmissibility ground who apply for extension of stay or change of status continue to be self-sufficient during the duration of their nonimmigrant stay.

Amending 8 CFR 245. Adjustment of status to that of person admitted for lawful permanent residence.	To outline requirements that aliens submit a declaration of self-sufficiency on the form designated by DHS and any other evidence requested by DHS in the public charge inadmissibility determination.	**Quantitative:**
		Direct Costs:
		• Total annual direct costs of the final rule will range from about $45.5 to $131.2 million, including:
		  • $25.8 million to applicants who must file Form I–944;
		  • $0.69 million to applicants applying to adjust status using Form I–485 with an increased time burden;
		  • $0.34 million to public charge bond obligors for filing Form I–945; and
		  • $823.50 to filers for filing Form I–356.
		• Total costs over a 10-year period will range from:
		  • $352.0 million for undiscounted costs;
		  • $300.1 million at a 3 percent discount rate; and
		  • $247.2 million at a 7 percent discount rate.
		Transfer Payments
		• Total annual transfer payments of the final rule would be about $2.47 billion from foreign-born non-citizens and their households who disenroll from or forego enrollment in public benefits programs. The federal-level share of annual transfer payments will be about $1.46 billion and the state-level share of annual transfer payments will be about $1.01 billion.

TABLE 1—SUMMARY OF MAJOR PROVISIONS AND ECONOMIC IMPACTS OF THE FINAL RULE—Continued

Provision	Purpose	Expected impact of final rule
		• Total transfer payments over a 10-year period, including the combined federal- and state-level shares, will be: • $24.7 billion for undiscounted costs; • $21.0 billion at a 3 percent discount rate; and • $17.3 billion at a 7 percent discount rate. **Quantitative:** *Benefits:* • Potential to make USCIS' in the review of public charge inadmissibility more effective. *Costs:* • DHS anticipates a likely increase in the number of denials for adjustment of status applicants based on public charge inadmissibility determinations due to formalizing and standardizing the criteria and process for public charge determination. • Costs to various entities and individuals associated with regulatory familiarization with the provisions of the final rule. Costs will include the opportunity cost of time to read the final rule and subsequently determine applicability of the final rule's provisions. DHS estimates that the time to read this final rule in its entirety would be 16 to 20 hours per individual. DHS estimates that the opportunity cost of time will range from about $583.52 to $729.40 per individual who must read and review the final rule. However, DHS cannot determine the number of individuals who will read the final rule.
Public Charge Bond Provisions		
Amending 8 CFR 103.6. Public charge bonds.	To set forth the Secretary's discretion to approve bonds, cancellation, bond schedules, and breach of bond, and to move principles governing public charge bonds to final 8 CFR 213.1.	**Quantitative:** *Costs:* • $34,166 annually to obligors for submitting Public Charge Bond (Form I–945); and • $823.50 annually to filers for submitting Request for Cancellation of Public Charge Bond (Form I–356).
Amending 8 CFR 103.7. Fees	To add fees for new Form I–945, Public Charge Bond, and Form I–356, Request for Cancellation of Public Charge Bond.	• Fees paid to bond companies to secure public charge bonds. Fees could range from 1–15 percent of the public charge bond amount based on an individual's credit score.
Amending 8 CFR 213.1. Admission or adjustment of status of aliens on giving of a public charge bond.	In 8 CFR 213.1, to add specifics to the public charge bond provision for aliens who are seeking adjustment of status, including the discretionary availability and the minimum amount required for a public charge bond.	**Quantitative:** *Benefits:* • Potentially enable an alien who was found inadmissible only on the public charge ground to adjust his or her status by posting a public charge bond with DHS.

Source: USCIS analysis.

DHS has prepared a full analysis of this rule according to Executive Orders (E.O.) 12866 and 13563. This analysis can be found in the docket for this rulemaking or by searching for RIN 1615–AA22 on *www.regulations.gov.*

II. Background

A. Public Charge Inadmissibility and Public Charge Bonds

Under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), an alien who is an applicant for a visa, admission, or adjustment of status is inadmissible if he or she is likely at any time to become a public charge. The public charge ground of inadmissibility, therefore, applies to any alien applying for a visa to come to the United States temporarily or permanently, for admission, or for adjustment of status to that of a lawful permanent resident.[31] Section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) does not directly apply to nonimmigrants seeking extension of stay or change of status,[32] because extension of stay and change of status applications are not applications for a visa, admission, or adjustment of status.

The INA does not define ''public charge.'' It does specify that when determining if an alien is likely at any time to become a public charge, consular officers and immigration officers must consider the alien's age; health; family status; assets, resources, and financial status; and education and skills, at a minimum.[33] Some immigrant and nonimmigrant categories are exempt from the public charge inadmissibility ground and other applicants may apply for a waiver of the public charge inadmissibility ground.[34]

Additionally, section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), permits the consular officer, immigration officer, or an immigration judge to consider any affidavit of support submitted under section 213A of the Act, 8 U.S.C. 1183a, on the applicant's behalf when determining whether the applicant may become a public charge.[35] In fact, with

[31] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[32] *See* INA section 214 and 248, 8 U.S.C. 1184 and 1258.

[33] *See* INA section 212(a)(4)(B)(i), 8 U.S.C. 1182(a)(4)(B)(i).

[34] *See* proposed 8 CFR 212.23.

[35] *See* INA section 212(a)(4)(B)(ii), 8 U.S.C. 1182(a)(4)(B)(ii). When required, the applicant must

Continued

very limited exceptions, aliens seeking family-based immigrant visas and adjustment of status, and a limited number of employment-based immigrant visas and adjustment of status, must have a sufficient affidavit of support or will be found inadmissible as likely to become a public charge.[36]

In general, if DHS has determined that an alien is inadmissible based on public charge, but is otherwise admissible, DHS may admit the alien at DHS's discretion upon the alien posting a suitable and proper bond as determined by DHS.[37] The purpose of issuing a public charge bond is to ensure that the alien will not become a public charge in the future.[38]

B. Current Public Charge Standards

As discussed in the NPRM,[39] DHS currently makes public charge determinations in accordance with the 1999 Interim Field Guidance.[40] This guidance explains how the agency determines if a person is likely at any time to become a public charge under section 212(a)(4) of the Act, 8 U.S.C. 1182(a), for admission and adjustment of status purposes, and whether a person has become a public charge within five years of entry from causes not affirmatively shown to have arisen since entry, and therefore deportable under section 237(a)(5) of the Act, 8 U.S.C. 1227(a)(5).[41] On May 26, 1999, INS issued a proposed rule that would have codified these policies in regulation. Ultimately, however, INS did not publish a final rule conclusively addressing these issues.[42] DOS also issued a cable to its consular officers at that time, implementing similar guidance for visa adjudications, and its Foreign Affairs Manual (FAM) was similarly updated.[43] USCIS has continued to follow the 1999 Interim Field Guidance in its adjudications, and DOS has continued following the public charge guidance set forth in the FAM.[44]

In the 1999 Interim Field Guidance, public charge is defined to mean an alien who is likely to become primarily dependent [45] on the government for subsistence, as demonstrated by either:

- Receipt of public cash assistance for income maintenance; or
- Institutionalization for long-term care at government expense.

Under the 1999 Interim Field Guidance, DHS did not consider receipt of non-cash, supplemental and certain limited cash, and special purpose benefits. Similarly, DHS did not consider institutionalization for short periods of rehabilitation because it does not constitute primary dependence.[46] As discussed in the NPRM, the use of public charge bonds has decreased since the introduction of enforceable affidavits of support in section 213A of the Act, 8 U.S.C. 1183a.[47]

C. Final Rule

Following careful consideration of public comments received, DHS has made modifications to the regulatory text proposed in the NPRM, as described above. The rationale for the proposed rule and the reasoning provided in the background section of that rule remain valid, except as described in this regulatory preamble. Section III of this preamble includes a detailed summary and analysis of the public comments. Comments may be reviewed at the Federal Docket Management System (FDMS) at *http://www.regulations.gov,* docket number USCIS–2010–0012.

III. Public Comments on the Proposed Rule

A. Summary of Public Comments

On October 10, 2018, DHS, USCIS published a proposed rule in docket USCIS–2010–0012. The comment period associated with the proposed rule closed at the end of December 10, 2018. DHS received a total of 266,077 public comment submissions in Docket USCIS–2010–0012 in response to the proposed rule. The majority of comment submissions were from individual or anonymous commenters. Other commenters included healthcare providers; research institutes and universities; law firms and individual attorneys; federal, state, local, and tribal elected officials; State and local government agencies; religious and community organizations; advocacy groups; unions; Federal Government officials; and trade and business organizations. While some commenters provided support for the rule, the vast majority of commenters opposed the rule.

B. Requests To Extend Comment Period

Comment: Some commenters requested that DHS extend the comment period. An individual commenter said the 60-day comment period is not enough time for such a drastic policy and asserted it would be unfair to American people to proceed with the proposed changes. Another individual commenter asked USCIS to extend the notice and comment period for an additional 90 days. A commenter wrote that the 60-day comment period provided inadequate time for its members to meaningfully comment on the proposed rule, and requested a further 60-day extension. Another commenter urged that DHS consider extending the notice and comment period for the docket until all interested individuals have the opportunity to provide input. The commenter said it is standard practice for an agency to extend a notice and comment period when circumstance suggest that additional input may be beneficial.

Response: DHS believes that the 60-day comment period provided an adequate opportunity for public input, and declines to extend the comment period. The Administrative Procedure Act (APA) is silent regarding the duration of the public comment period, and does not establish a minimum duration.[48] However, the 60-day comment period is in line with E.O. 12866, which encourages agencies to provide at least 60 days for the public

submit an Affidavit of Support Under Section 213A of the INA (Form I–864).

[36] *See* INA section 212(a)(4)(C), (D), 8 U.S.C. 1182(a)(4)(C), (D). A sufficient affidavit of support is one in which the sponsor has demonstrated that he or she has enough income and/or assets to maintain the sponsored alien and the rest of the sponsor's household at 125% of the FPG for that household size (or at 100 percent of the FPG if the sponsor is active duty in the U.S. Armed Forces or U.S. Coast Guard).

[37] *See* INA section 213, 8 U.S.C. 1183; *see also* 8 CFR 103.6; 8 CFR 213.1.

[38] *Matter of Viado,* 19 I&N Dec. 252, 253 (BIA 1985).

[39] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51133 (proposed Oct. 10, 2018).

[40] *See* 64 FR 28689 (May 26, 1999).

[41] *See* 64 FR 28689 (May 26, 1999). In addition to the 1999 Interim Field Guidance, INS proposed promulgating these policies through rulemaking, which was never concluded. *See* Inadmissibility and Deportability on Public Charge Grounds, 64 FR 28676 (proposed May 26, 1999).

[42] *See* Inadmissibility and Deportability on Public Charge Grounds, 64 FR 28676 (proposed May 26, 1999).

[43] *See* Inadmissibility and Deportability on Public Charge Grounds, 64 FR 28676, 28680 (proposed May 26, 1999).

[44] *See* Children's Health Insurance Program Reauthorization Act of 2009, Public Law 111–3, sec. 214, 123 Stat. 8, 56 (Feb. 4, 2009); 9 FAM 302.8–2(B)(2), Determining ''Totality of Circumstances,'' (g) Public Charge Bonds, *https://fam.state.gov/fam/09fam/09fam030208.html* (last visited July 26, 2019). Note, on July 10, 2018, DOS amended 9 FAM 302.8.

[45] Former INS defined ''primarily dependent'' as ''the majority'' or ''more than 50 percent.''

[46] Similar to DHS, DOS has been making public charge inadmissibility determinations using the same legal framework, as reflected in the FAM. *See* 9 FAM 302.8, Public Charge—INA 212(a)(4), *https://fam.state.gov/FAM/09FAM/09FAM030208.html* (last visited July 26, 2019).

[47] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51219 (proposed Oct. 10, 2018).

[48] *See* 5 U.S.C. 553(c).

to comment on economically significant rules. The sufficiency of the 60-day comment period provided in this rule is supported by the over 266,000 public comments received. The public, including attorneys; federal, state, local, and tribal elected officials; and advocacy organizations provided a great number of detailed and informative comments. In addition, DHS notes that the proposed rule had been listed in the publicly available Unified Agenda of Federal Regulatory and Deregulatory Actions since the Fall 2017 publication. Given the quantity and quality of comments received in response to the proposed rule, and other publicly available information regarding the rule, DHS believes that the 60-day comment period has been sufficient.

C. Comments Expressing General Support for the NPRM

Comment: Many commenters stated that immigrants should be self-sufficient. Many commenters stated that aliens should not be permitted to accept government benefits or depend on U.S. taxpayer money to support themselves if they want to obtain green cards. Commenters stated that immigrants should be productive members of society to gain admission to the United States and should not be a burden on the state. One commenter said that migrants should not be able to obtain welfare unless they have a minimum working record in the United States. Another commenter supported the rule and said that illegal immigration needs to stop. One commenter said that this country does not need more poor people. A commenter said that immigrants who cannot support themselves should not come to the United States. Other commenters said that the United States should not be responsible for taking care of people from other countries. One commenter noted that this rule will address the problem of public assistance use by unauthorized aliens seeking to legalize their status, DACA recipients, and any other immigrants who want to legalize their status but who are unable to support themselves or their families. Another commenter indicated that the rule will encourage immigrants to work hard and become self-sufficient.

Response: DHS agrees that applicants for admission and adjustment of status who are subject to the public charge ground of inadmissibility should be self-sufficient and should not depend on the government to meet their needs, and this rule seeks to better ensure self-sufficiency. DHS firmly believes that this was Congress' intent in enacting section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), including the changes to this ground made in 1996.[49] DHS, however, disagrees with comments suggesting that this rule addresses, or should address, eligibility for government benefits programs. DHS also disagrees that the rule addresses eligibility for public benefits by certain specified groups, such as aliens unlawfully present, or DACA recipients. Neither the public charge ground of inadmissibility nor this final rule govern eligibility for public benefits; they govern which aliens are inadmissible or ineligible for admission or adjustment of status. This final rule does not address the government's responsibility to care for foreign nationals and does not address which aliens are, or should be, eligible to receive public benefits.

DHS also disagrees with suggestions that this rule is aimed at making sure poor people are not able to enter the United States. As noted previously, the rule aims to ensure that aliens subject to the public charge ground of inadmissibility are self-sufficient. An alien's assets, resources, and financial status is one factor that is considered in the totality of the circumstances when making a public charge inadmissibility determination and is not outcome determinative.

Comment: Some commenters stated that the rule will have a positive impact on the U.S. economy and job creation, and will protect the social safety net. Numerous commenters mentioned that public assistance should be reserved for U.S. citizens who need help and not immigrants who arrive unable to contribute to the nation's well-being.

Other commenters stated that as more immigrants look to come to the United States, the proposed public charge rule is needed to preserve the ''American Dream'' for future generations and to prevent the current generation from having to shoulder the financial burden of paying for foreign nationals who cannot provide for themselves.

Response: This rule does not aim to address the U.S. economy, job creation, protection of the social safety net or the ''American dream,'' curtail spending on public assistance, or ensure that public assistance will be reserved for U.S. citizens. This rule also does not attempt to curtail efforts to address broader economic and health problems, including with respect to people outside the United States. Rather, the purpose of this rule is to implement the public charge ground of inadmissibility consistent with the principles of self-sufficiency set forth by Congress, and to minimize the incentive of aliens to attempt to immigrate to, or to adjust status in, the United States due to the availability of public benefits.[50] While the rule may result in reductions in overall alien enrollment in certain public benefit programs, improve the ability of U.S. citizens to obtain public benefits for which they are eligible, or otherwise benefit the U.S. economy, this rule does not directly regulate these matters.

Comment: Some commenters stated that there should be more stringent immigration standards generally and reductions in the number of immigrants in the United States. Some commenters stated that immigrants are ''abusing'' the U.S. welfare system. Other commenters offered general support for the NPRM without further explanation.

Response: DHS does not intend this rule to reduce overall immigration levels to the United States. Instead, this rule is an exercise of DHS's authority to interpret the public charge ground of inadmissibility. Fraud or abuse in alien enrollment in public benefits programs is of course problematic, but the public charge ground of inadmissibility applies to an alien who is likely at any time to become a public charge, regardless of whether such alien is likely to fraudulently obtain public benefits or abuse the public benefits system. With respect to comments about an alien receiving public benefits for which he or she was not eligible, DHS notes that to the extent that an alien obtains such a benefit by falsely claiming to be a U.S. citizen, the alien may be inadmissible for falsely claiming U.S. citizenship (section 212(a)(6)(C)(ii) of the Act, 8 U.S.C. 1182(a)(6)(C)(ii)), depending on the circumstances by which he or she received the benefits improperly. Additionally, to the extent that an applicant who has obtained public benefits through fraud or misrepresentation subsequently applies for an immigration benefit for which a favorable exercise of discretion is required, the fraud or misrepresentation can be considered in deciding whether to favorably exercise that discretion. However, public benefits that an alien obtains unlawfully are outside of the scope of this rulemaking, which only addresses inadmissibility based on the public charge ground of inadmissibility.

[49] *See* IIRIRA, Public Law 104–208, div. C, sec. 531, 110 Stat. 3009–546, 3009–674 (Sept. 30, 1996) (amending INA section 212(a)(4), 8 U.S.C. 1182(a)(4)); H.R. Rep. No. 104–828 at 240–41 (1996) (Conf. Rep.) (''This section amends INA section 212(a)(4) to expand the public charge ground of inadmissibility. . . . Self-reliance is one of the most fundamental principles of immigration law.'').

[50] *See* 8 U.S.C. 1601.

D. Comments Expressing General Opposition to the NPRM

1. Purpose of the Rule and Self Sufficiency

Comment: Commenters stated that the proposed rule represented an ineffective solution to a non-existent problem—a lack of self-sufficiency among immigrants. A commenter indicated that the proposed rule emphasized that the self-sufficiency of immigrants is a long-standing congressional policy, yet did not provide sufficient data that dependency on the government and/or government benefits is a problem within immigrant communities, especially in light of data showing that immigrants have been shown generally to make very strong economic contributions to the country. The commenter stated that, for example, in 2014 immigrant-led households in Massachusetts paid nearly $10 billion dollars in federal, state, and local taxes, and represented nearly $28 billion dollars in spending power.

Additionally, commenters expressed concern that the text of the rule suggests that it is the main responsibility of our nation's immigration system—and the agencies which run it—to cultivate or maintain a national ethos of ''self-sufficiency.'' A commenter indicated that immigration policies and systems are meant to achieve a number of different goals, such as family unity, diversity, humanitarian assistance, and ensuring sufficient labor. Commenters stated that safeguarding our nation from individuals that may at some point need government support is not the singular or even primary purpose of our system of immigration.

Response: DHS disagrees with the commenters that ensuring the self-sufficiency of immigrants is unnecessary, or that a lack of self-sufficiency is a non-existent problem. As outlined in the NPRM, Congress clearly declared, in its policy statement in PRWORA, that self-sufficiency has been a basic principle of United States immigration law since this country's earliest immigration statutes and that it should continue to be a governing principle in the United States.[51] Congress also has maintained the public charge ground of inadmissibility in law since 1882. DHS believes that applicants for admission and adjustment of status who are subject to the public charge ground of inadmissibility should be self-sufficient and should not depend on the government to meet their needs, and DHS firmly believes that this was Congress' intent in enacting section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), including as recently as 1996.[52] DHS agrees with the commenter that immigration laws and policies serve many purposes, including goals such as family unity, diversity, humanitarian assistance. However, U.S. immigration laws balance competing values. For example, the criminal grounds of inadmissibility[53] are designed to protect the United States and its citizens from harm and threats to public safety,[54] while health-related grounds of inadmissibility are intended to protect the health of the United States population.[55] These grounds of inadmissibility are valid exercises of congressional authority, notwithstanding that such grounds of inadmissibility may sometimes impede family unity, and notwithstanding that in many individual aliens' cases, such grounds of inadmissibility may not be implicated. Similarly, here, Congress, though legislation, addressed various policy considerations when determining whether a foreign national should be admitted to the United States, including whether an individual who is likely at any time in the future to become a public charge should be admitted to the United States. Therefore, while self-sufficiency may not be the primary purpose of U.S. immigration laws, it is one consideration put into place by Congress.

DHS is under no obligation to demonstrate that all or most aliens in the United States are not self-sufficient. To the extent that an alien is self-sufficient, the alien is unlikely to be affected by this rule. In the NPRM, DHS did provide extensive data on the lack of self-sufficiency among certain aliens, and showed how the minimum statutory factors identified by Congress relate to the self-sufficiency of individuals and their receipt of public benefits.[56] DHS acknowledges that immigrants provide significant contribution to the United States as a whole and within their communities, as demonstrated by data and information provided by many commenters. However, the focus of the inquiry for public charge purposes is whether an individual alien, who is seeking to be admitted to the United States or who is applying for adjustment of status, is likely to become a public charge at any time in the future. This determination is made following consideration of the totality of the alien's individual circumstances and is a predictive assessment.

Comment: A commenter stated that section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) neither mentioned or discussed self-sufficiency nor identified self-sufficiency as a criteria in the determination and therefore disagreed with primary purpose of the rule outlined in the NPRM. Given the close proximity in time when PRWORA and Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA) passed, the commenter considered it significant that Congress restricted an immigrant's eligibility for public benefits with PRWORA, yet IIRIRA codified the minimum mandatory factors without PRWORA's articulated self-sufficiency principles as relied on by DHS in the NPRM. The commenter indicated that both PRWORA and IIRIRA, were considered in the 1999 Interim Field Guidance because PRWORA and IIRIRA had created widespread confusion about permissible public benefit receipt in relation to public charge inadmissibility. The commenter stated that the current rule failed to identify post-1999 laws, data, or experience, such as congressional authorities or other information not already taken into account by INS in developing the 1999 Interim Field Guidance that informed DHS's development of the proposed rule. The commenter therefore requested that DHS in its final rule identify and describe legal authorities or information other than the authorities which predated the 1999 Interim Field Guidance and that were relied on by INS, which DHS considered in developing its proposed definition of public charge. The commenter stated that if Congress had wanted to achieve the self-sufficiency or cost-savings goals identified by the NPRM it could alter the eligibility rules for the enumerated programs, but has not changed the public benefit eligibility requirements, and expanded eligibility for some programs following the enactment of PRWORA and IIRIRA in 1996, such as in 2002, when Congress restored SNAP eligibility for all qualified immigrant children.

Response: Although DHS agrees with the commenter that self-sufficiency is not mentioned in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), DHS maintains, as outlined in the NPRM,

[51] *See* 8 U.S.C. 1601.

[52] *See* IIRIRA, Public Law 104–208, div. C, sec. 531, 110 Stat. 3009–546, 3009–674 (Sept. 30, 1996) (amending INA section 212(a)(4), 8 U.S.C. 1182(a)(4)); H.R. Rep. No. 104–828 at 240–41 (1996) (Conf. Rep.) (''This section amends INA section 212(a)(4) to expand the public charge ground of inadmissibility. . . . Self-reliance is one of the most fundamental principles of immigration law.'').

[53] *See* INA section 212(a)(2), 8 U.S.C. 1182(a)(2).

[54] *See* INA section 212(a)(2), 8 U.S.C. 1182(a)(2).

[55] *See* INA section 212(a)(1), 8 U.S.C. 1182(a)(1).

[56] *See* throughout the NPRM, Inadmissibility on Public Charge Grounds, 83 FR 51114 (proposed October 10, 2018).

that this principle, a congressional' policy objective, informs and has informed public charge determinations. Based on the administrative and legislative context discussed in the NPRM,[57] including congressional records relating to debates addressing self-sufficiency prior to Congress' passing of IIRIRA,[58] DHS's view of self-sufficiency and its role in the public charge determination remains unchanged. In fact, DHS considers the proximity of the passage of both PRWORA and IIRIRA as an indication that Congress associated public charge closely with the principles governing PRWORA, and that Congress must have recognized that it made certain public benefits available to some aliens who are also subject to the public charge grounds of inadmissibility, even though receipt of such benefits could render the alien inadmissible as likely to become a public charge. Additionally, as outlined in the NPRM, DHS does not believe that the plain text of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), INS's discussion of PRWORA and IIRIRA, and the case law cited by INS or DHS requires the adoption of the legacy INS interpretations for purposes of public charge. As discussed in detail throughout the NPRM and below, the term public charge is ambiguous, and neither the statute nor case law prescribe the degree to which an alien must be receiving public benefits to be considered a public charge. DHS remains convinced that its interpretation is permissible and reasonable.

DHS disagrees with the commenter that the NPRM failed to identify post-1999 laws, data, or experience, such as congressional authorities or other information not already taken into account by INS in developing current public charge policy that informed DHS's development of the proposed rule. Post-PRWORA, Congress did restore some public benefit eligibility for aliens. DHS acknowledged these developments in the NPRM preamble.[59] For example, DHS incorporated the discussion that in 2002, the Farm Security and Rural Investment Act of 2002, Public Law 107–17, (May 13, 2002), Section 4401, restored SSI benefits for any person who was lawfully residing in the United States on August 22, 1996; restored SNAP for all children under 18; and provided that ''qualified aliens'' [60] were eligible for SNAP after five years of entry into the United States. In 2007, Section 525 of the Consolidated Appropriations Act for Fiscal Year (FY) 2008 [61] provided for Iraqi and Afghan foreign nationals to obtain benefits.

These provision and others restoring or providing public benefit access to immigrants are incorporated to the statutory provisions governing PRWORA, 8 U.S.C. 1611. Therefore, this rule is informed by all the documentation and data presented before the 1999 Interim Field Guidance, as well as relevant subsequent legislation, and relevant case law. DHS would note that precedential decisions and other materials cited by DHS do not lose persuasive value for purposes of DHS's interpretation simply because they were also addressed in the 1999 proposed rule and 1999 Interim Guidance.[62] Further, although subsequent legislation, such as Congress's expansion of SNAP, expanded eligibility of public benefits to certain aliens, Congress has not subsequently changed the section 212(a)(4) of the Act, 8 U.S.C. 1182, which governs the public charge inadmissibility determination.[63]

Comment: A commenter stated that Congress, not DHS, may change statutory eligibility requirements for federally-administered public benefits programs, including the ones listed in the NPRM. The commenter stated that DHS's regulatory framework was designed to achieve the same effects as changing eligibility requirements—decreased and foregone enrollment in public benefit programs by certain populations—and therefore, usurped Congress' role.

Response: DHS strongly disagrees with the comment that that DHS's regulatory framework was designed to achieve the same effects as changing eligibility requirements—decreased and foregone enrollment in public benefit programs by certain populations—and therefore, usurped Congress' role. Although DHS acknowledges that the rule, once effective, may lead individuals to disenroll or choose to forego enrollment from public benefits, the rule does not change eligibility requirements for public benefits. The rule only provides for whether an alien is admissible into the United States, which is a matter of immigration law for the Federal Government and delegated to DHS.

2. Requests for Reconsideration and Withdrawal of NPRM

Comment: Several commenters asked that DHS reconsider the rule and withdraw it, stating that the rule is unnecessary and would place an undue burden on DHS and immigrants. One commenter stated the proposed rule's preamble does not establish a sufficient justification for the proposed revisions. Another commenter stated that the NPRM was too long and discouraged the public from commenting on the proposed rule. Some commenters expressed concern that the rule conflicts with local, state, and federal initiatives, including undermining community-based, non-profit efforts, and making the immigration system inefficient. Several commenters stated that DHS should focus on promoting a rule that strengthens, rather than undermines, immigrants' ability to support themselves. Some commenters requested that the rule be withdrawn in its entirety, and that the 1999 Interim Field Guidance remain in effect.

Response: DHS will not retract the proposed rule and is concluding the public charge inadmissibility rulemaking through the publication of this final rule. DHS is committed to implementing section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), consistent with the principles of self-sufficiency set forth by Congress. As required by the statute and reflected in this rule, DHS's public charge inadmissibility determinations will involve an assessment of the mandatory factors as they relate to the likelihood of an applicant becoming a public charge at any time in the future.

Comment: Multiple commenters said the rule should be withdrawn, the 1999 Interim Field Guidance should remain in place, and that the proposed rule is a drastic change from the 1999 Interim Field Guidance. Many said that the 1999

[57] *See* 83 FR 51114 (Oct. 10, 2018).

[58] *See* 142 Cong. Rec. S4609 (May 2, 1996) (statement of Sen. Byrd) (''[S]elf-sufficiency will be the watchword for those coming to the United States. By making noncitizens ineligible for Federal means-tested programs, and by 'deeming' a sponsor's income attributable to an immigrant, the American taxpayer will no longer be financially responsible for new arrivals.''), *available at https://www.congress.gov/crec/1996/05/02/CREC-1996-05-02-pt1-PgS4592.pdf.* (last visited July 26. 2019).

[59] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51126–51133 (proposed October 10, 2018).

[60] ''Qualified aliens'' generally includes lawful permanent resident aliens, refugees/asylees, and other non-temporary legal residents (such as Cuban/Haitian entrants).

[61] Public Law 110–161 (Dec. 26, 2007).

[62] For example, precedent decisions issued by the Executive Office for Immigration Review (EOIR) and the Attorney General are binding on DHS until overruled. *See* 8 CFR 103.3(c), 103.10(b), 1003.1(g); *see, e.g., Matter of E–L–H–*, 23 I&N Dec. 814, 817 (BIA 2005) (finding that a published Board decision has precedential effect unless and until modified or overruled by the Attorney General, the Board, Congress, or a Federal court.).

[63] *Cf. Cyan, Inc.* v. *Beaver Cty. Emp. Ret. Fund,* 138 S. Ct. 1061, 1070 (2018) (explaining that, if Congress had wanted to deprive state courts of jurisdiction over certain class actions, it could have easily done so by inserting a provision).

Interim Field Guidance is consistent with congressional intent and case law and should not be abandoned. One commenter noted that the 1999 Interim Field Guidance's exclusion of certain public health, nutrition, and in-kind community service programs was consistent with the intent of Congress as expressed in its 1996 Conference Report regarding PRWORA and that rule was a departure from this intent.

Response: DHS disagrees that the 1999 Interim Field Guidance should remain in place. DHS has chosen to define public charge more broadly than in the 1999 NPRM and 1999 Interim Field Guidance. DHS believes this broader definition is consistent with Congress' intention that aliens should be self-sufficient. Self-sufficiency is, and has long been, a basic principle of immigration law in this country.[64] DHS believes that this rule aligns DHS regulations with that principle.[65]

Comment: A commenter urged DHS to either withdraw the proposed rule or if moving to finalize it, to provide a full and complete analysis of all public comments received on the proposed rule, including the total number of comments, (and the number of those signing individual comments), composition of, relative numbers of commenters supporting and opposing the overall proposal, the volume and nature of comments regarding specific provisions, and the rationale for specific choices made by DHS in light of comments. The commenter stated that doing so would provide transparency regarding the extent to which DHS considered public input in accordance with the APA.

Response: DHS declines to withdraw the NPRM and will conclude rulemaking with the publication of this final rule. DHS has responded to public comments that raise substantive issues or offer significant alternatives.[66] In this final rule, DHS is providing both an overview of public comments and commenters, and a complete analysis of public comments including those addressing specific aspects of the proposed rule. DHS has fully considered the public input on this rule in accordance with the APA.

Comment: Commenters stated that DHS's position is inconsistent with the 1999 NPRM.

Response: DHS agrees that this rule takes a different approach to interpreting the public charge ground of inadmissibility than the 1999 NPRM, and withdrew the 1999 NPRM as part of the 2018 NPRM.[67] The 2018 NPRM explained DHS's proposed change of position. DHS is not bound by a twenty-year-old proposed rule, and believes that this rule represents a permissible implementation of the public charge inadmissibility standard that Congress provided when it enacted section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). This public charge inadmissibility rule provides long-absent guidance on how to interpret key statutory terms, which have never been fully defined by Congress, and which the agency has the authority and responsibility to define.

3. Alternatives to the Public Charge Rule

Comment: An individual commenter proposed creating a ''self-sufficiency program'' in place of the proposed rule, modeled after the Office of Refugee Resettlement's (ORR) Voluntary Agencies Matching Grant Program that provides intensive case management, English language and vocational training, and a variety employment services, which would serve as an alternative to public benefits receipt by immigrants and nonimmigrants. A commenter suggested that rather than creating this rule to disincentivize receipt of public assistance by revoking or denying citizenship status based on receipt of public assistance, DHS should instead create classes or provide resources to aliens to help them understand the importance of self-sufficiency.

Response: DHS notes that this rule does not address eligibility for citizenship and neither the statute nor this final rule permit revocation or denial of citizenship status based on the public charge inadmissibility ground. This rule establishes guidelines for determining whether aliens who are applicants for admission or adjustment of status, and who are subject to section 212(a)(4) of the Act, are inadmissible as likely to become a public charge at any time in the future.[68] DHS further notes that it will not create programs in lieu of this rule that will help aliens attain self-sufficiency, as DHS believes, consistent with Congress's intent set forth in PRWORA, that aliens should be self-sufficient before they seek admission or adjustment of status.

Comment: A commenter requested a national stakeholder workgroup be convened to accomplish the Administration's goals rather than proceeding with the public charge rule, which the commenter asserted will have a negative impact on the health and financial security of aliens.

Response: DHS disagrees that a stakeholder working group is an alternative to this rulemaking. As indicated elsewhere in this rule, DHS is exercising its authority to interpret the INA consistent with its congressional mandate. This final rule provides necessary guidance for purposes of implementing section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), including, by defining statutory terms that have never been defined by Congress in the over 100 years since the public charge inadmissibility ground first appeared in the immigration laws.

The rulemaking process allowed for ample public participation. DHS notes that it received over 266,000 public comments. DHS also participated in over 20 OMB E.O. 12866 meetings with public stakeholders related to the proposed rule. Therefore, DHS does not believe that national stakeholder group would work as substitute for this rulemaking.

In addition, DHS notes that USCIS has a robust stakeholder communication and engagement program that covers all aspects of the agency's operations. This program will engage stakeholders when this rule becomes final to help ensure that applicants for immigration benefits and their representatives fully understand the new rule.

4. Discrimination and Disparate Impact

Comment: Several commenters stated that this rule discriminates against both aliens and citizens and unduly affects certain individuals. Commenters stated that the rule discriminates against immigrants based on age, gender, income, race, health, and social status. Some commenters expressed concerns that the proposed changes to the definition of public charge are inhumane and discriminatory to immigrants, particularly minors, the elderly, the poor, those will chronic medical conditions and disabilities, immigrants with limited English proficiency, Latinos, Black families, and other communities of color, and goes against core American values. A number of commenters stated this rule would discriminate against individuals with chronic health conditions, such as heart disease. Some commenters stated that the new definition of ''likely at any time in the future to become a public charge'' in 8 CFR 212.21(c) would be discriminatory towards blind individuals who rely on public

[64] *See* 8 U.S.C. 1601(1).

[65] *See Southern S.S. Co.* v. *N.L.R.B.,* 316 U.S. 31, 47 (1942) (''Frequently the entire scope of Congressional purpose calls for careful accommodation of one statutory scheme to another. . . .'').

[66] *Reytblatt* v. *U.S. Nuclear Regulatory Comm'n,* 105 F.3d 715, 722 (D.C. Cir. 1997); *Northside Sanitary Landfill, Inc.* v. *Thomas,* 849 F.2d 1516 (D.C. Cir 1988).

[67] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114 (proposed Oct. 10, 2018).

[68] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

assistance to make ends meet, due to the 70 percent unemployment rate for blind individuals. The commenters stated that the proposed definition exhibits a clear and inherent bias against the blind and other individuals with a disability and urged DHS to abandon the rule.

Commenters generally stated the rule creates an ageist system that favors wealthy, healthy, and highly educated individuals. One commenter said that this rule creates a ''merit-based'' system that punishes immigrants and discriminates against them based on their race, religion, and ethnicity. A commenter stated that the rule's consideration of an applicant's English proficiency amounts to discrimination.

Several commenters observed that U.S. born children often qualify for and receive assistance, because their immigrant parents are struggling. The commenters stated that DHS should not penalize the parents or the children for accepting public benefits that were legally available to them. One commenter questioned the legality of the rule and stated that the Supreme Court in *Plyler* v. *Doe* [69] held that states cannot discriminate against children on the basis of undocumented status. The commenter said numerous other cases have held that children cannot be penalized for their parentage (*e.g., Levy* v. *Louisiana,* 391 U.S. 68 (1968) and *Clark* v. *Jeter,* 486 U.S. 456 (1988)).

Response: To the extent that this rule, as applied, may result in negative outcomes for certain groups, DHS notes that it did not codify this final rule to discriminate against aliens based on age, race, gender, income, health, and social status, or to create an ''ageist'' system that selectively favors wealthy, healthy, and highly educated individuals. Rather, this rule is intended to better ensure that aliens subject to this rule are self-sufficient. To the extent that this rule specifically or disproportionately affects those of a particular age or those with lower incomes, less education, limited English proficiency, or poor health, DHS notes that Congress requires DHS to consider, among other factors, an applicant's age, assets, resources, financial status, education, and skills as part of the public charge inadmissibility determination.

Additionally, this rule does not create a merit-based system more broadly or apply a wealth or poverty litmus test to make public charge inadmissibility determinations. Instead, DHS has established a systematic approach to implement Congress' totality of the circumstances standard and has given the mandatory statutory factors meaning, value, and weight strictly in relationship to determining whether or not an alien who is otherwise admissible of eligible for adjustment of status in the context of the existing system is likely at any time in the future to become a public charge. DHS acknowledges that one likely outcome of this change is that some individuals who would may have been able to immigrate under the 1999 Interim Field Guidance will now be deemed inadmissible as likely public charges.

Section 212(a)(4) of the INA, 8 U.S.C. 1182(a)(4), sets forth the public charge ground of inadmissibility that makes aliens ineligible for visas, admission, and adjustment of status. Section 212(a)(4) of the INA, 8 U.S.C. 1182(a)(4), also requires DHS to consider minimum factors in the public charge inadmissibility analysis. The Federal Government is responsible for ''regulating the relationship between the United States and our alien visitors,'' which includes regulating the manner and conditions of entry, as well as the residence of aliens.[70] DHS is the federal agency with the authority to establish regulations regarding the public charge inadmissibility determination.[71] As required by statute, DHS must consider how an alien's age, health, family status, assets and resources, financial status, education, and skills impact the alien's likelihood at any time of becoming a public charge. Under the statute, DHS may also consider an applicant's affidavit of support, if applicable. The statute does not direct DHS to consider an alien's race, gender, or social status. Consequently, DHS will not consider an alien's race, gender, or social status when making a public charge inadmissibility determination. Other than an absent or insufficient affidavit of support, where required, DHS will not find an alien inadmissible based on any single factor without consideration of all of the other factors and the totality of their effect on an applicant's likelihood of becoming a public charge at any time in the future.

In addition, rational basis scrutiny generally applies to immigration regulations applicable to aliens.[72] As set forth in NPRM,[73] DHS's public charge rule is rationally related to the government's interest to minimize the incentive of aliens to immigrate to the United States because of the availability of public benefits and to promote the self-sufficiency of aliens within the United States.[74]

Equally important, the public charge inadmissibility rule does not discriminate against or penalize U.S. citizens, including children. The public charge inadmissibility rule does not directly regulate the conduct of U.S. citizens because the grounds of inadmissibility do not apply to U.S. citizens. Moreover, this rule does not regulate eligibility for, or access to, public benefits. Neither the NPRM nor this final rule take into consideration receipt of public benefits by U.S. citizens who are part of the alien's household, including benefits received by U.S. citizen children. The receipt of public benefits by household members is not considered as part of an alien's application, although such receipt is excluded from the alien's household income, assets, and resources.

Furthermore, DHS disagrees that this rule is inconsistent with *Plyler* v. *Doe* and the other cited cases. *Plyler* does not apply to this rule. As courts have recognized, *Plyler* relates to distinctions made by states rather than the Federal Government.[75] Similarly, neither *Levy* v. *Louisiana* nor *Clark* v. *Jeter* is applicable here. These cases did not address the immigration status of children or Federal regulations. Instead, both cases

[69] 457 U.S. 202 (1982).

[70] *Mathews* v. *Diaz,* 426 U.S. 67, 81–82 (1976).

[71] *See* Homeland Security Act of 2002, Public Law 107–296, sec. 102, 116 Stat. 2135, 2142–44 (Nov. 25, 2002) (codified at 6 U.S.C. 112); INA section 103, 8 U.S.C. 1103.

[72] *See Korab* v. *Fink,* 797 F.3d 572, 577–79 (9th Cir. 2014) (''[F]ederal statutes regulating alien classifications are subject to the easier-to-satisfy rational-basis review . . . Although aliens are protected by the Due Process and Equal Protection Clauses, this protection does not prevent Congress from creating legitimate distinctions either between citizens and aliens or among categories of aliens and allocating benefits on that basis . . . The difference between state and federal distinctions based on alienage is the difference between the limits that the Fourteenth Amendment places on discrimination by states and the power the Constitution grants to the federal government over immigration.'') (citation omitted); *Lewis* v. *Thompson,* 252 F.3d 567, 570 (2d Cir. 2001), citing *Lake* v. *Reno,* 226 F.3d 141, 148 (2d Cir. 2000) (''We have recently recognized that a 'highly deferential' standard is appropriate in matters of immigration . . . .''). Generally, laws and regulations that neither involve fundamental rights nor include suspect classifications are reviewed under rational basis scrutiny, under which the person challenging the law must show that the government has no legitimate interest in the law or policy or that there is no rational link between the interest and the challenge law or regulation. *See also Heller* v. *Doe by Doe,* 509 U.S. 312, 319 (1993).

[73] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51122–23 (proposed Oct. 10, 2018).

[74] *See* 8 U.S.C. 1601.

[75] *See, e.g., Aleman* v. *Glickman,* 217 F.3d 1191, 1198 (9th Cir. 2000) (''*Plyler* [is] inapposite, however, because [it] involve[s] *state* classifications of aliens.'' (emphasis in the original)); *Rodriguez ex rel. Rodriguez* v. *U.S.,* 169 F.3d 1342, 1350 (11th Cir. 1999) (''*Plyler* is inapposite because it deals with a Fourteenth Amendment challenge to a *state's* classification of aliens.'' (emphasis in the original).

dealt with impacts of state laws on illegitimate children.[76]

5. Potential Disenrollment Impacts

Numerous commenters raised concerns about the rule's asserted ''chilling effect.'' Commenters indicated that the rule would cause aliens and citizens to either disenroll from public benefit programs or forego enrollment in public benefit programs, which would negatively impact the nation, states, local communities, families, vulnerable populations, and health care providers. Because most of these comments reflect the same theme, the discussion below provides a detailed breakdown of public comments separated by topic, followed by a consolidated DHS response.

Choice Between Public Benefits and Immigration Status

Commenters stated that the rule puts the country at risk by forcing choices no family should have to make. Commenters noted that alien parents will limit or forego their U.S. citizen children's receipt of public benefits to avoid adverse immigration consequences. Commenters stated that the rule would force eligible immigrants to withdraw their families from assistance programs for fear of adverse immigration consequences, which would undermine access to essential health, nutrition, and other critical benefits and services. Several commenters, expressing the view that no person in the United States should be denied federal assistance programs or public benefits, said that immigrants should not have to make impossible choices between their health or providing for their family's immediate needs and risking their immigration status or keeping their family together. Some commenters said that the proposed rule would cause patients diagnosed with cancer or HIV to choose between accessing needed health services or suffering adverse consequences with respect to their immigration status. A commenter stated that their state had the highest rate of insurance coverage in the nation, and that it is vital that patients and families continue to access care without fear of adverse immigration consequences. A number of commenters expressed concerns that families must choose between public housing or citizenship as a result of this rule.

Many commenters provided studies or data related to the current or potential number of individuals who will forego and/or disenroll from public benefit programs, including specific groups of individuals, such as children. Commenters involved in social services reported that they were already seeing immigrants refraining from accessing services in clinics, food banks, childcare centers, emergency shelters, and local school districts, including immigrants who are exempt from public charge inadmissibility. Several commenters said that the chilling effect would not be limited to immigrants subject to the proposed rule and would discourage many legal residents from utilizing services to which they are legally entitled, leading to negative health and economic outcomes. For example, a commenter said that refugees, who are automatically enrolled in Medicaid upon arrival in its state, may believe they will be deported if they re-enroll in Medicaid after their initial resettlement period. Some commenters said the rule may provide an incentive for U.S. citizens and lawful permanent residents to terminate their subsidized health care in order to remain eligible to petition for their family members living abroad.

General Assertions as to Effects

Commenters said that the rule's disenrollment effect would have lasting impacts on the health and safety of our communities and that immigrant families are experiencing significant levels of fear and uncertainty that has a direct impact on the health and well-being of children. Citing studies and research, many commenters asserted that the chilling effect will increase hunger, food insecurity, homelessness and poverty. They added that the chilling effect will also decrease educational attainment and undermine workers' ability to acquire new skills for in-demand occupations. Many commenters stated that negative public health, social, and economic outcomes (*e.g.,* hunger, food insecurity, decreased nutrition, unmet physical and mental health needs, unimmunized individuals, disease, decreased school attendance and performance, lack of education, poverty, homelessness) collectively damage the prosperity and health of our communities, schools, and country. Several commenters said that the rule would drive up uncompensated care costs, increase use of medical emergency departments, increase healthcare costs, endanger maternal and infant health and heighten the risk of infectious disease epidemics. One commenter indicated that the rule would make child poverty worse and harm communities as well as infrastructure that serves all of us.

Housing Benefit-Related Effects

Many commenters said some individuals will leave public housing as a result of this rule and become homeless or face housing instability. Commenter stated that the rule will cause disenrollment from subsidized housing programs, which will create additional costs for local governments. Commenters stated that the chilling effect on using HCVs will cause the loss of ''wraparound services'' for residents, including case management, mental healthcare, peer support, and child care. Commenters raised concerns about the effects of housing insecurity in specific cities, including health problems and downstream economic impacts. One commenter stated that while the proposed public charge rule does not directly count benefits received by the U.S. citizen children of immigrant parents, it would still interfere with the ability of U.S. citizens to receive housing assistance, because many citizens live in mixed-status households with individuals who are subject to the public charge ground of inadmissibility.

Food and Nutrition Benefit-Related Effects

Commenters noted that disenrollment from programs like SNAP would worsen food insecurity in the United States. Some commenters provided estimates of the number of children in certain states or cities currently accessing SNAP benefits who could be affected by the rule. Several commenters stated that the proposed rule would force millions of children and families to disenroll from the SNAP program. For example, one commenter cited a study that found that 2.9 million U.S. citizen children would forego SNAP benefits as a result of the proposed public charge rule. Another commenter stated that research shows that immigrants' loss of eligibility reduced participation in the ''Food Stamp Program'' among U.S.-born children of immigrants by 50 percent and reduced the average benefits they received by 36 percent. Some commenters stated that including SNAP in the public charge determination would worsen food insecurity primarily among families with older adults, children, and people with disabilities. Many commenters opined that the inability of individuals in need to access food assistance programs like SNAP would impact health outcomes and those health outcomes would impact healthcare utilization rates and costs. A few commenters emphasized that disenrollment from programs such as SNAP and Special Supplemental Nutrition Program for Women, Infants,

[76] *Levy* v. *Louisiana,* 391 U.S. 68 (1968); *Clark* v. *Jeter,* 486 U.S. 456 (1988).

and Children, (WIC) would specifically put children at risk for learning difficulties, increased emergency room visits, chronic asthma, and other diseases and would cause a steep decline in the health and well-being of pregnant women and infants.

Several commenters noted that the rule would increase the number of individuals seeking help from state and local non-profit feeding programs, which would burden local government facilities, volunteer-lead organizations and food pantries and compromise the amount and quality of nutritious food provided. Some commenters added that restricting access to nutrition benefits could make things harder in communities with high volumes of homeless residents.

Some commenters said decreased participation in SNAP or Medicaid will likely have a profound impact on WIC's ability to serve all eligible participants by introducing new barriers to access and heaping additional costs on WIC agencies. A few commenters stated that disenrollment from WIC could be as high as 20 percent. A commenter stated that enrollment in WIC dropped from 7.4 million to 6.8 million from January to May 2018, and the commenter stated that families feel forced to decide between their safety as immigrants and the food and services that their children need.

Health Benefit-Related Effects

A commenter opposed the rule, stating that DHS failed to present anything in the proposed rule that would discredit, or justify ignoring, the evidence in the 1999 Interim Field Guidance that aliens' reluctance to receive benefits for which they are eligible will have a negative impact on public health and general welfare. Commenters expressed concern that the rule would undo historic gains in health coverage and associated positive health outcomes over the past few years. Some commenters stated that the proposed rule would result in immigrants staying away from social service agencies and will negatively impact health in many ways. Another commenter noted that the rule will cause people to get sick or go hungry and indicated that ''penalizing'' immigrants who utilize benefits to support their family only worsens racial, gender, and economic inequality.

A number of commenters cited the Kaiser Family Foundation study, which provided estimates on Medicaid/Children's Health Insurance Program (CHIP) disenrollment. The Kaiser Family Foundation estimated that if the proposed rule leads to Medicaid disenrollment rates ranging from 15 percent to 35 percent, then between 2.1 million and 4.9 million Medicaid/CHIP enrollees living in a family with at least one noncitizen would disenroll. Many commenters said that DHS vastly underestimates the numbers of people who will disenroll from Medicaid and warned that DHS was underestimating the ''negative consequences'' in the proposed rule. Collectively, these commenters described the positive health and economic benefits associated with health coverage through programs like Medicaid. They also highlighted research findings about the dangers associated with being uninsured. They warned that decreased participation in Medicaid would lead to decreased utilization of preventative services, worse health outcomes and financial standing for families and children, increased health spending on preventable conditions, and heightened strain on the healthcare system.

Other commenters said the inclusion of Medicare Part D in the rule will cause affected individuals to disenroll or otherwise be restricted from Medicare access, resulting in negative health outcomes for individuals and communities (*e.g.,* increased uninsured rated, decreased access to prescriptions). Another commenter said that seniors who use Medicare Part D will be deterred from filling prescriptions, which could increase acute care and overall healthcare costs. Several commenters stated that the sanctions associated with the use of Medicaid and Medicare Part D benefits would result in reduced access to medical care and medications for vulnerable populations, including pregnant women, children, people with disabilities, and the elderly. A couple of commenters said the inclusion of Medicare Part D would punish immigrants for accessing healthcare services. Another commenter said the proposed rule would dissuade thousands of low-income residents in its state from seeking health coverage.

Effects on Vulnerable Populations

Many commenters said that reduced enrollment in federal assistance programs would most negatively affect vulnerable populations, including people with disabilities, the elderly, children, survivors of sexual and domestic abuse, and pregnant women. Some of these commenters suggested that the chilling effect associated with the proposed rule would cause vulnerable individuals and families to avoid accessing services, even if they are legally residing in the United States and not subject to the proposed rule. Several commenters said the proposed rule would adversely affect immigrant women, because they will be more likely to forego healthcare and suffer worsening health outcomes. A comment described the detrimental impact of reduced Medicaid enrollment on maternal and infant health. Multiple commenters said the proposed rule would lead to negative health outcomes in general, but especially for pregnant and breastfeeding women, infants, and children. Another commenter indicated that refugees and victims of trafficking, who are exempt from public charge, would also disenroll because of fear and gave the example that in 1996 the use of TANF fell 78 percent among the refugee population despite the fact that refugees were not subject to the public charge test.

Several commenters said the health of children is inextricably linked to the health of their parents, asserting that parents who are enrolled in health insurance are more likely to have children who are insured. Some of these commenters went on to say that disenrollment from health insurance by parents will result in a loss of coverage and access to preventive healthcare for their children. A couple of commenters said that they were already seeing these consequences due to confusion over the proposed rule, including parents choosing to avoid needed health services for their children. A couple of commenters said every child in America should have access to quality, affordable healthcare.

Many commenters, citing studies and research, stressed the chilling effect of this rule will negatively affect the health and well-being of children. Other commenters cited a study that predicted the numbers of children who would disenroll from Medicaid and included figures on the numbers of children with various medical conditions in need of medical attention. Healthcare providers said uninsured children would be less likely to receive preventative care and necessary treatment, and generally would be less healthy compared to children with health insurance. Several commenters said that fewer children with disabilities would receive home and community based services, because Medicaid covers these services. Another commenter said that many children receive critical dental services through Medicaid and that a lack of access to these services can cause oral diseases that impact diet, emotional well-being, sleep, and the ability to work and study.

Several commenters voiced concern about the adverse impact on Medicaid-funded health services in schools. A few commenters provided data on the

funding school districts receive from Medicaid for school-based health services and the numbers of students who benefit from these programs. The commenters pointed out that this funding is tied to the number of Medicaid-eligible students enrolled. Many commenters said the proposed rule's exemption of school-based health services was insufficient given the larger repercussions of the chilling effect and the likelihood that many children would be disenrolled. Commenters said that schools would need to provide healthcare and special education to children regardless of whether the school could request payment from Medicaid for such services. These commenters further stated that the school would need to use local funds to cover the cost of services that Medicaid would ordinary cover because parents would be unwilling to give consent to the school to enroll the children in Medicaid. Some commenters said special education administrators routinely engaged with families around issues related to health, wellness and school attendance, and said the proposed rule would diminish many students' chances for academic success. A commenter said that it was important for schools to create safe, supportive and inclusive communities, and that the proposed rule could undermine efforts to accomplish this goal. One commenter said Medicaid covers behavioral treatments for children and that providers often partner with schools who are not equipped to provide these targeted services. Two commenters said that the language of the proposed rule was concerning for children who receive services through the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program, which is a federally mandated benefit that provides children with the routine and preventive care services they need to grow into healthy adults.

Effects on U.S. Citizens

Several commenters said that rule would cause the greatest harm to U.S. citizen children of immigrant parents. Many commenters said that U.S. citizen children need SNAP, CHIP, Medicaid, food stamps, and other public benefits to survive if their immigrant parents cannot afford such services, and U.S. citizen children have a right to these benefits. A commenter said research demonstrates that barriers to participation in public programs like Medicaid that affect immigrants also have harmful spillover effects on U.S. citizens, because many U.S. citizens live in mixed-status households. The commenter stated that in these cases, research shows that U.S. citizens in the household are less likely to obtain needed services such as health insurance through Medicaid due to concerns about the immigration status of other family members. A number of commenters said the rule would discourage U.S. citizens who live in mixed-status households from accessing assistance programs for which they are eligible, including Medicaid and CHIP, or deprive them of the benefits of those programs entirely.

Increased Costs to Health Care Providers, States, and Localities

Many commenters particularly emphasized that disenrollment or foregoing enrollment would be detrimental to the financial stability and economy of communities, States, local organizations, hospitals, safety net providers, foundations, and healthcare centers. Commenters offering estimates on the number of people who would disenroll from Medicaid under the proposed rule warned that the costs associated with the resultant rise in uncompensated care would be borne by health systems, hospitals, and insured patients. A commenter said that this situation presents an ethical dilemma for physicians counseling patients on treatment options, who are ''already beginning to field questions from patients and are having to explain the immigration risks of using healthcare services.'' A commenter citing research that found a high percentage of emergency room visits could be managed in physicians' offices warned that the proposed rule would increase costly emergency room usage.

A couple of commenters said that Medicaid was the largest source of funding for community health centers and provided estimates of financial losses due to reduced Medicaid reimbursement. A commenter said that Medicaid and CHIP were the underpinning for reimbursement for pediatric subspecialists. Commenters stated that the proposed rule would impact their reimbursements and would force them to cut patient services. One of these commenters cited a study on the anticipated reductions in services, which included an estimated $17 billion reduction in hospital payments. Other commenters said that Medicaid enables many individuals to access needed behavioral health services and that a rise in uncompensated care will diminish providers' ability to render these services. A commenter said reductions in federal funding for Medicaid and Medicare resulting from decreased enrollment would force States to increase funding levels, a challenge that could potentially lead to increased wait list times, rolling enrollment freezes, and other program cuts that would impact the broader health system.

Response: With respect to the rule's potential ''chilling effects'' or disenrollment impacts, DHS notes that (1) the rule's overriding consideration, *i.e.,* the Government's interest as set forth in PRWORA, is a sufficient basis to move forward; (2) it is difficult to predict the rule's disenrollment impacts with respect to the regulated population, although DHS has attempted to do so in the accompanying Final Regulatory Impact Analysis; and (3) it is also difficult to predict the rule's disenrollment impacts with respect to people who are not regulated by this rule, although, again, DHS has attempted to do so in the accompanying Final Regulatory Impact Analysis.

First, as discussed above, this rule is rationally related to the Government's interest, as set forth in PRWORA, to: (1) Minimize the incentive of aliens who attempt to immigrate to, or adjust status in the United States due to the availability of public benefits; and (2) Promote the self-sufficiency of aliens within the United States.[77] DHS has defined public benefits by focusing on cash assistance programs for income maintenance, and an exhaustive list of non-cash food, housing, and healthcare, designed to meet basic living needs. This definition does not include benefits related exclusively to emergency response, immunization, education, or social services, nor does it include exclusively state and local non-cash aid programs. DHS acknowledges that individuals subject to this rule may decline to enroll in, or may choose to disenroll from, public benefits for which they may be eligible under PRWORA, in order to avoid negative consequences as a result of this final rule. However, DHS has authority to take past, current, and likely future receipt of public benefits into account, even where it may ultimately result in discouraging aliens from receiving public benefits.

Although individuals may reconsider their receipt of public benefits as defined by this rule in light of future immigration consequences, this rule does not prohibit an alien from obtaining a public benefit for which he or she is eligible. DHS expects that aliens seeking lawful permanent resident status or nonimmigrant status in the United States will make purposeful and well-informed decisions commensurate with the immigration status they are seeking. But regardless,

[77] *See* 8 U.S.C. 1601.

DHS declines to limit the effect of the rulemaking to avoid the possibility that individuals subject to this rule may disenroll or choose not to enroll, as self-sufficiency is the rule's ultimate aim.

Second, DHS finds it difficult to predict how this rule will affect aliens subject to the public charge ground of inadmissibility, because data limitations provide neither a precise count nor reasonable estimate of the number of aliens who are both subject to the public charge ground of inadmissibility and are eligible for public benefits in the United States. This difficulty is compounded by the fact that most applicants subject to the public charge ground of inadmissibility and therefore this rule are generally unlikely to suffer negative consequences resulting from past receipt of public benefits because they will have been residing outside of the United States and therefore, ineligible to have ever received public benefits. For example, most nonimmigrants and most immediate relative, family-sponsored, and diversity visa immigrants seek admission to the United States after issuance of a nonimmigrant or immigrant visa, as appropriate.[78] The majority of these individuals are likely to have been ineligible for public assistance in the United States, because they generally have resided abroad and are not physically present in the United States.

Aliens who are unlawfully present and nonimmigrants physically present in the United States also are generally barred from receiving federal public benefits other than emergency assistance.[79] For example, applicants for admission and adjustment of status—are generally ineligible for SNAP benefits and therefore, would not need to disenroll from SNAP to avoid negative consequences.[80] Once admitted, lawful permanent residents are generally prohibited from receiving SNAP benefits for a period of five years.[81] Notwithstanding the inclusion of SNAP as a designated public benefit, DHS will not consider for purposes of a public charge inadmissibility determination whether applicants for admission or adjustment of status are receiving food assistance through other programs, such as exclusively state-funded programs, food banks, and emergency services, nor will DHS discourage individuals from seeking such assistance.

DHS recognizes a plausible connection between the NPRM and reduction in alien enrollment in WIC to the extent that aliens who are subject to public charge inadmissibility are also eligible to receive WIC benefits. While DHS did not list WIC as a designated public benefit under proposed 8 CFR 212.21(b), DHS also did not expressly exclude WIC from consideration as a public benefit. Indeed, DHS sought public comments on whether an alien's receipt of benefits other than those proposed to be included in this rule as public benefits should nonetheless be considered in the totality of circumstances, which understandably could have given the impression that DHS was contemplating the inclusion of WIC among other public benefits. This final rule makes clear that WIC will not be an enumerated public benefit under 8 CFR 212.21(b).

DHS also acknowledges that under the NPRM, certain lawfully present children and pregnant women [82] in certain states and the District of Columbia might have chosen to disenroll from or forego enrollment in Medicaid if they are otherwise eligible to maintain or pursue an immigration benefit and are subject to public charge inadmissibility. As noted above, however, this final rule exempts receipt of Medicaid by such persons.

Third, DHS finds it difficult to predict the rule's disenrollment impacts with respect to people who are not regulated by this rule, such as people who erroneously believe themselves to be affected. This rule does not apply to U.S. citizens and aliens exempt from public charge inadmissibility. In the proposed rule, DHS provided an exhaustive list of immigration classifications that are exempt from the public charge ground of inadmissibility, and this final rule retains those exemptions. DHS is including in the Applicability section of this final rule Tables 3 and 4 that are similar to those included in the NPRM, which also reflect additional clarifications made in this final rule with respect to T, U, and VAWA aliens. This rule does not prohibit or otherwise discourage individuals who are not subject to the public charge inadmissibility from receiving any public benefits for which they are eligible.

Because DHS will not consider the receipt of public benefits by U.S. citizens and aliens not subject to public charge inadmissibility, the receipt of public benefits by these individuals will not be counted against or made attributable to immigrant family members who are subject to this rule. Accordingly, DHS believes that it would be unwarranted for U.S. citizens and aliens exempt from public charge inadmissibility to disenroll from a public benefit program or forego enrollment in response to this rule when such individuals are not subject to this rule. DHS will not alter this rule to account for such unwarranted choices.

DHS appreciates the potential effects of confusion regarding the rule's scope and effect, as well as the potential nexus between public benefit enrollment reduction and food insecurity, housing scarcity, public health and vaccinations, education health-based services, reimbursement to health providers, and increased costs to states and localities. In response to comments, DHS will also issue clear guidance that identifies the groups of individuals who are not subject to this rule, including, but not limited to, U.S. citizens, lawful permanent residents returning from a trip abroad who are not considered applicants for admission, and refugees.

In addition, as explained in greater detail elsewhere in this rule, DHS has made a number of changes in the final rule that may mitigate some of the concerns raised by the public regarding disenrollment impacts. For example, DHS has excluded the Medicare Part D LIS from the definition of public benefit because DHS has determined that Medicare Part D benefits, including LIS, are earned by working or being credited with 40 qualifying quarters of work and establishing eligibility for Medicare. While children are not exempt from public charge inadmissibility, DHS has decided against the inclusion of CHIP in the definition of public benefit. DHS has

[78] The United States admitted over 541 million nonimmigrants between Fiscal Years 2015 and 2017. See DHS, Yearbook of Immigration Statistics 2017, Table 25. Nonimmigrant Admissions by Class of Admission: Fiscal Years 2015 to 2017, available at *https://www.dhs.gov/immigration-statistics/yearbook/2017/table25*. Among immediate relative, family sponsored, and diversity visa immigrants who acquired lawful permanent resident status between Fiscal Years 2015 and 2017, sixty-seven percent were admitted to the United States and thirty-three percent adjusted their status in the United States. See DHS, Yearbook of Immigration Statistics 2017, Table 6, Persons Obtaining Lawful Permanent Resident Status by Type and Major Class of Admission: Fiscal Years 2015 to 2017, available at *https://www.dhs.gov/immigration-statistics/yearbook/2017/table6*. The 2017 Yearbook of Immigration Statistics is a compendium of tables that provide data on foreign nationals who are granted lawful permanent residence (*i.e.,* immigrants who receive a ''green card''), admitted as temporary nonimmigrants, granted asylum or refugee status, or are naturalized.

[79] DHS understands that certain aliens may be eligible for state-funded cash benefits. As there are multiple state, local, and tribal programs that may provide cash benefits, DHS does not have a specific list of programs or data on the number of aliens that may be affected by the rule by virtue of their enrollment in such programs.

[80] *See* 8 U.S.C. 1611(a); 8 U.S.C 1612(a)(2)(D)(ii).

[81] *See* 8 U.S.C. 1613(a).

[82] U.S. Department of Health and Human Services, Centers for Medicaid and Medicare Services, Medicaid and CHIP Coverage of ''Lawfully Residing'' Children and Pregnant Women (July 1, 2010), *https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO10006.pdf* (last visited May 7, 2019).

excluded from the public benefits definition, public benefits received by children eligible for acquisition of citizenship, and Medicaid benefits received by aliens under the age of 21 and pregnant women during pregnancy and 60 days following the last day of pregnancy.

In sum, DHS does not believe that it is sound policy to ignore the longstanding self-sufficiency goals set forth by Congress or to admit or grant adjustment of status applications of aliens who are likely to receive public benefits designated in this rule to meet their basic living needs in an the hope that doing so might alleviate food and housing insecurity, improve public health, decrease costs to states and localities, or better guarantee health care provider reimbursements. DHS does not believe that Congress intended for DHS to administer section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), in a manner that fails to account for aliens' receipt of food, medical, and housing benefits so as to help aliens *become* self-sufficient. DHS believes that it will ultimately strengthen public safety, health, and nutrition through this rule by denying admission or adjustment of status to aliens who are not likely to be self-sufficient.

6. Inconsistent With American Values and Historic Commitment to Immigrants

Comment: Several commenters said the rule puts immigration and/or obtaining ''green cards'' out of reach for working class or poor immigrant families and re-shapes, penalizes, or impedes legal immigration. Many commenters said the rule goes against fundamental American values and morality, including religious values and principles of faith, upon which this nation was built. Many commenters stated the importance of diversity and immigration to United States' history and strength, and expressed that the rule would fundamentally change our nation's historic commitment to welcoming immigrants where the United States would no longer be the country that serves as a beacon for the world's dreamers and strivers. Many commenters pointed out that many immigrants here today would not have been able to enter the country under the proposed rule. Several commenters said that the United States should be receptive to those seeking a better life in the United States and should not seek to penalize them, especially to those fleeing violence. One commenter stated that the rule will force more people to live in the shadows. Two commenters expressed that the rule is scapegoating, is the result of Congress' failure to compromise on immigration policy, and is not a solution to immigration reform. Two other commenters said that the rule is motivated by fear and greed.

Response: While immigration and diversity have strengthened the United States, DHS strongly disagrees that this rule is motivated by fear or greed, or is un-American or immoral. DHS does not seek to frustrate the United States' long-standing commitment to family unity, humanitarian relief, and religious liberty through this rule. DHS also disagrees that this rule re-shapes, penalizes, or impedes the overall flow of legal immigration, and disagrees that the rule puts lawful permanent resident status beyond the reach of working-class and poor immigrant families. DHS reiterates that this rule does not and cannot alter the process of obtaining immediate relative, family-sponsored, employment-based, diversity, or nonimmigrant visas, as required and permitted by law. Rather, this rule clarifies the standard by which DHS will assess whether an alien subject to section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), is inadmissible as likely to become a public charge at any time in the future. Through this final rule, DHS seeks to better ensure that applicants are self-sufficient. Even if an applicant has a low income, or belongs to a low-income family, that is only one consideration in the totality of the circumstances. Even if an applicant has household income that falls below 125 percent of FPG, DHS must consider the applicant's age, health, family status, education, and skills in determining whether the applicant is more likely than not to become a public charge at any time in the future. DHS also notes that the public charge inadmissibility ground does not apply to all applicants who are seeking a visa, admission, or adjustment of status. Congress specifically exempted certain groups, *e.g.,* refugees and asylees at the time of admission and adjustment of status, pursuant to sections 207(c)(3) and 209(c) of the Act, 8 U.S.C. 1157(c)(3), 1159(c).

7. Contributions to American Society and Consideration of Self-Sufficiency

Comment: Commenters stated that immigrants already significantly contribute to the economy, citing IRS data showing how much income tax the IRS received from immigrants and undocumented workers. Many commenters said that DHS should evaluate immigrants based on their contributions to communities in the United States and not based on their income level or financial status. Many commenters stated that the rule would negatively affect immigrants who contribute to the American economy, including satisfying this country's need for younger workers. Several commenters stated that immigrants take jobs that Americans are not willing to perform (*e.g.,* landscaping, construction, caregivers, manufacturing) and that immigrants are hardworking and contributing members that increase the diversity of our culture and communities.

Several commenters stated that use of public benefits in a manner commensurate with their purpose should not be ''punishable.'' They emphasized that immigrants want to work and be self-sufficient, but that immigrants access public assistance programs to help them through periods of temporary hardship on the path to self-sufficiency and successfully contributes to society just as U.S. citizens do, if not less so. They added that immigrants often need public assistance due to insecure jobs, inadequate wages, lack of employer-sponsored health insurance, the high cost of medical care and housing, inaccessibility of health insurance, and other societal barriers. Multiple commenters provided anecdotes about how they or their family member's receipt of federal assistance helped them or their children go on to thrive and become productive members of American society. Similarly, some commenters told personal anecdotes about their interactions with hardworking immigrants who rely on temporary public assistance to survive and contribute to society. A few commenters added that a large portion of U.S. born citizens would not meet the public charge standards proposed by DHS.[83]

Response: DHS believes that immigrants, in general, make significant contributions to American society and enhance the culture of American life and communities. DHS also recognizes that public assistance programs provide food and nutrition, housing, and healthcare, and other benefits that meet individual needs, serve the public interest, and help people to become productive members of society. The relevant inquiry that this rule aims to address, however, is whether an applicant who is subject to the public charge ground of inadmissibility is likely to become a public charge at any time in the future. DHS believes that an alien who uses certain types of public benefits for the more than 12 months

[83] USCIS–2010–0012–0151; USCIS–2010–0012–0264; USCIS–2010–0012–1689; USCIS–2010–0012–13212 (Form Letter Master).

within a 36 month period of time can reasonably be said to lack self-sufficiency because her or she cannot meet his or her basic living needs. DHS has limited the type of public benefits to generally means-tested benefits that provide cash for income maintenance or meet the basic living needs of food and nutrition, housing, and healthcare. DHS believes that receipt of these public benefits alone for more than 12 months in the aggregate within any 36-month period suggests a lack of self-sufficiency, as such receipt exceeds what could reasonably be defined as a nominal or temporary need.

8. Adjudication and Processing

Comment: Multiple commenters stated that the rule would exacerbate USCIS and immigration court processing backlogs. Other commenters stated that the proposed rule outlined a process that was confusing at best, and would increase the number of appeals and deepen nationwide immigration processing delays. Similarly, several commenters said the rule, while not binding on the immigration courts, would further exacerbate an already record high case volume in the immigration courts. They further expressed concerns that increased evidentiary requirements, heightened scrutiny, and uncertainty as to what standard to apply, will delay adjudications, add to the backlog and result in inconsistent outcomes. One commenter said that this rule will further delay visa processing. Some commenters asserted that the proposed changes would greatly complicate the adjudication process by placing a greater burden on individuals who will be required to provide more evidence and paperwork to establish that they are not likely at any time to become a public charge and will require adjudicators to spend more time sifting through and verifying information. Several commenters stated that the rule's heightened evidentiary requirements and totality of the circumstances standard would exacerbate backlogs and cause uncertainty in adjudications.

Several commenters provided data on current processing times and estimated processing times under the proposed rule. Commenters stated that families would suffer the consequences of case processing delays such as job loss and food insecurity. Several commenters cited studies and stated that the increased processing times would hinder immigrants' ability to become or remain self-sufficient because the delays could financially impair immigrants during the time they could not legally work.

A commenter wrote that the backlog for adjustment of status reviews was already significant, and new requirements in the proposed rules would simply exacerbate those conditions. A commenter stated that immigration officers and consular officers will have a limited amount of time to properly review documents and employment letters, and will not undertake an effective, case-by-case appraisal of applications. Similarly, supervising officers will not have enough time to review each denial thoroughly.

Response: As noted by commenters, this rule is not binding on the immigration courts or the Board of Immigration Appeals (BIA). It is DHS's understanding that DOJ is developing a public charge proposed rule, which would address DOJ's standard for assessing public charge inadmissibility and deportability. DHS will work with DOJ to ensure consistent application of the public charge ground of inadmissibility. DHS reiterates, however, that this final rule pertains only to public charge inadmissibility determinations made by DHS for applicants seeking admission or adjustment of status, public charge bonds, as well the conditions DHS has set for nonimmigrants applying for an extension of stay or change of status with USCIS. DHS believes that concerns about DOJ's adjudication of cases pending before immigration courts, including immigration court backlogs, are more appropriately addressed by DOJ in the context of their public charge rulemaking.

With respect to commenters' concerns that the DHS final rule would result in inconsistent outcomes, DHS disagrees with the assertion that the rule will lead to inconsistent determinations, or that it creates confusion, in a way that is at all inconsistent with congressional intent. Given the wording of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), which states that the public charge inadmissibility determination is ''in the opinion of'' the Attorney General and based on consideration of a range of circumstances particular to the alien, DHS believes that the determination is inherently subjective in nature.[84] Because each case will be determined on its own merits, and applicants' individual circumstances will vary, it is reasonable to expect that public charge inadmissibility determinations will vary.

Additionally, while the rule may increase USCIS processing times, such is the burden of robust enforcement of the law. USCIS is committed to timely, accurate, and lawful adjudications, and plans to increase resources for affected applications as appropriate. USCIS, as a fee funded agency, may set fees to support the additional workload associated with adjudication of cases subject to section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). USCIS officers will receive training on the new standards set forth in this final rule, which will include training on how to treat public benefits received before the effective date of this rule. Any increases to adjudication time will not affect an applicant's ability to apply for an employment authorization document if otherwise eligible.[85]

Finally, with respect to comments regarding visa processing time for consular officers, DHS believes that such matters are more appropriately addressed by DOS. This rule only addresses DHS's public charge inadmissibility determinations in applications for admission or adjustment of status. However, it is DHS's understanding that DOS will update its FAM to ensure consistency with the DHS rule.

Comment: Many commenters addressed concerns about the adjudication of extension of stay and change of status applications, adjudication delays, and the uncertainty of being able to obtain a future status when seeking an extension of stay or change of status. Some commenters stated that the proposed rule failed to identify the potential Request for Evidence (RFE) and denial rate for applicants. Similarly, commenters stated that the proposed rule's RFE provision would cause significant uncertainty for employers, create obstacles to effective business planning, and increase costs for employers because of potential processing delays and backlogs. Many commenters raised concerns about adjudication delays for workers and other nonimmigrant categories, such as H–2A nonimmigrant workers and their employers, and other categories.

[84] *See Matter of Harutunian,* 14 I&N Dec. 583, 588 (Reg'l Cmm'r 1974) (''[T]he determination of whether an alien falls into that category [as likely to become a public charge] rests within the discretion of the consular officers or the Commissioner . . . Congress inserted the words 'in the opinion of' (the consul or the Attorney General) with the manifest intention of putting borderline adverse determinations beyond the reach of judicial review.'' (citation omitted)); *Matter of Martinez-Lopez,* 10 I&N Dec. 409, 421 (Att'y Gen. 1962) (''[U]nder the statutory language the question for visa purposes seems to depend entirely on the consular officer's subjective opinion.'').

[85] 8 CFR 274a.12(c)(9).

Response: DHS does not anticipate any significant processing delays in the adjudication of extension of stay and change of status requests filed by or on behalf of nonimmigrants based on the new conditions imposed in the rule relating to the past and current receipt of public benefits. This is especially so in light of that fact that DHS is removing the requirement that an officer assess the alien's likelihood of receiving public benefits in the future and that USCIS will no longer seek to request that the alien submit Form I–944. Overall, DHS is committed to ensuring that USCIS has the necessary resources to provide for the timely adjudication of immigration benefits. Additionally, USCIS believes that the number of RFEs actually issued relating to these rule changes will be relatively small as long as the employers and petitioners/beneficiaries submit properly documented petition.

9. Privacy Concerns

Comment: A commenter expressed concern about the lack of clarity on how DHS plans to use, store, access and protect the health data it receives. The commenter stated that copies of medical records provided by applicants may contain highly sensitive information unrelated to the immigration application or the likelihood of the person becoming a public charge. A few commenters expressed concern that the proposed rule's use of health insurance information and data raises data and privacy concerns, stating USCIS would accumulate an overbroad body of data, and this could violate the Health Insurance Portability and Accountability Act (HIPAA).

Response: DHS rejects the comment that the rule raises data and privacy concerns that could violate HIPAA. Congress mandated that DHS consider an applicant's health as part of every public charge inadmissibility determination.[86] In order to assess an alien's health in the totality of the circumstances, DHS will generally rely on medical information provided by civil surgeons on the Report of Medical Examination and Vaccination Record (Form I–693), or report of a panel physician, to assess whether the alien has been diagnosed with a medical condition that is likely to require extensive medical treatment or institutionalization, or that will interfere with the alien's ability to provide and care for himself or herself, to attend school, or to work, upon admission or adjustment of status. DHS will also consider whether the alien has resources to pay for reasonably foreseeable medical costs.

In other words, DHS will be relying on existing medical reports and information submitted with the alien's applications; such information, once submitted by the alien, will become a part of the alien's administrative record. Such data is collected and maintained consistent with the Privacy Act of 1974 [87] (Privacy Act) and the System of Records Notice (SORN), which identifies the purpose for which Personally Identifiable Information (PII) is collected, from whom and what type of PII is collected, how the PII is shared externally (routine uses), and how to access and correct any PII maintained by DHS.[88]

Additionally, while USCIS is generally not a covered entity bound by HIPAA,[89] USCIS complies with the Privacy Act in safeguarding information in the applicable systems of records. Such information is generally confidential and is used primarily for immigration purposes.[90] The data is collected and kept in an alien's administrative record consistent with the Privacy Act,[91] which applies to information that is maintained in a ''system of records'' from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

E. General Comments Regarding Legal Authority and Statutory Provisions

1. Lack of Statutory Authority/ Inconsistent With Congressional Intent

Comment: Several commenters said DHS lacks statutory authority to promulgate the NPRM. Multiple commenters stated the rule is an over-reach, requires congressional consideration, involvement, or approval, and that only Congress can enact such specific policy changes. One commenter stated that the rule's attempt to change public charge policy in a regulation rather than in legislation is inconsistent with the Administration's stated goal to reduce the power of administrative agencies.

Response: The public charge inadmissibility rule is within DHS's authority and does not require congressional action. The Secretary has the authority to enforce and administer the immigration laws of the United States.[92] The Secretary is also authorized to prescribe regulations, forms, and instructions necessary to carry out the authority provided in section 103(a)(1) of the Act, 8 U.S.C. 1103(a)(1).[93] Additionally, the Secretary is charged with administering the public charge ground of inadmissibility. Therefore, this rule does not exceed or overreach the Secretary's authority, and further, does not require congressional involvement, consideration, or approval.

This public charge inadmissibility rule is a permissible implementation of the public charge inadmissibility statute enacted by Congress.[94] The public charge inadmissibility rule provides important guidance for purposes of implementing the statute, including by defining statutory terms that have never been defined by Congress in the over 100 years since the public charge inadmissibility ground first appeared in the immigration laws.

DHS believes the terms set forth in the public charge inadmissibility ground need clarification so that DHS can consistently adjudicate applications subject to public charge inadmissibility determinations in a manner that better ensures aliens are self-sufficient and not reliant on the government (*i.e.,* public benefits) for assistance to meet their basic needs.[95]

Finally, DHS disagrees that the public charge rule is inconsistent with the Administration's goals to reduce the role of executive agencies. The rule's

[86] *See* INA 212(a)(4), 8 U.S.C. 1182(a)(4).

[87] *See* 5 U.S.C. 552.

[88] *See generally* Notice of Modified Privacy Act System of Records, 82 FR 43556, 43564 (Sept. 18, 2017) (''DHS/USCIS safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. USCIS has imposed strict controls to minimize the risk of compromising the information that is being stored.'').

[89] *See* 45 CFR 160.103.

[90] *See also* E.O. No. 13768, Enhancing Public Safety in the Interior of the United States 82 FR 8799, 8802 (Jan. 30, 2017). Section 14 of E.O. 13768 limits the rights and protections of the Privacy Act, subject to applicable law, to U.S. citizens and lawful permanent residents. *See also* DHS Privacy Policy Regarding Collection, Use, Retention, and Dissemination of Personally Identifiable Information (Apr. 25, 2017), *https://www.dhs.gov/sites/default/files/publications/PPGM%202017-01%20Signed_0.pdf* (last visited May 8, 2019). The latter memorandum sets out DHS policy requiring that decisions regarding the collection, maintenance, use, disclosure, retention, and disposal of information being held by DHS must be consistent with and take into consideration the Fair Information Practice Principles: Transparency, Individual Participation, Purpose Specification, Data Minimization, Use Limitation, Data Quality and Integrity, Security, and Accountability and Auditing.

[91] *See* 5 U.S.C. 552.

[92] INA section 103(a)(1), 8 U.S.C. 1103(a)(1).

[93] INA section 103(a)(3), 8 U.S.C. 1103(a)(3).

[94] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[95] *See* 8 U.S.C. 1601.

aims are consistent with the Administration's goal of rigorously enforcing all grounds of inadmissibility.[96]

Comment: A number of commenters stated that the rule is generally inconsistent with Congress' intent and past policies. Commenters said the proposed rule is a significant, unjustified change from the current public charge policy. One commenter said that DHS should not re-interpret a term that Congress had left undefined, and said that if future administrations similarly revised policy based on their understanding of congressional intent, such policy would ''change wildly with every administration,'' and would result in ''vast inconsistencies in the law.'' A commenter specifically stated that the rule is an ''unlawful attempt to rewrite Congress's rules'' and that DHS cannot ''exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law'' and needs to comply with Congress's intent in creating the public charge inadmissibility ground. One commenter said the proposed rule would effectively overturn decades of congressional and State decision-making regarding alien access to public benefits with one unilateral executive action. Multiple commenters said the rule is contrary to, or inconsistent with, current law, congressional intent, and the traditional interpretation of public charge, as well as inconsistent with the history of how public charge has been understood. One commenter noted that DHS's contention that ''Congress 'must have recognized that it made certain public benefits available to some aliens who are also subject to the public charge ground of inadmissibility, even though receipt of such benefits could render the alien inadmissible as likely to become a public charge' . . . strains credulity and is simply not a reasonable interpretation of the statutes, as required by *Chevron, U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837 (1984).''

Response: This rule is not inconsistent with Congress' intent in enacting the public charge ground of inadmissibility in IIRIRA, or in enacting PRWORA. DHS believes that the policy goals articulated in PRWORA and underlying the creation of the mandatory factors for public charge inadmissibility determinations in IIRIRA inform DHS's administrative implementation of the public charge ground of inadmissibility. When passing IIRIRA, Congress added factors to consider in public charge inadmissibility determinations in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4)), but left it to DHS and DOJ to specify how and which public benefits should be considered in a public charge inadmissibility determination.[97] In the same year, Congress passed PRWORA with the clear intent to promote self-sufficiency of those entering the United States and to ensure that public benefits do not provide an incentive for immigration to the United States.[98] This public charge inadmissibility rule, in accordance with PRWORA, disincentivizes immigrants from coming to the United States in reliance on public benefits.[99] As explained in the NPRM and this final rule, DHS agrees that this rule takes a different approach to interpreting the public charge ground of inadmissibility than the 1999 Interim Field Guidance. In the NPRM, DHS acknowledged that it was making a change and provided a detailed explanation and justification for that change. Therefore, DHS disagrees that these changes are unjustified.

With respect to commenter statements that the rule departs from the historical and traditional understanding of what it means to be a public charge, DHS disagrees. As an initial matter, this is the first time that DHS is defining in regulation an ambiguous terms that Congress itself left undefined. As discussed in greater detail in the section addressing the regulatory definition of public charge, DHS believes that its definition is consistent with what it means to be a public charge—a lack of self-sufficiency and a need to rely on the government for support. DHS believes that its rigorous and fair regulatory framework will ensure that aliens coming to or opting to stay in the United States permanently are self-sufficient. DHS explains the basis for its interpretation of the term ''public charge'' more fully below.

DHS also disagrees with commenters that this rule changes federal and state decision-making regarding aliens' access to public benefits. The rule itself does not prohibit any eligible alien or citizen from accessing public benefits for which they qualify. As explained above, DHS has the legal authority to promulgate the rule and believes the rule provides needed guidance to determine whether an alien is inadmissible as likely to become a public charge.

Comment: One commenter stated that ''[c]ontrary to DHS's interpretation, the enactment of PRWORA and section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), close in time suggests that Congress assumed that receipt of these public benefits would *not* be counted against a person in determining whether the individual is likely to become a public charge.'' A commenter stated that the rule is ''an intentional attempt at using the specific language within PRWORA as justification for a new, more restrictive rule which would override portions of PRWORA.'' Other commenters stated that the proposed rule is unnecessary in light of PRWORA's restrictions on access to benefits to certain immigrants and their families. One commenter noted that in advancing the Administration's goals, the rule undercuts Congress' original intent in creating nutrition, health, and human services programs.

Response: The public charge inadmissibility rule is not inconsistent with PRWORA, nor does it contravene PRWORA's requirements. When passing IIRIRA in 1996, Congress added the mandatory factors to be considered in public charge inadmissibility determinations to section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), but left discretion to the relevant agencies, including DHS, to interpret those factors, including how to incorporate a consideration of public benefit receipt into the public charge inadmissibility determination. As discussed in the NPRM, consideration of receipt of public benefits was part of the public charge determination before Congress

[96] *See, e.g.,* Memorandum from the President to the Secretary of State, the Attorney General, and the Secretary of Homeland Security, Implementing Immediate Heightened Screening and Vetting of Applications for Visas and Other Immigration Benefits, Ensuring Enforcement of All Laws for Entry Into the United States, and Increasing Transparency Among Departments and Agencies of the Federal Government and for the American People, 82 FR 16279, 16280 (Apr. 3, 2017) (''I direct the Secretary of State, the Attorney General, the Secretary of Homeland Security, and the heads of all other relevant executive departments and agencies (as identified by the Secretary of Homeland Security) to rigorously enforce *all existing grounds of inadmissibility* and to ensure subsequent compliance with related laws after admission. The heads of all relevant executive departments and agencies shall issue new rules, regulations, or guidance (collectively, rules), as appropriate, to enforce laws relating to such grounds of inadmissibility and subsequent compliance. To the extent that the Secretary of Homeland Security issues such new rules, the heads of all other relevant executive departments and agencies shall, as necessary and appropriate, issue new rules that conform to them.'' (emphasis added)).

[97] *See* Public Law 104–208, div. C, sec. 531, 110 Stat. 3009–546, 3009–674 (Sept. 30, 1996) (amending INA section 212(a)(4), 8 U.S.C. 1182(a)(4)).

[98] *See* Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601).

[99] *See Lewis* v. *Thompson,* 252 F.3d 567, 583–84 (2d Cir. 2001) (''it is reasonable for Congress to believe that some aliens would be less likely to hazard the trip to this country if they understood that they would not receive government benefits upon arrival . . . .'')

passed IIRIRA and PRWORA.[100] At the same time that Congress added mandatory factors to be considered in the public charge inadmissibility analysis, Congress passed PRWORA, establishing eligibility restrictions for aliens receiving public benefits with the clear intent to promote the self-sufficiency of those entering the United States and to ensure that public benefits do not provide an incentive for immigrants to come to the United States.[101] Congress did nothing, however, to constrain DHS (then INS) from considering the receipt of public benefits in a public charge inadmissibility determination as INS had done previously. In light of this history, DHS's proposed public charge rule is consistent with the principles of PRWORA and aligns this regulation to those principles. As such, this public charge rule is rationally related to Congress' intent to create a disincentive for immigrants to rely on public benefits if they are seeking admission to the United States,[102] and a permissible interpretation of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4).

Comment: One commenter stated that the rule is inconsistent with congressional intent set forth in the IIRIRA Conference Report, because that report noted that certain benefits, such as public health, nutrition, and in-kind community service programs, should not be included in the prohibition on aliens receiving public benefits.[103] Other commenters stated that when Congress expanded the definition of ''public charge'' in 1996, it rejected a definition of ''public charge'' that would have included food and healthcare assistance; thus, expanding the definition of ''public charge'' to include such assistance would ignore Congress' legislative intent.

Response: It is not clear what the commenters are referencing when referring to Congress' rejection of a definition of public charge that included food and healthcare assistance. It may be a reference to the proposed ground of *deportability* in the version that passed the U.S. Senate that included Medicaid and food stamps (now SNAP), among other programs, in the list of public benefits that were considered one of the grounds of deportability for public charge.[104] DHS notes that the Senate-passed bill would not have amended the public charge ground of inadmissibility.[105] Additionally, the administration of the public charge inadmissibility ground under this rule is significantly different from the public charge deportability provisions considered by the Senate. The proposed ground of deportability, for instance, made aliens automatically deportable (with certain exceptions) if they received certain public benefits, including Medicaid and food stamps, for 12 months within five years of admission. This rule, by contrast, focuses on future receipt of public benefits for more than 12 months in the aggregate in a 36-month period. The prospective nature of the determination under this rule renders the definition significantly different. With respect to past receipt, this rule requires DHS to evaluate such receipt as one of several factors to be considered in the totality of circumstances. This rule therefore does not impose the provision included in the Senate-passed bill that Congress had rejected.[106]

DHS notes that the quotation from IIRIRA Conference Report [107] does not relate to public charge inadmissibility, but to PRWORA and exceptions to the prohibition on aliens accepting certain public benefits. While language in a Conference Report, especially when discussing a separate piece of legislation, is not binding, the rule is not inconsistent with the language in the report because the public benefits covered by the rule do not include those excepted under PRWORA.

Comment: Commenters stated that reversing the policies set forth in the 1999 Interim Field Guidance, which have allowed immigrants to rely on the previously excluded benefits for decades, is contrary to congressional intent. One commenter stated that the rule is inconsistent with congressional intent, which ''recognizes the importance of access to preventive care and nutrition benefits for all people, including immigrants.''

Response: DHS acknowledges that this rule is a departure from the 1999 Interim Field Guidance. DHS also acknowledges that some aliens subject to this rule will need to make decisions with respect to the receipt of public benefits for which they are eligible. Ultimately, however, DHS does not believe that its inclusion of previously-excluded benefits is contrary to congressional intent, particularly with respect to access to preventive care and nutrition benefits. In fact, DHS believes it would be contrary to congressional intent to promulgate regulations that encourage individuals subject to this rule to rely on any of the designated public benefits, or to ignore their receipt of such benefits, as this would be contrary to Congress's intent in ensuring that aliens within the United States are self-sufficient and rely on their own resources and capabilities, and those of their family, sponsors, and private organizations.[108]

To the extent that commenters are concerned with the consequences of receipt of previously-excluded public benefits, DHS notes that it is not considering an alien's receipt of previously excluded public benefits in the public charge inadmissibility determination, if such receipt occurred before the effective date of this final rule and receipt of such benefits was not considered under the 1999 Interim Field Guidance.[109] However, DHS is considering an alien's receipt of public benefits that were included in the 1999 Interim Field Guidance and received prior to the effective date of the rule as a negative factor in the totality of the circumstances analysis. DHS also is not considering past receipt of public benefits by an alien if such receipt occurred while the alien was in a classification or status that was exempt from public charge inadmissibility or for which a waiver of public charge inadmissibility was received.

Comment: Some commenters stated that DHS only has the authority to administer individual reviews of an applicant's likelihood of becoming dependent on the government in the future, and cannot consider government expenditures on means-tested programs. One of these commenters suggested that

[100] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51158 (proposed Oct. 10, 2018) (''In *Matter of Martinez-Lopez,* the Attorney General indicated that public support or the burden of supporting the alien being cast on the public was a fundamental consideration in public charge inadmissibility determinations''); *Matter of Martinez-Lopez,* 10 I&N Dec. 409, 421 (Att'y Gen. 1964).

[101] *See* 8 U.S.C. 1601.

[102] *See Lewis* v. *Thompson,* 252 F.3d 567, 583–84 (2d Cir. 2001) (''it is reasonable for Congress to believe that some aliens would be less likely to hazard the trip to this country if they understood that they would not receive government benefits upon arrival . . . .'').

[103] *See* H.R. Rep. No. 104–828, at 238 (1996) (Conf. Rep.).

[104] H.R. 2202, 104th Cong. sec. 202 (as amended and passed by Senate, May 2, 1996).

[105] *See* H.R. 2202, 104th Cong. sec. 202 (as amended and passed by Senate, May 2, 1996).

[106] *See Hamdan* v. *Rumsfeld,* 548 U.S. 557, 579–80 (2006) (''Congress' rejection of the very language that would have achieved the result the Government urges here weighs heavily against the Government's interpretation.''); *see also Competitive Enterprise Inst.* v. *U.S. Dep't of Transp.,* 863 F.3d 911, 917 (DC Cir. 2017) (''Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change.'' (citations and internal quotations omitted)).

[107] *See* H.R. Rep. No. 104–828, at 238 (1996) (Conf. Rep.).

[108] *See* 8 U.S.C. 1601(2)(A).

[109] *See* 8 CFR 212.22(d).

to the extent DHS is considering aggregate costs of public benefits, it also should consider aggregate benefits. This commenter suggested that DHS abandon its effort to use public charge reform as a back door means of realizing the political goals of reducing government expenditures on means-tested programs authorized by Congress. Another commenter stated that whether or not there is a large government expenditure on a particular program is irrelevant to the assessment of whether a particular individual may become a public charge.

Response: DHS believes that these commenters misunderstood DHS's proposal. DHS is not taking expenditures on public benefit programs into account for purposes of any single public charge inadmissibility determination. Rather, DHS has taken into consideration expenditures on public benefit programs in order to appropriately circumscribe, for the purpose of administrative efficiency, the list of public benefits that will be considered in public charge inadmissibility determinations. Therefore, under this rule, DHS will take into consideration all of the mandatory factors in the totality of the alien's circumstances, including whether the alien received public benefits as defined in 212.21(b).

2. Additional Legal Arguments

a. Allegations That the Rule Is Arbitrary and Capricious

Comment: Many commenters stated that the proposed rule is arbitrary and capricious. Commenters said that the rule would be struck down under the APA. Commenters stated that DHS failed to provide a reasoned or adequate explanation for the rule, including one based on facts and data. Other commenters asserted that the public charge rule, as proposed, is unnecessary, has no legal justification, and is overbroad. Other commenters stated that the rule ''address[es] a problem that doesn't even exist.'' One commenter stated that ''DHS has not cited any evidence that the current statute is ineffective in promoting self-sufficiency or that there is some need for increasing the pool of inadmissibility. Without substantiating the need for this change, DHS is simply proposing unnecessary and harsh restrictions against immigrants.'' One commenter stated that current immigration policy provides sufficient protection for the nation's interests, including through existing eligibility limits for public benefits.

A few commenters stated that ''DHS offered inadequate reasoning for rejecting the 1999 Interim Field Guidance and making a massive change in the agency's interpretation of federal law.'' The commenter stated that DHS failed to provide an explanation as to why the interpretation used for the last 20 years is inappropriate, or to justify the particular articulation of resource and health factors contained in the rule. Many commenters stated that the rule failed to provide a reasonable or rational nexus between the data cited and the policy decisions made. One commenter claimed that the proposed rule did not offer adequate justification that access to public benefits create an incentive to migrate to the United States. The commenter also asserted that the proposal is based on inaccurate and misleading data concerning low-wage work, and thus fails to account for the societal benefit of low-wage workers who depend on benefits to supplement their income.

Response: DHS believes that it has provided adequate justification for the rule. DHS has interpreted its authorizing statute to clarify the criteria for when an alien would be found inadmissible as likely at any time to become a public charge, based on the consideration of statutory factors. DHS provided an explanation for why and how the proposed rule furthers congressional intent behind both the public charge inadmissibility statute and PRWORA in ensuring that aliens being admitted into and intending to settle permanently in the United States be self-sufficient and not reliant on public resources. DHS also explained the deficiencies of the current standard established by the 1999 Interim Field Guidance, including that the guidance assumed an overly permissible definition of dependence on public benefits by only including consideration of certain cash benefits, rather than a broader set of benefits, whether cash or non-cash, that similarly denote reliance on the government rather than the alien's own resources and capabilities, or the resources and capabilities of the alien's family, sponsors, and private organizations. In expanding the list of benefits to be considered, DHS explained why a broader list should be considered, and provided data to support the specific list proposed in the proposed rule. For instance, DHS referenced Federal Government data for the rates of participation in such benefit programs by non-citizens across factors related to the public charge inadmissibility determination, such as income. DHS disagrees that the data provided to support these conclusions was either inaccurate or misleading, and notes that DHS followed accepted practices for making inferences at a 95 percent confidence level.

DHS also explained that the 1999 Interim Field Guidance failed to offer meaningful guidance for purposes of considering the mandatory factors and was therefore ineffective in guiding adjudicators in making a totality of the circumstances public charge inadmissibility determinations. In response to this deficiency, DHS proposed to establish definitive legal standards and evidentiary criteria for each of the mandatory factors as relevant to the determination of whether an alien will be more likely than not to become a public charge at any time in the future.

DHS agrees with commenters that the public charge inadmissibility rule constitutes a change in interpretation from the 1999 Interim Field Guidance. Courts have long established that agencies are not bound forever to maintain the same statutory interpretation.[110] To change its prior interpretation, an agency need not prove that the new interpretation is the best interpretation, but should acknowledge that it is making a change, provide a reasoned explanation for the change, and indicate that it believes the new interpretation to be better.[111] DHS has laid out the proposed changes from the 1999 Interim Field Guidance in great detail and provided a justification for each. DHS also explained why it believes the new rule to be a superior interpretation of the statute to the 1999 Interim Field Guidance and explained why such interpretation is desirable from a public policy perspective. Moreover, as explained above, DHS is clearly authorized to promulgate regulations interpreting the public charge inadmissibility ground. DHS carefully considered the public comments on this rule and made

[110] *See, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 186–87 (1991) (acknowledging that changed circumstances and policy revision may serve as a valid basis for changes in agency interpretations of statutes); *Chevron, U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837, 863–64 (1984) (''The fact that the agency has from time to time changed its interpretation of the term 'source' does not, as respondents argue, lead us to conclude that no deference should be accorded the agency's interpretation of the statute. An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis.''); *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983) (agencies ''must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances' '' (quoting *Permian Basin Area Rate Cases,* 390 U.S. 747, 784 (1968))).

[111] *See generally FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502 (2009).

adjustments based on the input it received. Accordingly, DHS believes this rule has been issued in compliance with the APA.

DHS acknowledges that its broader definitions for public benefits and public charge may result in additional applicants being determined to inadmissible and therefore ineligible for admission or adjustment of status because they are likely at any time to become a public charge. However, as noted elsewhere in this rule, DHS believes that expanding the definitions of public benefits and public charge and any resulting denials of applications based on section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) are reasonable and are consistent with Congress' intent and will better ensure that aliens seeking to come to the United States temporarily or permanently are self-sufficient.[112]

DHS also notes that as stated previously, available data neither provides a precise count nor reasonable estimates of the number of aliens who are both subject to the public charge ground of inadmissibility and are eligible for public benefits in the United States.

b. Alternatives

Comment: Commenters stated that, under E.O. 13563 and other applicable authority, DHS should have considered other feasible regulatory alternatives to its proposed rule. One commenter asserted that the proposed rule failed to consider a less restrictive alternative, specifically, enforcing affidavits of support. This commenter stated that this failure makes the rule arbitrary and capricious.

Response: DHS disagrees with commenters who argued that the proposed rule failed to consider other alternatives to this rule, or that the proposed rule was unnecessary because DHS can simply increase enforcement of Form I–864. Under E.O. 13563, the agency must identify available alternatives. In this case, DHS did just that and explained the alternatives considered in the proposed rule, including a ''no-action'' alternative—continuing to administer this ground of inadmissibility under the 1999 Interim Field Guidance.[113] DHS also considered a more expansive definition of ''public benefit,'' that would have potentially included a range of non-cash benefit programs falling in specific categories (such as programs that provide assistance for basic needs such food and nutrition, housing, and healthcare). DHS rejected these alternatives for the reasons discussed in the proposed rule.[114]

With respect to enforcing Form I–864 as an alternative to this rule, DHS notes that this proposal is neither an adequate nor available alternative to this rule. As explained in the proposed rule, DHS's objective in promulgating this rule is to better ensure that aliens seeking admission or adjustment of status do not rely on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations. While Form I–864 serves a crucial function where required to be submitted by section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), it is not an alternative to consideration of the mandatory factors established by Congress in determining whether an alien is likely at any time to become a public charge. As discussed elsewhere in this rule, Form I–864 ensures that the sponsor is available to support the sponsored alien in the event the sponsored alien is unable or unwilling to support himself or herself and is also intended to provide a reimbursement mechanism for the government to recover from the sponsor the amount of public benefits distributed to the sponsored alien. In fact, the plain language of the statute permits sponsored aliens to sue to enforce the support obligation, if necessary.[115] In addition, Form I–864 *may* also be taken into consideration in the totality of the circumstances public charge inadmissibility determination.[116] Had Congress intended enforcement of Form I–864 to be the sole mechanism by which DHS could ensure that an alien does not become a public charge after admission or adjustment of status, Congress would have included it as the sole mandatory factor to be considered when making public charge inadmissibility determinations. Instead, Congress required DHS to consider the mandatory factors to assess whether the alien is likely at any time to become a public charge based on his or her present circumstances and relevant past actions (*e.g.,* any past receipt of public benefits, employment history, etc.), even if a sufficient Form I–864 is submitted on behalf of an alien.[117]

In addition, if the sponsor does not provide financial support to the sponsored alien, the sponsored alien may bring a suit in the court of law.[118] In the event a sponsored alien receives public benefits, seeking reimbursement pursuant to the agreement made in Form I–864 requires deployment of relevant resources by the agency that granted the benefit and/or use of judicial resources.

Simply put, the affidavit of support is not a substitute for the assessment of the mandatory factors. For these reasons, DHS determined that simply enforcing the affidavit of support under section 213A of the Act was not an adequate legal or practical alternative to ensuring that DHS appropriately applies mandatory factors established by Congress to assess whether the alien is likely at any time in the future to become a public charge. Furthermore, considering a sufficient affidavit of support under section 213A of the Act does not, alone, achieve Congress' goal to limit the incentive to immigrate to the United States for the purpose of obtaining public benefits.

c. Retroactivity

Comment: A commenter stated that, despite the apparent attempt to draft the proposed rule appropriately, its plain language would allow it to be applied retroactively. The commenter stated that because not all sections specifically exempt benefits received prior to the rule's effective date, DHS could apply the rule retroactively. For example, under 8 CFR 212.22(c), an alien's receipt of SNAP within 36 months preceding application for adjustment of status would weigh heavily in favor of a finding of public charge inadmissibility, but that paragraph does not specifically limit DHS's consideration of SNAP receipt to benefits received on or after the effective date of the rule. This commenter also stated that the proposed rule violated reasonable reliance law and violates the APA.

Response: DHS disagrees that the rule will be applied retroactively to aliens subject to the public charge ground of inadmissibility. As stated in the **DATES** section of this final rule, this rule will become effective 60 days after it is

[112] *See Nat'l Cable & Telecommunications Ass'n* v. *Brand X internet Servs.,* 545 U.S. 967, 1001 (2005) (''the Commission is free within the limits of reasoned interpretation to change course if it adequately justifies the change.''); *Competitive Enter. Inst.* v. *United States Dep't of Transportation,* 863 F.3d 911, 918 (D.C. Cir. 2017) (''The benefits of the regulation are also modest, but the Department reasonably concluded that they justify the costs.'')

[113] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51276 (proposed Oct. 10, 2018).

[114] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51276 (proposed Oct. 10, 2018).

[115] *See* INA section 213A(a)(1)(B), 8 U.S.C. 1183a(a)(1)(B); 71 FR 35732, 35743 (Jun. 21, 2006).

[116] *See* INA section 212(a)(4)(B)(ii), 8 U.S.C. 1182(a)(4)(B)(ii).

[117] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[118] *See, e.g., Wenfang Lieu* v. *Mund,* 686 F.3d 418 (7th Cir. 2012) (the sponsored immigrant is a third party beneficiary whose rights exist apart from whatever rights she might or might not have under Wisconsin divorce law, and she has no legal obligation to mitigate damages).

published in the **Federal Register**, and the rule will be applied to applications and petitions postmarked (or if applicable, electronically submitted) on or after that date. Thus, for instance, the public charge inadmissibility determination factors and criteria will apply only to applications that are postmarked (or if applicable, electronically submitted) on or after that date; applications that were postmarked before the effective date and accepted by USCIS pursuant to 8 CFR 103.2(a)(1) and (a)(2), and are pending on the effective date will be adjudicated under the criteria set forth in the 1999 Interim Field Guidance. For the purposes of determining whether a case was postmarked before the effective date of the rule, DHS will consider the postmark date for the application or petition currently before USCS, not the postmark date for any previously-filed application or petition that USCIS rejected pursuant to 8 CFR 103.2(a)(7)(ii).

Similarly, the condition related to public benefit receipt in the context of extensions of stay and change of status will only apply to petitions and applications postmarked (or if applicable, submitted electronically) on or after the effective date of this rule.

In addition, and as stated in this final rule, DHS will not apply the new expanded definition of public benefit to benefits received before the effective date of this final rule. Therefore, any benefits received before that date will only be considered to the extent they would have been covered by the 1999 Interim Field Guidance. In the commenter's example, SNAP benefits received by an alien prior to the effective date of the final rule would not be considered as part of the alien's public charge inadmissibility determination, because SNAP was not considered in public charge inadmissibility determinations under the 1999 Interim Field Guidance. By contrast, as explained in more detail later in this preamble, for applications postmarked (or if applicable, electronically submitted) on or after the effective date of this final rule, an applicant's receipt of cash assistance for income maintenance prior to the effective date of this rule will be treated as a negative factor in the totality of the circumstances. However, regardless of the length of time such benefits were received before the effective date of this rule, for the purposes of public charge inadmissibility determinations made for applications postmarked (or if applicable, submitted electronically) on or after the effective date, DHS will not treat the receipt of these benefits as a heavily weighted negative factor.

Comment: One commenter noted that the rule punishes noncitizens for past conduct and therefore violates the *ex post facto* clause and is unconstitutionally retroactive.''

Response: DHS rejects the comment that the public charge inadmissibility rule violates that *ex post facto* clause of the U.S. Constitution. The *ex post facto* clause prohibits changes to the legal consequences (or status) of actions that were committed before the enactment of the law.[119] The *ex post facto* clause would generally only apply to laws that impose criminal penalties.[120] Although inadmissibility determinations are not criminal penalties, and so are generally not subject to the *ex post facto* clause,[121] this rule, in any event, is not impermissibly retroactive in application, as noted in the immediately preceding response.

d. Due Process/Vagueness and Equal Protection

Comment: Commenters stated that the public charge inadmissibility determination called for by the proposed rule is too open-ended and unpredictable. Some commenters pointed to likely confusion about which benefits will be included or excluded for purposes of a public charge determination. These commenters further stated that failing to define the term ''likely,'' as that term is used in the phrase ''likely to become a public charge,'' would grant too much discretion to adjudicators in an complex weighing system that would lead to arbitrary outcomes. Another commenter recommended that the determination system be scored. Another commenter stated that that the vagueness of the proposed framework would lead to inconsistent and unfair determinations.

Response: DHS disagrees that the rule is vague or unpredictable. Some commenters who alleged that the rule is vague did not provide specific details to identify which provisions of the rule they were referring and DHS is therefore unable to specifically address those claims other than stating general disagreement. In the NPRM, DHS provided specific examples of various concepts and laid out in great detail the applicability of the rule to different classes of aliens, and clearly identified the classes of aliens that would be exempt from the rule. DHS also provided an exhaustive list of the additional non-cash public benefits that would be considered, including receipt thresholds for all designated benefits. DHS explained that it would make public charge inadmissibility determinations in the totality of the circumstances, and following consideration of the minimum statutory factors. The ''vagueness'' associated with a totality of the circumstances determination is to a significant extent a byproduct of the statute's requirement that DHS consider a range of minimum factors as part of the public charge inadmissibility determination. DHS recognizes that the statutory multi-factor framework will likely result in more inadmissibility determinations when combined with the standard in this rule (as compared to the 1999 Interim Field Guidance), but fundamentally, as it relates to vagueness, the commenters' quarrel is with Congress, not with DHS.

In any case, in response to public comments, the list of public benefits has been revised in this final rule, and the threshold has been simplified such that there is only a single, objective duration-based threshold applicable to the receipt of all included public benefits. And DHS has determined, consistent with public commenter suggestions, that it will not consider the receipt of any benefits not listed in the rule, therefore removing potential uncertainty. In addition, DHS remains committed to providing clear guidance to ensure that there is adequate knowledge and understanding among the regulated public regarding which benefits will be considered and when, as well as to ensure that aliens understand whether they are or are not subject to the public charge ground of inadmissibility.

DHS has also further defined ''likely'' as more likely than not. While DHS agrees with commenters that the regulation must be sufficiently clear so that the regulated public can comply with it, DHS notes that some adjudicator discretion must exist where determinations are based on a totality of the circumstances examination that is highly fact-specific. Congress specifically called for a fact-specific,

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[119] U .S. Const. art. I, sec. 9, cl. 3; *see Calder* v. *Bull,* 3 Dall. 386, 390–391, 1 L.Ed. 648 (1798) (opinion of Chase, J.).

[120] *See, e.g., Rhines* v. *Young,* 899 F.3d 482, 495 (8th Cir. 2018) (''A criminal or penal law has a prohibited *ex post facto* effect if it is ''retrospective, that is, it must apply to events occurring before its enactment, and it must disadvantage the offender affected by it.'') (citations omitted), *cert. denied,* No. 18–8030, 2019 WL 826426 (U.S. Apr. 15, 2019); *Bremer* v. *Johnson,* 834 F.3d 925, 932 (8th Cir. 2016);

[121] *Galvan* v. *Press,* 347 U.S. 522, 531 (1954) (Frankfurter, J.) (''[W]hatever might have been said at an earlier date for applying the *ex post facto* Clause, it has been the unbroken rule of this Court that it has no application to deportation.''); *Alvarado–Fonseca* v. *Holder,* 631 F.3d 385, 391–92 (7th Cir. 2011); *Montenegro* v. *Ashcroft,* 355 F.3d 1035, 1037 (7th Cir. 2004).

discretionary determination in the public charge context.[122] As is the case with most regulations, over the course of adjudications, new fact patterns arise that may require additional guidance to adjudicators; however this does not make the regulation impermissibly vague.[123]

DHS does not believe that a scoring system would be appropriate for this analysis, namely because of the wide variations between individual circumstances of aliens. Both the proposed rule and this final rule adequately explain how the criteria are to be applied and what evidence should be considered. USCIS will provide training to its adjudicators and will engage with the regulated public to the extent necessary to foster a better understanding and compliance with the regulation.

Comment: One commenter stated that although the Federal Government has great leeway to enact immigration laws, its actions are still subject to review for constitutionality. The commenter stated that proposed rule restricts the rights of non-citizens to access crucial healthcare benefits, housing vouchers, and other government benefits by using ''heavily weighted factors,'' such as English proficiency, and ''exorbitant'' bond measures, and that the proposed rule would disproportionately impact women and people of color. The commenter stated that the Supreme Court has struck down state laws that restricted public benefits based on alienage and noted that in one such case, the Court reviewed the law under intermediate scrutiny. The commenter suggested that this rule could similarly be subject to intermediate scrutiny. The commenter stated that even if a heightened scrutiny argument loses, the rule would fail rational basis scrutiny because is not rationally related to a legitimate public interest since ''there is no legitimate government interest furthered by the proposed rule, as 212(a)(4) [of the Act, 8 U.S.C. 1182(a)(4)] is already in place and effective.'' The commenter stated that the proposed measures will disparately impact female immigrants and immigrants of color and is not rationally related to a legitimate public interest. The commenter indicated that the ''legitimate public interest (which in and of itself is contestable) is already served by the current provision.'' Another commenter similarly stated that the rule would have a disparate impact on immigrants of color and women. The commenter cited to a Manatt, Phelps & Phillips independent analysis of the U.S. Census Bureau's (Census Bureau) American Community Survey Data 5-year 2012–2016 data. The commenter stated that the application of the public charge rule would be unequally distributed along racial lines. According to the commenter, the effects of the proposed rule are expected to have a disparate impact on communities of color, affecting as many as 18.3 million members (or one-third) of the Hispanic and Latino community in the United States. The commenter stated that the DHS's proposed ''250-percent-FPG threshold'' would have disproportionate effects based on national origin and ethnicity, blocking 71 percent of applicants from Mexico and Central America, 69 percent from Africa, and 52 percent from Asia—but only 36 percent from Europe, Canada and Oceania. The commenter stated that ''because the proposed rule facially implicates national origin, strict scrutiny applies.''

Response: DHS disagrees that this rule would fail any level of scrutiny (*i.e.,* strict, intermediate, or rational basis scrutiny).[124] As discussed previously, DHS is not changing rules governing which aliens may apply for or receive public benefits, nor is this rule altering any eligibility criteria for such benefits. Instead, DHS is exercising its authority to administer the public charge ground of inadmissibility in a way that better ensures that aliens being admitted into the United States, or seeking to remain here permanently, are self-sufficient and not reliant on the government for support. While this rule may influence an alien's decision to apply for, or disenroll from, public benefits, it does not constitute a restriction on accessing such benefits. However, even if the rule did place additional restrictions on aliens, the Supreme Court, even prior to PRWORA, determined that the equal protection analysis of Federal action that differentiates between citizens and aliens in the immigration context is different from the equal protection analysis of State actions that differentiate between citizens of another state and citizens of another country. In *Mathews* v. *Diaz,* the Court specifically distinguished between state statutes that deny welfare benefits to resident aliens, or aliens not meeting duration residence requirements, from similar actions taken by the political branches of the Federal Government that are specifically empowered to regulate the conditions of entry and residence of aliens. 426 U.S. 67, 85–86 (1976). In that case, the court found that the enforcement of a 5-year residency requirement against aliens applying for a supplemental medical insurance program did not deprive the aliens of life, liberty or property without due process of law under the Due Process Clause of the Fifth Amendment.[125]

DHS agrees that if this rule were regulating eligibility for public benefits outside of the immigration context, heightened scrutiny might apply.[126] As explained above, however, the rule places no obstacles to aliens' eligibility for public benefits. Furthermore, the rule is not facially discriminatory and DHS does not intend a discriminatory effect based on race, gender, or any other protected ground.

Finally, the commenter misstated the proposed rule's income threshold as 250 percent of the FPG. While USCIS will generally consider 250 percent of the FPG to be a heavily weighted positive factor in the totality of the

[122] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4) (''Any alien, who *in the opinion* of the consular officer at the time of application for a visa, or *in the opinion* of the Attorney General at the time of the application for admission or adjustment of status, is likely at any time to become a public charge is inadmissible.'') (emphasis added).

[123] *Cf., e.g., Freeman United Coal Mining Co.* v. *Fed. Mine Safety & Health Review Comm'n,* 108 F.3d 358, 362 (D.C. Cir. 1997) (''Regulations generally satisfy due process so long as they are sufficiently specific that a reasonably prudent person, familiar with the conditions the regulations are meant to address and the objectives the regulations are meant to achieve, would have fair warning of what the regulations require.'').

[124] *See Korab* v. *Fink,* 797 F.3d 572, 577–79 (9th Cir. 2014) (''[F]ederal statutes regulating alien classifications are subject to the easier-to-satisfy rational-basis review . . . Although aliens are protected by the Due Process and Equal Protection Clauses, this protection does not prevent Congress from creating legitimate distinctions either between citizens and aliens or among categories of aliens and allocating benefits on that basis.'') (citation omitted); *Lewis* v. *Thompson,* 252 F.3d 567, 570 (2d Cir. 2001) (describing the level of scrutiny owed under the constitution to federal regulation of immigration and naturalization as ''highly deferential'') (citing *Lake* v. *Reno,* 226 F.3d 141, 148 (2d Cir. 2000).) Generally, laws and regulations that neither involve fundamental rights nor include suspect classifications are reviewed under rational basis scrutiny, under which the person challenging the law must show that the government has no legitimate interest in the law or policy or that there is no rational link between the interest and the challenge law or regulation. *Heller* v. *Doe by Doe,* 509 U.S. 312, 319 (1993).

[125] ''The fact that all persons, aliens and citizens alike, are protected by the Due Process Clause does not lead to the further conclusion that all aliens are entitled to enjoy all the advantages of citizenship . . .'' 426 U.S. at 79–80.

[126] *See, e.g., Personal Administrator of Mass* v. *Feeney,* 442 U.S. 256, 272 (1996) (Classifying persons according to their race is more likely to reflect racial prejudice than legitimate public concerns.), *McLaughlin* v. *Florida,* 379 U.S. 184, 196 (1964) (''Such classifications are subject to the most exacting scrutiny; to pass constitutional muster, they must be justified by a compelling governmental interest and must be 'necessary . . . to the accomplishment' of their legitimate purpose.' ''); *United States* v. *Virginia,* 518 U.S. 515 (1996) (ruling that the Virginia Military Institute's gender-based admission policy violated the Equal Protection Clause).

circumstances, the minimum income threshold to be considered a positive factor in the totality of the circumstances is generally 125 percent of the FPG. More specifically, if the alien has income below that level, it will generally be a heavily weighed negative factor in the totality of the circumstances.

As set forth in NPRM,[127] DHS's public charge rule is rationally related to the government's interest in ensuring that aliens entering the United States or seeking to settle here permanently are not likely to become public charges, consistent with the requirements of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). The regulation minimizes the incentive of aliens to immigrate to the United States because of the availability of public benefits and promotes the self-sufficiency of aliens within the United States.[128] Finally, DHS does not understand commenters' statements about the ''unequal application'' of the public charge inadmissibility rule and disagrees that the public charge inadmissibility rule would be unequally applied to different groups of aliens along the lines of race or gender.

Comment: Several commenters objected that the rule violates due process and equal protection rights. One commenter said that aliens seeking adjustment of status should be granted due process rights closer to those of United States citizens, and this rule should be subject to stricter standards for judicial review to ''ensure that more immigrants are protected from the detrimental effects of this proposal.'' The commenter stated that such a review ''would require that Congress ha[ve] a dual review process.'' Another commenter stated that the DHS rule could be challenged on the grounds that it affords nonimmigrants inside the United States less due process rights than they should be afforded. The commenter stated that USCIS should construct an appeals process that satisfies due process and gives applicants the opportunity to present evidence of admissibility. The commenter also stated that a person should not have ''their status as a resident revoked'' prior to a full review of the case.

Response: DHS disagrees with comments asserting that this rule violates aliens' due process or equal protection rights. Although aliens present in the United States are protected by the due process and equal protections clauses, federal immigration laws and their implementing regulations generally enjoy a highly deferential standard of review, even where the federal laws and regulations treat aliens differently from citizens and create distinctions between different classes of aliens (*i.e.,* lawful permanent residents vs. nonpermanent residents).[129] DHS's public charge inadmissibility rule falls within the agency's broad authority, granted by Congress, to regulate immigration matters, and therefore, if challenged on equal protection grounds as discriminating based on alienage, would be subject to rational basis scrutiny.[130] The public charge inadmissibility rule is indeed rationally related to the government's interest, as set forth in IIRIRA and PRWORA, to determine which aliens are inadmissible on public charge grounds in accordance with section 212(a)(4) of the INA, 8 U.S.C. 1182(a)(4), minimize the incentive of aliens to immigrate to the United States due to the availability of public benefits, and promote the self-sufficiency of aliens within the United States.[131] This is true even if this rule results in a disincentive for aliens to avail themselves of public benefits for which they are eligible under PRWORA.[132] Moreover, although the rule could impact an alien's decision to access public benefits for which he or she is eligible under PRWORA and state and local laws, it does not directly regulate the right to apply for or receive public benefits, and the Due Process Clause would not be implicated by whether, due to the rule, an alien chooses not to access benefits for which he or she qualifies.[133] The Due Process Clause of the Fifth Amendment ''has never been supposed to have any bearing upon, or to inhibit laws that indirectly work harm and loss to individuals.'' [134] Similarly, and as discussed in greater detail above, any potential chilling impacts of the rule would not violate the equal protection guarantee of the Fifth Amendment's Due Process Clause [135] because this rule is not facially discriminatory nor does DHS intend a discriminatory effect.[136]

The standards of judicial review are established by statute and judicial interpretation [137] and are therefore beyond the scope of this rulemaking. The proposal to institute a review by Congress is also beyond the scope of this rulemaking because only the legislative branch can create a role for itself.[138] DHS rejects the proposal to create an appellate process to allow applicants to present evidence of their admissibility since there is an existing process to present such evidence. Although not specific to this rule, USCIS will notify applicants of deficiencies in their applications with respect to any ineligibility including public charge in accordance with the principles outlined in 8 CFR 103.2 and USCIS policy in regard to notices, RFEs, or notices of intent to deny (NOIDs), and denials.[139] Likewise, DHS will not accept the proposal to decline to revoke a lawful permanent resident's status pending any appeals of a public charge

[127] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51122–23 (proposed Oct. 10, 2018).

[128] *See* 8 U.S.C. 1601.

[129] *See Korab* v. *Fink,* 797 F.3d 572, 579 (9th Cir. 2014); *Lewis* v. *Thompson,* 252 F.3d 567, 570 (2d Cir. 2001) (citing *Lake* v. *Reno,* 226 F.3d 141, 148 (2d Cir. 2000)); *Brooks* v. *Ashcroft,* 283 F.3d 1268, 1274 (11th Cir. 2002) (''Classifications that distinguish among groups of aliens are subject to rational basis review, and will be found valid if not arbitrary or unreasonable'').

[130] *See Mathews* v. *Diaz,* 426 U.S. 67, 81 n.17 (1976).

[131] *See* 8 U.S.C. 1601.

[132] *See Lewis* v. *Thompson,* 252 F.3d 567, 583–84 (2d Cir. 2001) (''[I]t is reasonable for Congress to believe that some aliens would be less likely to hazard the trip to this country if they understood that they would not receive government benefits upon arrival . . . Although it seems likely that many alien women will illegally immigrate to obtain the benefit of citizenship for their children, undeterred by ineligibility for prenatal care in the event of pregnancy, Congress is entitled to suppose that the denial of care will deter some of them. In the realm of immigration, where congressional discretion is extremely broad, this supposition, even if dubious, satisfies rational basis review.'') (citations omitted).

[133] In *O'Bannon* v. *Town Court Nursing Ctr.,* 447 U.S. 773, 789 (1980), the Supreme Court concluded, consistent with long-standing precedent that ''the due process provision of the Fifth Amendment does not apply to the indirect adverse effects of governmental action.''

[134] *O'Bannon* v. *Town Court Nursing Ctr.,* 447 U.S. 773, 789 (1980) (quoting *The Legal Tender Cases,* 79 U.S. 457, 551 (1870)).

[135] Although the Equal Protection Clause of the Fourteenth Amendment does not apply to the Federal government, the Supreme Court in *Bolling* v. *Sharpe,* 347 U.S.497, 500 (1954), held that while '''equal protection of the laws' is a more explicit safeguard of prohibited unfairness than 'due process of law,' . . . discrimination may be so unjustifiable as to be violative of due process.'' In the case of racial discrimination in DC public schools, the Court found that no lesser Constitutional protections apply to the Federal government through the application of the Due Process Clause in the Fifth Amendment than by application of the Equal Protection Clause of the Fourteenth Amendment.

[136] *See Pers. Adm'r* v. *Feeney,* 442 U.S. 256, 272 (1979).

[137] *See, e.g.,* INA section 242(b)(4), 8 U.S.C. 1252(b)(4) (providing the scope and standard of judicial review of removal orders); *McNary* v. *Haitian Refugee Center, Inc.,* 498 U.S. 479, 493 (1991) (discussing the appropriate standard of review for challenges to the Special Agricultural Worker program).

[138] *See generally Trans Ohio Sav. Bank* v. *Director, Office of Thrift Supervision,* 967 F.2d 598, 620 (DC Cir. 1992) (agency promise to bind Congress would be *ultra vires* and unenforceable).

[139] DHS notes that the failure to submit a completed Form I–944 and Form I–864 with the Form I–485, when required, may result in a rejection or a denial of the Form I–485 without a prior RFE or NOID. *See* 8 CFR 103.2(a)(7), (b)(8)(ii).

finding. Revocation of existing status is generally distinct from the process of adjudicating applications for immigration benefits. For example, a person maintaining a valid nonimmigrant status whose adjustment of status application is denied because he or she is inadmissible on public charge grounds would not lose his or her nonimmigrant status based on the denial of adjustment.[140] To the degree the commenter's concerns relate to the loss of lawful permanent resident status, such status generally terminates upon the entry of a final order of removal [141] unless the alien voluntarily abandons lawful permanent resident status.

e. Coordination With Other Federal Agencies

Comment: Several commenters said the proposed definition of public charge conflicts with the definition of public charge used by DOS, which focuses on an alien's primary dependence on public benefits. Other commenters noted that the inconsistency with DOS's definition of public charge would lead to delays and denials of Application for Provisional Unlawful Presence Waiver (Form I–601A).

Response: DHS is working and will continue to work with DOS to ensure consistent application of the public charge ground of inadmissibility. As noted in the NPRM, DHS expects that DOS will make any necessary amendments to the FAM in order to harmonize its approach to public charge inadmissibility determinations with the approach taken in this final rule.[142] As previously, indicated, DHS does not believe that the rule would unduly increase the delays or denials of provisional unlawful presence waivers filed on Form I–601A, as such waivers are unrelated to the public charge ground of inadmissibility.[143]

Comment: Several commenters stated that in the absence of DOJ regulations on public charge inadmissibility, U.S. Immigration and Customs Enforcement (ICE) attorneys will be compelled to argue in removal proceedings that DHS's public charge inadmissibility standard should be applied. And because there would not be binding precedent on DHS's interpretation of public charge inadmissibility, some immigration judges would adopt DHS's rule while others would not. This would result in inconsistent determinations and burden the immigration court system.

Response: DOJ has acknowledged ongoing work on a proposed public charge rule, which would propose to change how adjudicators within the Executive Office for Immigration Review (EOIR) determine whether an alien is inadmissible to the United States as a public charge consistent with section 212(a)(4) of the INA.[144] According to DOJ, the rule is intended to make certain revisions to more closely conform EOIR's regulations with the DHS public charge inadmissibility rule. DHS will work with DOJ to ensure consistent application of the public charge ground of inadmissibility. DHS reiterates, however, that this final rule pertains only to public charge inadmissibility determinations made by DHS for applicants seeking admission or adjustment of status, public charge bonds, as well the conditions DHS has set for applicants applying for an extension of stay or change of status before DHS.

If USCIS denies an adjustment of status application after determining that the applicant is likely at any time to become a public charge at any time, and the alien is not lawfully present in the United States, USCIS will generally issue a Notice to Appear (NTA),[145] which may charge the alien as inadmissible under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), if the alien is an alien is an arriving alien or an alien present in the United States without having been admitted or paroled. Under section 240(c)(2)(A) of the Act, 8 U.S.C. 1229a(c)(2)(A), an applicant for admission in removal proceedings has the burden of establishing that he or she is clearly and beyond doubt entitled to be admitted and is not inadmissible under section 212 of the Act, 8 U.S.C. 1182. The alien may renew the adjustment of status application before an immigration judge unless the immigration judge does not have jurisdiction over the adjustment application.[146]

Additionally, when encountering an alien, who is an arriving alien or an alien present in the United State without admission or parole, ICE will use the criteria set forth in this rule with respect to determining whether to charge such an alien under section 212(a)(4), 8 U.S.C. 1182(a)(4).

DHS notes that it has no general authority over the EOIR inadmissibility determinations in removal proceedings and believes such matters are more appropriately addressed by DOJ in the context of its public charge rulemaking.

f. International Law and Related Issues

Comment: One commenter suggested, but did not explicitly state, that the rule would violate international refugee law. Another commenter suggested that the rule would discriminate against individuals waiting for their asylum applications to be adjudicated. Other commenters noted that the rule would be a violation of, or is inconsistent with, various international agreements such as the Universal Declaration of Human Rights (UDHR), the 1959 Declaration of the Rights of the Child, the International Convention on the Elimination of All Forms of Racial Discrimination (CERD), and the International Covenant on Civil and Political Rights (ICCPR). A commenter stated that treaties that have been ratified ''should be considered as being Constitutional Amendments under the Supremacy Clause.''

Response: DHS rejects the comment that this rule would violate the United States' international treaty obligations relating to refugees or that the rule discriminates against individuals in the United States who have asylum applications pending on the effective date of this rule. As noted in the NPRM, this rule does not apply to asylum applicants, those granted asylum (asylees), and those seeking to adjust their status to that of a lawful permanent resident based on their asylee or refugee status. Applicants for asylum are not required to demonstrate admissibility as part of demonstrating their eligibility for asylum.[147] Additionally, while asylees who travel outside of the United States are examined for admissibility upon returning to the United States with a refugee travel document and are admitted as such if admissible, asylees are not subject to the public charge inadmissibility ground when seeking readmission as an asylee.[148] Similarly,

[140] It is possible that the basis for the denial could also make the alien deportable under the different requirements for deportability at section 237(a)(5) of the Act, 8 U.S.C. 1227(a)(5). Aliens placed in removal will be afforded al due process rights accorded to aliens in removal proceedings. *See* INA section 240(b)(4), 8 U.S.C. 1229a(b)(4).

[141] *See* 8 CFR 1.2, definition of ''lawfully admitted for permanent residence.''

[142] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51135 (proposed Oct. 10, 2018).

[143] Form I–601A is filed by aliens inside the United States to request a provisional waiver of the unlawful presence grounds of inadmissibility section 212 (a)(9)(B) of the Act, 8 U.S.C. 1182(a)(9)(B), before departing the United States to appear at a U.S. Embassy or Consulate for an immigrant visa interview.

[144] *See* Unified Agenda of Regulatory and Deregulatory Actions, DOJ, Inadmissibility on Public Charge Grounds, RIN 1125 AA74 (Spring 2019), *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=1125-AA84* (last visited June 11, 2019).

[145] INA sections 103(a) and 239, 8 U.S.C. 1103(a) and 1229; 8 CFR 2.1 and 239.1.

[146] 8 CFR 245.2(a)(5)(ii) and 1245.2(a)(1).

[147] *See* INA section 208, 8 U.S.C. 1158.

[148] *See* 8 CFR 223.3(d)(2).

asylees and refugees who are applying for adjustment of status are not subject to the public charge inadmissibility ground under section 209(c) of the Act, 8 U.S.C. 1159(c).[149] Because the rule does not apply to or otherwise impact asylum applicants, asylees, and applicants for asylee or refugee adjustment, the rule does not violate international treaty obligations relating to refugees, to the extent those obligations are applicable.[150]

DHS also disagrees that the rule would violate international treaties such as the CERD [151] and the ICCPR [152] or that it would be inconsistent with non-binding instruments such as the UDHR [153] and the 1959 Declaration of the Rights of the Child.[154] First, the rule is not inconsistent with those treaties and instruments. As discussed above, the rule does not prevent anyone subject to the public charge ground of inadmissibility from applying for and receiving any benefits for which they are eligible, including benefits related to food and nutrition, housing, and healthcare, and basic social services. Additionally, to the extent that this rule does have a negative effect on those from particular groups, it is not DHS's intent, in issuing this final rule, to target aliens from certain countries or of a particular race. Instead, DHS's intent in codifying the public charge inadmissibility rule is to better ensure the self-sufficiency of aliens who seek to come to or remain in the United States.

Second, the two referenced declarations do not bind DHS as a matter of U.S. domestic law. As the Supreme Court has held, the UDHR ''does not of its own force impose obligations as a matter of international law.'' [155] The Declaration of the Rights of the Child, like the UDHR is a U.N. Declaration rather than a binding treaty. Moreover, the CERD and the ICCPR, were both ratified on the express understanding that they are not self-executing and therefore do not create judicially enforceable obligations.[156] DHS disagrees with the comment that ratified treaties should be considered as constitutional amendments as this is legally inaccurate.[157]

g. Contract Law

Comment: A commenter said that it would contradict principles of contract law to hold a child responsible for the public benefits they receive before the age of majority.

Response: DHS rejects the suggestion that DHS would be precluded, under contract law principles, from considering the receipt of public benefits in a public charge inadmissibility determination by an alien under the age of 18. With the exception of the affidavit of support statute, section 213A of the Act, 8 U.S.C. 1183a, which requires a sponsor to be at least 18 years of age, decisions as to the admissibility of aliens subject to section 212(a))(4) of the Act, 8 U.S.C. 1182(a)(4), are questions regarding the burden the alien will place on the government in the future, and does not implicate contract law. While individuals under the age of 18 generally lack the capacity under most States' laws to enter into a contract, such considerations are inapposite to this rulemaking. Aliens under the age of 18 are subject to the provisions of section 212(a))(4) of the Act, 8 U.S.C. 1182(a)(4), except where Congress has specifically provided an exemption of public charge inadmissibility, or otherwise provided the possibility of a waiver of the public charge inadmissibility ground. By its very nature, the public charge ground of inadmissibility frequently affects people who lack the capacity or competence to enter into contracts. Contract law does not limit DHS's ability to enforce the public charge ground of inadmissibility.

However, as noted elsewhere in this rule, DHS has decided, as a matter of policy, to exclude consideration of the receipt of Medicaid by aliens under the age of 21, as well as services or benefits funded by Medicaid but provided under the IDEA or school-based benefits provided to children who are at or below the oldest age of children eligible for secondary education as determined under State law. DHS also has excluded consideration of the receipt of all public benefits received by children of U.S. citizens whose lawful admission for permanent residence and subsequent residence in the legal and physical custody of their U.S. citizen parent(s) will result automatically in the child's acquisition of citizenship; or whose lawful admission for permanent residence will result automatically in the child's acquisition of citizenship as described in the rule.

F. Applicability of the Public Charge Ground of Inadmissibility, and the Public Benefit Condition to Extension of Stay and Change of Status

1. Applicability of the Public Charge Ground of Inadmissibility Generally

Comment: A commenter opposed the application of the rule to applicants for admission because, according to the commenter, it is impossible for DHS to make a prediction about future circumstances based upon the totality of the alien's circumstances at the time of the application for admission; the commenter said that life circumstances cannot be predicted. Many commenters said the proposed rule would directly affect a large number of individuals (some commenters cited 1.1 million individuals seeking to obtain lawful permanent resident status), half of whom already reside in the United States and would be subject to a public charge inadmissibility determination. Another commenter stated that the proposed rule would dramatically alter which immigrants are permitted to enter and stay in the United States. This commenter stated that quantitative and qualitative data, including the DHS Yearbook of Immigration Statistics, show that increases in restrictions to the legal means to immigration over the last hundred years are responsible for increases in unauthorized border crossings, visa overstays, and increases in an international network of private and public profiteers. Another

[149] ''The provisions of paragraphs (4), (5), and (7)(A) of section 212(a) shall not be applicable to any alien seeking adjustment of status under this section . . . .''

[150] Asylum is a discretionary benefit implementing Article 34 of the 1951 Convention Relating to the Status of Refugees (as incorporated in the 1967 Protocol Relating to the Status of Refugees), which is ''precatory,'' *INS* v. *Cardoza-Fonseca,* 480 U.S. 421, 441 (1987), and the 1967 Protocol is not self-executing, *e.g., Cazun* v. *U.S. Att'y Gen.,* 856 F.3d 249, 257 n.16 (3d Cir. 2017).

[151] 660 U.N.T.S. 195, U.N. Doc. A/6014 (1965).

[152] Dec. 16, 1966, 999 U.N.T.S. 171.

[153] G.A. Res. 217A (III), U.N. Doc. A/810 (1948).

[154] G.A. Res. 1386 (XIV), U.N. Doc. A/4354 (1959).

[155] *Sosa* v. *Alvarez-Machain,* 542 U.S. 692, 734–35 (2004).

[156] U.S. Reservations, Declarations, and Understandings, International Convention on the Elimination of All Forms of Racial Discrimination, 140 Cong. Rec. S7634–02 (1994) (''[T]he United States declares that the provisions of the Convention are not self-executing.''); U.S. Reservations, Declarations and Understandings, International Covenant on Civil and Political Rights, 138 Cong. Rec. 8071 (1992) (''[T]he United States declares that the provisions of Articles 1 through 27 of the Covenant are not self-executing.''); *see also Alvarez-Machain,* 542 U.S. at 735 (''[T]he United States ratified the Covenant [on Civil and Political Rights] on the express understanding that it was not self-executing and so did not itself create obligations enforceable in the federal courts.''); *Johnson* v. *Quander,* 370 F. Supp. 2d 79, 101 (D.D.C. 2005) (same—CERD), *aff'd,* 440 F.3d 489 (D.C. Cir. 2006).

[157] *See Reid* v. *Covert,* 354 U.S. 1, 18 (1957) (''This Court has also repeatedly taken the position that an Act of Congress, which must comply with the Constitution, is on a full parity with a treaty, and that when a statute which is subsequent in time is inconsistent with a treaty, the statute to the extent of conflict renders the treaty null.''); *La Abra Silver Min. Co.* v. *United States,* 175 U.S. 423, 460 (1899) (''Congress by legislation, and so far as the people and authorities of the United States are concerned, could abrogate a treaty made between this country and another country which had been negotiated by the President and approved by the Senate.'' (citation omitted)).

commenter indicated that the new regulation would adversely affect immigrants and nonimmigrants alike and discourage people from lawfully entering the United States through visas offered by the DOS.

Response: DHS disagrees that the rule cannot apply to applicants for admission because it is impossible to make a prediction about future circumstances based upon the totality of the alien's circumstances at the time of the application for admission. As mandated by Congress under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), any alien applying for admission to the United States is inadmissible if he or she is likely at any time to become a public charge. DHS must make a public charge inadmissibility determination unless the applicant for admission is within one of the exempted categories. Only those categories of aliens designated by Congress are exempt from the public charge ground of inadmissibility.[158] Additionally, although it will impact all aliens subject to the public charge ground of inadmissibility under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), the goal of this rule is to implement the public charge inadmissibility ground as established by Congress. DHS rejects the notion that there is a relationship between the implementation of the congressionally-mandated ground of inadmissibility through this rulemaking and any increase in the number of illegal border crossings or other illegal behavior.

Comment: Multiple commenters stated that the proposed rule would negatively affect those seeking a ''green card'' (lawful permanent residence) and would notably affect family-based immigration.

Response: Although this rule will impact those seeking lawful permanent resident status based on an approved family-based petition, only aliens who are subject to the public charge ground of inadmissibility will be required to demonstrate that they are not likely to become a public charge at any time in the future, as prescribed in the rule.

Comment: Another commenter indicated that current green card holders and other aliens lawfully present in the United States, like recipients of Deferred Action for Childhood Arrivals (DACA), could see their status jeopardized, as they may not meet the income standard in the proposed rule.

Response: DHS notes that a person who is already a lawful permanent resident has already undergone a public charge inadmissibility determination, unless she or he was exempt from such a determination at the time of application for such status. Such a person would not undergo another public charge inadmissibility determination unless U.S. Customs and Border Protection (CBP) determines, upon the alien's return from a trip abroad, that the returning lawful permanent resident is an applicant for admission based on one of the criteria set forth in section 101(a)(13)(C) of the Act, 8 U.S.C. 1101(a)(13)(C), such as the alien has been absent from the United States for more than 180 days. Aliens who are lawfully present in the United States as nonimmigrants have also undergone a public charge inadmissibility determination, where applicable, and this rule does not impact their status unless they are seeking an immigration benefit for which admissibility is required or if they are seeking an extension of stay or change of status.

With respect to DACA recipients, DHS notes that an alien is not required to demonstrate that he or she is not inadmissible on the public charge ground when requesting DACA. A DACA recipient would only be subject to this rule when applying for a benefit for which admissibility is required.

Comment: A commenter indicated that the NPRM excludes too many applicants for admission from public charge review. The commenter stated that the category of ''applicants for admission'' is clearly defined in section 235(a) of the Act, 8 U.S.C. 1225(a) as ''aliens present in the United States who have not been admitted'' [159] and ''all aliens'' who have not been ''inspected by immigration officers.'' The commenter indicated that although most of these categories of aliens are barred from most of the public benefits designated under the proposed rule, the commenter's research indicates that the very high use of welfare programs by noncitizens cannot be explained unless at least half of the non-citizens surveyed in the Survey of Income and Program Participation (SIPP) data are in the country illegally. The commenter further stated that the NPRM fails to provide any guidance on how this population will be assessed for public charge inadmissibility.

Response: DHS disagrees that the rule excludes too many aliens from the public charge inadmissibility determination and disagrees that DHS failed to provide adequate guidance with respect to how DHS would apply the public charge inadmissibility determination with respect to the population identified by the commenter. Congress identified which aliens are subject to the public charge ground of inadmissibility and specified which aliens are exempt from, or can obtain a waiver of, public charge inadmissibility. DHS does not have the authority to add additional categories of aliens that must establish admissibility based on public charge. This rule only applies to those categories of aliens that Congress has designated as subject to the public charge ground of inadmissibility.[160]

In addition, although the commenter indicated that DHS fails to specify how to determine that aliens illegally present in the United States are inadmissible on the public charge ground, this determination is only made when aliens subject to this ground of inadmissibility apply for an immigration benefit for which admissibility is required, such as adjustment of status, or when determining what charges to lodge on an NTA when initiating removal proceedings under section 240 of the Act, 8 U.S.C. 1229a.[161] DHS notes that the SIPP data on receipt of public benefits by noncitizens includes asylees and refugees and lawful permanent residents who are lawfully present in the United States.

Comment: Some commenters stated that the regulation would be arbitrary and capricious because DHS would apply it to lawful permanent residents who were abroad for a trip exceeding 180 days, but DHS did not estimate the size of this population in the proposed rule. These commenters further stated that if the returning lawful permanent resident is placed in removal proceedings, the burden of proof of inadmissibility should remain on the government to establish by ''clear and convincing evidence'' [162] that he or she is lawfully present in the United States pursuant to a prior admission. This burden, per the commenters, should not be transferred to the lawful permanent

[158] *See* 8 CFR 212.23.

[159] *See* INA section 235(a) and (b), 8 U.S.C. 1225(a) and (b).

[160] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4) (Any alien who, . . . in the opinion of the Attorney general at the time of application for admission . . . is likely to become a public charge, is inadmissible). *See* 8 CFR 212.20.

[161] For example, to be eligible for adjustment of status under INA section 245(a) and (c), 8 U.S.C. 1255(a) and (c), an applicant must generally have been, among other requirements, inspected and admitted or paroled, and in legal immigration status. Therefore, in most cases, the applicant must have been legally entered the United States and be legally present in the United States. In contrast, under INA section 244(a), 8 U.S.C. 1154a, an alien cannot be denied Temporary Protected Status on account of his or her immigration status or lack thereof.

[162] *See* INA section 240(a)(3), 8 U.S.C. 1229a(a)(3).

resident through completion of the Form I–944 or similar forms that CBP may request. The commenter stated that doing so, would violate the lawful permanent resident's due process rights as a permanent resident by shifting the burden of proof to returning lawful permanent residents, contrary to *Woodby* v. *INS,* 385 U.S. 276 (1966), *Landon* v. *Plasencia,* 459 U.S. 21 (1982), and *Matter of Rivens,* 25 I&N Dec. 623 (BIA 2011).

Response: DHS does not believe such a quantitative estimate is necessary. DHS further disagrees that the rule impermissibly shifts the government's burden of proof onto the returning lawful permanent residents, that the applicability of inadmissibility grounds to returning lawful permanent residents is unlawful, or that it would violate an alien's due process rights. Congress specified when lawful permanent residents returning from a trip abroad will be treated as applicants for admission, and also specified who bears the burden of proof in removal proceedings when such an alien is placed in proceedings. In general, the grounds of inadmissibility set forth in section 212(a) of the Act, 8 U.S.C. 1182(a), including public charge inadmissibility, do not apply to lawful permanent residents returning from a trip abroad.[163] Congress set forth the circumstances under which lawful permanent residents returning from a trip abroad are considered applicants for admission, and therefore, are subject to admissibility determinations, including an assessment of whether the alien is inadmissible as likely at any time to become a public charge.[164] If CBP determines that the returning lawful permanent resident is an applicant for admission based on one of the criteria set forth in section 101(a)(13)(C) of the Act, 8 U.S.C. 1101(a)(13)(C), including that the alien has been absent for more than 180 days, and that the alien is inadmissible under one of the grounds set forth in section 212(a) of the Act, 8 U.S.C. 1182(a), the law requires that the alien be placed into removal proceedings.[165] In such removal proceedings, DHS bears the burden of proof to demonstrate by clear and convincing evidence that the lawful permanent resident is properly considered an applicant for admission based on being outside of the United States for more than 180 days, or any of the grounds set forth in 101(a)(13)(C) of the Act, 8 U.S.C. 1101(a)(13)(C).[166] And, if the lawful permanent resident is not an applicant for admission, but is removable from the United States for any reason, DHS may charge the alien under section 237 of the INA, 8 U.S.C. 1227.

For these reasons, DHS disagrees that the rule impermissibly places the burden on returning lawful permanent residents in violation of their rights under *Woodby* v. *INS,*[167] *Landon* v. *Plasencia,*[168] and *Matter of Rivens* as alleged by the commenters.[169] Specifically, in *Woodby* and *Landon,* which predate IIRIRA, the Court addressed the government's burden in deportation proceedings against a lawful permanent resident and indicated that the government would bear the burden to demonstrate that the alien is a returning resident seeking admission. Subsequently, with IIRIRA, Congress specified the circumstances under which a lawful permanent resident will be treated as an applicant for admission, and provided that when an alien is an applicant for admission that the alien has the burden to establish that he or she is clearly and beyond doubt entitled to be admitted and is not inadmissible; however, Congress remained silent with respect to the burden and standard of proof required to determine whether an alien is an applicant for admission.[170] The BIA in *Matter of Rivens,*[171] did not deviate from longstanding case law on this question [172] and affirmed that DHS continues to bear the burden of proving by clear and convincing evidence that a returning lawful permanent resident should be treated as an applicant for admission.[173] This rule does not alter DHS's burden of proof with respect to the treatment of returning lawful permanent residents as applicants for admission in any way, *i.e.,* the only burden DHS bears is establishing that the retuning lawful permanent resident should be treated as an applicant for admission.[174] The BIA, in *Matter of Rivens,* did not reach the issue of who then bears the burden of showing admissibility, or a lack of inadmissibility, once it has been determined that an alien is an applicant for admission.[175]

DHS notes, as was pointed out by the commenters, that under section 291 of the Act, 8 U.S.C. 1361, an applicant for admission always bears the burden of proof to establish that he or she is not inadmissible to the United States under any provision of the Act; similarly, under section 240(c)(2)(A) of the Act, 8 U.S.C. 1229a(c)(2)(A), an applicant for admission in removal proceedings has the burden of establishing that he or she is clearly and beyond doubt entitled to be admitted and is not inadmissible under section 212(a) of the Act, 8 U.S.C. 1182(a). Therefore, the burden still lies with the returning resident to establish that he or she is not inadmissible based on public charge.

Comment: One commenter asks whether the public charge regulation would apply to applicants seeking naturalization.

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[163] Although Congress did not subject those admitted as lawful permanent residents to grounds of inadmissibility under INA section 212(a), 8 U.S.C. 1182(a), it did codify that an alien's certain conduct or conditions will lead to the alien's removal from the United States, including inadmissibility on public charge. *See* INA section 237, 8 U.S.C. 1227, generally, and INA section 237(a)(5), 8 U.S.C. 1227(a)(5). One basis of removal is an alien's inadmissibility at the time of admission or adjustment of status, including being inadmissible for public charge under INA section 212(a)(4), 8 U.S.C. 1182(a)(4). *See* INA section 237(a)(1)(A), 8 U.S.C. 1227(a)(1)(A). If the alien is charged as a deportable alien, the burden of proof is on the government to show by clear and convincing evidence that the alien, who has been admitted, is not deportable. *See* INA section 240(c)(3), 8 U.S.C. 1229a(c)(3).

[164] *See* INA section 101(a)(13)(C), 8 U.S.C. 1101(a)(13)(C). According to this provision, lawful permanent residents are regarded as an applicant for admission when they: (1) Have abandoned or relinquished that status; (2) have been outside the United States for a continuous period in excess of 180 days; (3) have engaged in illegal activity after departing the United States; (4) have departed the United States while under legal process seeking removal of the alien from the United States, including removal proceedings and extradition proceedings; (5) have committed an offense identified in INA section 212(a)(2), 8 U.S.C. 1182(a)(2), unless granted a waiver of inadmissibility for such offense or cancellation of removal; and (6) are attempting to enter at a time or place other than as designated by immigration officers or who have not been admitted to the United States after inspection and authorization by an immigration officer.

[165] As explained above, lawful permanent resident s are not subject to grounds of inadmissibility after being properly admitted to the United States as an lawful permanent resident within the meaning of INA section 101(a)(20), 8 U.S.C. 1101(a)(20). *See* INA sections 235(b)(2)(A) and 240, 8 U.S.C. 1225(b)(2)(A) and 1229a.

[166] *See Matter of Rivens,* 25 I&N Dec. 623 (BIA 2011).

[167] *See Woodby* v. *INS,* 385 U.S. 276 (1966).

[168] *See Landon* v. *Plascencia,* 459 U.S. 21 (1982).

[169] *Matter of Rivens,* 25 I&N Dec. 623 (BIA 2011).

[170] *See* INA sections 235 and 240, 8 U.S.C. 1225 and 1229a; *see Matter of Rivens,* 25 I&N Dec. 623, 625 (BIA 2011). *See* INA sections 101(a)(13)(C), 240(c)(2), and 291, 8 U.S.C. 1101(a)(13)(C), 1229a(c)(2), and 1361.

[171] 25 I&N Dec. 623, 626 (BIA 2011).

[172] *See Matter of Rivens,* 25 I&N Dec. 623, 625 (BIA 2011) (citing *Matter of Huang,* 19 I&N Dec. 749 (BIA 1988); *Woodby* v. *INS,* 385 U.S. 276 (1966); and *Landon* v. *Plasencia,* 459 U.S. 21 (1982)).

[173] *See Matter of Rivens,* 25 I&N Dec. 623, 625 (BIA 2011).

[174] *See Matter of Rivens,* 25 I&N Dec. 623, 626 (BIA 2011).

[175] *See Matter of Rivens,* 25 I&N Dec. 623, 626 (BIA 2011) (not reaching the issue because it was unnecessary to address the ''open question of who then bears the burden of showing admissibility, or a lack of inadmissibility, once it has been determined that an alien is an applicant for admission.'').

Response: The laws governing naturalization can be found in Title III of the INA. The public charge ground of inadmissibility does not apply in naturalization proceedings. DHS notes, however, that USCIS assesses as part of the naturalization whether the applicant was properly admitted as a lawful permanent resident and therefore was eligible for adjustment based upon the public charge ground of inadmissibility at the time of the adjustment of status.[176]

Comment: Multiple commenters indicated that the proposed rule makes the path to citizenship more difficult and would give the Government the ability to deny a ''broad swath'' of applicants for green cards, especially children who are likely to be self-sufficient as adults, teenagers and students completing their education, infant caregivers, the elderly, immigrants from certain countries, and an immigrant previously deemed admissible who becomes disabled.

Many commenters stated that the rule should not apply to children, and that doing so would destabilize families, make children unhealthy or more likely than not to become a public charge as adults, and may cause some children to be excluded while the parent is admitted. Some commenters provided data on the number of children who would be impacted by the rule. A commenter proposed an exemption from public charge for all children up to age 18, because such children are subject to child labor laws and in most cases still engaged in mandatory education. The commenter also proposed a three-year grace period beyond age 18, until age 21. Finally, the commenter recommended further extending the commenter's proposed exemption for those aliens who are currently engaged in full-time college or vocational education, and for a three-year grace period after graduation or certification. The commenter stated that this will be a strong incentive for young immigrants toward self-sufficiency and positive GDP contribution. A few commenters added that children born in the United States to immigrant parents are United States citizens and therefore are eligible for public benefits under the same eligibility standards as all other United States citizens.

A commenter requested that asylum seekers and entrepreneurs, crime victims, victims and survivors of domestic violence, and T nonimmigrants seeking adjustment of status should be excluded from the rule and public charge ground of inadmissibility. Similarly, commenters stated that victims of domestic violence, human trafficking, and sexual assault would be harmed as a consequence since family members sponsored by victims would be impacted by the proposed rule.

Response: Generally, the public charge ground of inadmissibility applies to all aliens who are applicants for a visa, admission, or adjustment of status. However, as noted previously, Congress—not DHS—has the authority to specify which aliens are exempt from public charge inadmissibility determinations, as well as those who may obtain a waiver of public charge inadmissibility. Therefore, the public charge inadmissibility provisions set forth in this final rule will apply to all aliens seeking admission or adjustment of status, or any other immigration benefit for which admissibility is required, unless otherwise exempted by Congress, irrespective of the alien's age, medical condition, economic status, place of origin, or nationality. With respect to comments suggesting that DHS specifically exclude children, teenagers, caregivers of infants, the elderly, and entrepreneurs, and other categories of individuals from the public charge inadmissibility provisions, section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), applies to such aliens applying for a visa, admission, or adjustment of status, unless otherwise specified by Congress. DHS has tailored the effects of this rule somewhat for certain populations. On the whole, however, DHS lacks the authority to create wholesale exemptions or provide a grace period for broad categories of aliens, as suggested by the commenters.

DHS notes that does have the authority to define public charge as it has in this rule and in doing so, decide which public benefits are considered for the purposes of this rule. As discussed in greater detail below, DHS has made some changes to the public benefits that DHS will consider, particularly as it relates to receipt of Medicaid benefits by aliens under the age of 21 and pregnant women, including women for the 60 days following pregnancy, and for receipt of Medicare Part D LIS. DHS has also clarified the role that age and other factors play in the public charge inadmissibility determination. DHS believes that these changes may at least partially address some of the commenters' concerns, and that such changes are more in line with the statute.

With respect to the commenter's suggestions that asylees, crime victims, victims of domestic violence, and T nonimmigrants be exempt from this rule, DHS notes that such individuals are generally exempted by statute from public charge inadmissibility determinations, and that such exemptions are also set forth in 8 CFR 212.23.[177] As explained in the NPRM,[178] and addressed further below, DHS codified in the regulation those classifications of nonimmigrants and immigrants that Congress exempted from public charge grounds of inadmissibility. DHS will not, and cannot, exempt other classes of aliens unless these exemptions are created by Congress.[179]

2. Applicability and Content of the Public Benefits Condition

Comment: Citing to the statutory policy statement set forth in PRWORA, a commenter indicated that nonimmigrant applications or petitions for extension of stay or change in status should be subject to inadmissibility on public charge grounds in order to ensure their self-sufficiency. By contrast, some commenters stated that DHS lacked the authority to condition of eligibility for extension of stay or change of status on past, current, or future receipt of public benefits because the public charge inadmissibility ground does not apply to extension of stay or change of status; commenters stated that this provision was therefore not supported by the plain language of the statute and is unlawful. A commenter stated in regards to extension of stay and change of status that DHS's bald assertion that it generally has discretion to apply the test to new categories cannot overcome clear and unambiguous language from Congress to the contrary.

Some of these commenters also indicated that nobody would be eligible for extension of stay or change of status because the proposed regulation asks applicants to prove a negative. Another commenter disagreed with the proposed rule because no one can determine whether an applicant seeking an extension of stay or change of status will receive public benefits at any time in the future.

[176] *See* INA section 318, 8 U.S.C. 1429. Additionally, an individual may become removable on account of public charge while in lawful permanent resident status, which is a consideration which may be assessed at the time of naturalization. *See* INA section 237(a)(5), 8 U.S.C. 1227(a)(5). However, the assessment of removability for public charge is different from the assessment of public charge inadmissibility and is not a part of this rule.

[177] However, DHS notes that T nonimmigrants are not excluded from public charge inadmissibility when applying for employment-based adjustment of status. *See* INA section 212(a)(4)(E), 8 U.S.C. 1182(a)(4)(E).

[178] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51156–57 (proposed Oct. 10, 2018).

[179] *See* 8 CFR 212.23.

One commenter stated that because employment-based nonimmigrant categories require the employer to demonstrate the ability to financially support the nonimmigrant, and further, because other nonimmigrants classifications such as F and M nonimmigrant students must demonstrate sufficient financial support during the duration of the nonimmigrant stay, that there are sufficient financial safeguards in place for these nonimmigrants such that this rule poses an unnecessary administrative burden. A commenter indicated that the expansion of the public charge rule to include additional classifications of nonimmigrants will reduce immigration or admission rates.

Response: Neither the NPRM nor this final rule is intended to apply the public charge ground of inadmissibility to extension of stay or change of status applicants. Instead, DHS is exercising its statutory authority to set a new condition for approval of extension of stay and change of status applications—that the applicant establish that the alien has not received since obtaining the nonimmigrant status he or she seeks to extend or from which he or she seeks to change, and through adjudication, one or more public benefits for more than 12 months in the aggregate within any 36-month period.[180] This condition will apply to any extension of stay or change of status application or petition postmarked (or if applicable, submitted electronically) on or after the effective date of the rule.

If the nonimmigrant status the individual seeks to extend or to which the applicant seeks to change is statutorily exempt from the public charge ground of inadmissibility,[181] then the public benefits condition will not apply.

After considering the comments, DHS agrees with the commenters that an assessment of whether the nonimmigrant is ''likely to receive public benefits'' for the expected period of stay, which included the option for USCIS to request submission of a Form I–944 as part of an RFE, might have been similar to a public charge inadmissibility assessment. In addition, applying a prospective element to the public benefits condition would likely be redundant and unnecessary given the finite nature of nonimmigrant status and stay. To the extent DHS grants an extension of stay to a nonimmigrant subject to the public benefit condition after determining that the alien had not received public benefits, and a nonimmigrant subsequently wishes to apply for another, the condition would apply again. The same would apply to a change of status. If, however, an alien leaves the United States after holding nonimmigrant status, and seeks a new nonimmigrant or immigrant visa based on a classification that is subject to INA 212(a)(4), 8 U.S.C. 1182(a)(4), then the public charge ground of inadmissibility will apply. Similar to aliens who are not required to obtain a visa but are subject to INA 212(a)(4), 8 U.S.C. 1182(a)(4)—DHS would apply the public charge ground of inadmissibility at the port of entry.[182] Finally, with respect to an alien in the United States who is eligible to adjust status from a nonimmigrant classification to that of a lawful permanent resident, and the alien is subject to INA 212(a)(4), 8 U.S.C. 1182(a)(4), DHS will at the time of adjudication of an adjustment of status application make a public charge inadmissibility determination consistent with the requirements of INA 212(a)(4), 8 U.S.C. 1182(a)(4), and regulations promulgated through this rulemaking. Therefore, DHS removed the future-looking aspect of this condition and will not request applicants for an extension of stay or change of status to submit a Form I–944. Additionally, DHS made a technical edit to remove ''currently receiving public benefits,'' as the reference to the alien having ''received'' public benefits is sufficiently inclusive of receipt up to the date of adjudication. According to preexisting DHS regulations, an applicant must meet an eligibility requirement or a condition not only at the time of filing but also at the time of adjudication,[183] which renders superfluous the proposed text regarding ''currently receiving public benefits.'' Finally, because DHS has moved the public benefits receipt threshold from the public benefits definition to the public charge definition, DHS added the ''for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months)'' threshold to the public benefits condition in the extension of stay and change of status provisions as well because the threshold applies to the receipt of public benefits in these provisions, as well.

Under this final rule, nonimmigrants who are seeking an extension of stay or a change of status must only demonstrate that they have not received, since obtaining the nonimmigrant status they seek to extend or from which they seek to change, *up to the time of the adjudication of the application,*[184] one or more public benefits for more than 12 months in the aggregate within any 36-month period.[185] This condition will apply to any extension of stay or change of status application or petition postmarked (or if applicable, electronically submitted) on or after the effective date of the rule. DHS will not consider any receipt of public benefits prior to the rule's effective date, for purposes of the public benefits condition for extension of stay or change of status.

Imposing conditions on extension of stay and change of status applications is within DHS's authority, as Congress granted DHS the authority, in sections 214 and 248 of the Act, 8 U.S.C. 1184 and 1258, to regulate conditions and periods of admission of nonimmigrants and conditions for change of status, respectively. As explained in the NPRM, however, the government's interest in a nonimmigrant's ability to maintain self-sufficiency does not end with his or her initial admission as a nonimmigrant.[186] Therefore, given DHS's authority to set conditions [187] and Congress' policy statement ''that aliens *within* the Nation's borders not depend on public resources to meet their needs,'' [188] it is reasonable for DHS to require, as a condition of obtaining an extension of stay or change of status, evidence that nonimmigrants inside the United States have remained self-sufficient during their nonimmigrant stay.

DHS will continue to require that the alien meets his or her burden of proof that he or she is eligible for the status requested, including whether the alien has the financial means, if required by the laws governing the particular nonimmigrant classification. The two aspects of the adjudication (eligibility for the status requested and the public benefit condition) are not duplicative. DHS notes that although eligibility for a

[180] *See, e.g.,* INA sections 103(a)(3), 214(a)(1), 248(a).

[181] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51135–36 (proposed Oct. 10, 2018).

[182] *See, e.g.,* 8 CFR 217.4(a)(1) (Visa Waiver Program participants must not be ''inadmissible to the United States under one or more of the grounds of inadmissibility listed in section 212 of the Act (other than for lack of a visa).'').

[183] *See* 8 CFR 103.2(b).

[184] *See* 8 CFR 103.2(b) (*Demonstrating eligibility.* An applicant or petitioner must establish that he or she is eligible for the requested benefit at the time of filing the benefit request and must continue to be eligible through adjudication.).

[185] *See* 8 CFR 214.1(a)(3)(iv) and (c)(4)(iv); *see* 8 CFR 248.1(a) and (c)(4).

[186] *See* PRWORA's policy statement at 8 U.S.C. 1601, reiterating that self-sufficiency of all aliens coming to the United States continues to be national policy.

[187] *See* INA sections 214 and 248, 8 U.S.C. 1184, 1258.

[188] *See* 8 U.S.C. 1601(2)(A).

nonimmigrant status might require some indication of future self-support, it would generally not require an assessment of public benefits received since the alien obtained the nonimmigrant status he or she seeks to extend or from which he or she seeks to change.

Comment: One commenter said that, according to *Mathews* v. *Eldridge,* 424 U.S. 319 (1976), it would be improper to implement the public benefits condition for change of status applicants with no available appeal process. To comply with due process rights as prescribed by *Goldberg* v. *Kelly,* 397 U.S. 254 (1970), the commenter suggested that DHS give applicants a chance to respond with evidence that supports their admissibility, and that DHS should not revoke the status until the decision had been fully appealed through all stages of review.

Response: DHS disagrees that imposing the public benefits condition on extension of stay and change of status applications is improper because it violates due process. DHS notes that to the extent that USCIS obtains derogatory information unknown to the applicant relevant to the extension of stay or change of status application, consistent with 8 CFR 103.2(b)(16)(i), USCIS will provide notice of the derogatory information and give the applicant an opportunity to respond. Moreover, applicants for extension of stay and change of status will receive notice of deficiencies as appropriate and consistent with 8 CFR 103.2(b)(8) and consistent with USCIS' policy on the issuance of certain requests for evidence and notices of intent to deny,[189] before denying an application for an extension of stay or change of status. In general, under DHS regulations, a denial of an extension of stay or change of status application cannot be appealed.[190] Upon denial of an extension of stay or a change of status application, if the alien is removable, DHS can issue an NTA and place the alien in removal proceedings.[191] In removal proceedings, the alien can challenge the basis for removal, and appeal the immigration judge's decision, if desired.[192] These proceedings provide due process to the extent required by law.[193]

Comment: Many commenters noted that consular officers already conduct public charge inadmissibility assessments and CBP would conduct an admissibility determination at the port of entry. Others indicated that the proposed changes extension of stay and change of status applications create duplicative work for applicants and USCIS.

Response: As explained in the proposed rule,[194] DHS believes that the Government interest in ensuring an alien's self-sufficiency does not end once a nonimmigrant is admitted to the United States. The Government has an interest in ensuring that aliens present in the United States are self-sufficient. This interest does not end once the alien is admitted; aliens should remain self-sufficient for the entire period of their stay, including any extension of stay or additional period of stay due to a change of status. Indeed, as set forth by Congress in PRWORA, ''aliens *within* the Nation's borders [should] not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' [195] The fact that DHS already considers the applicant's financial status in adjudicating some extension of stay and change of status applications further supports this policy. Moreover, although the extension of stay or change of status provisions in the INA and the regulations do not specifically reference an alien's self-sufficiency, consideration of an alien's self-sufficiency in these applications is consistent with the self-sufficiency principles of PRWORA and aligns the INA to those principles.[196]

DHS therefore does not believe that considering an extension of stay or change of status applicant's past and current receipt of public benefits over the designated threshold in the United States is duplicative of the consular officer's public charge inadmissibility assessment at the nonimmigrant visa stage, given that a certain amount of time has passed between an alien's consular interview or the alien's admission to the United States in nonimmigrant status, and the alien's request for an extension of stay or change of nonimmigrant status.[197] The alien's financial situation may have changed since the visa was issued or the alien was admitted to the United States.

a. Nonimmigrant Students and Exchange Visitors

Comment: A commenter pointed out that the new public charge rule would apply to students and exchange visitors who would seek to change or extend their status. The commenter indicated that the new rule, therefore, would impose new standards and barriers for students. The commenter added that drops in international enrollment would have broader ripple effects for United States higher education institutions.

Response: To the extent that the rule may impose barriers to those seeking to extend their stay or change their status, as explained previously, given DHS's authority [198] and Congress' policy statement with respect to self-sufficiency,[199] it is reasonable for DHS to impose, as a condition of obtaining an extension of stay or change of status, the requirement that the alien demonstrate that he or she has not received public benefits as defined in 8 CFR 212.21(b).[200] As discussed previously, DHS has removed the forward-looking aspect of the public benefits condition. This may ameliorate the consequences of the public benefits condition for certain nonimmigrants.

Comment: Another commenter stated that subjecting extension of stay and change of status applications and petitions to the public charge test produces multiple legal contradictions: The commenter provided the example of international students in F–1 status who are not eligible to work more than 20 hours off campus or in federally-subsidized work study positions, asserting that these restrictions greatly reduced the amount of income students can earn and thus, reduces their self-sufficiency. The commenter stated that the determinations on self-sufficiency in one status bear no significance on an individual's ability to be self-sufficient within the legal confines of a different classification.

Response: As noted above, DHS disagrees that the rule would require

[189] *See* USCIS Policy Memorandum Issuance of Certain RFEs and NOIDs; Revisions to *Adjudicator's Field Manual* (*AFM*) Chapter 10.5(a), Chapter 10.5(b) PM–602–0163 (Jul. 13, 2018) (*https://www.uscis.gov/sites/default/files/USCIS/Laws/Memoranda/AFM_10_Standards_for_RFEs_and_NOIDs_FINAL2.pdf* (last visited June 21, 2019).

[190] *See* 8 CFR 214.1(c)(5) and 8 CFR 248.3(g).

[191] *See* USCIS Policy Memorandum, Updated Guidance for the Referral of Cases and Issuance of Notices to Appear (NTAs) in Cases Involving Inadmissible and Deportable Aliens (June 28, 2018), *https://www.uscis.gov/sites/default/files/USCIS/Laws/Memoranda/2018/2018-06-28-PM-602-0050.1-Guidance-for-Referral-of-Cases-and-Issuance-of-NTA.pdf* (last visited May 8, 2019).

[192] *See* INA sections 240 and 242, 8 U.S.C. 1229a and 1252.

[193] *E.g., Zadvydas* v. *Davis,* 533 U.S. 678, 693 (2001).

[194] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51135–36 (proposed Oct. 10, 2018).

[195] *See* 8 U.S.C. 1601(2)(A).

[196] *See Southern S.S. Co.* v. *N.L.R.B.,* 316 U.S. 31, 47 (1942) (requiring ''careful accommodation of one statutory scheme to another. . . .'').

[197] DHS's authority to specify the conditions, as a matter of discretion, under which an alien is eligible for either a change of status or extension of stay can be found in INA section 214(a)(1) and INA section 248(a); 8 U.S.C. 1184(a)(1) and 1258(a); and 8 CFR 214.1 and 8 CFR 248.1.

[198] *See* INA section 214 and 248, 8 U.S.C. 1184 and 1258.

[199] *See* 8 U.S.C. 1601.

[200] *See* 8 CFR 214.1(a)(3)(iv) and (c)(4)(iv), and 8 CFR 248.1(c)(4).

individuals seeking extension of stay or change of status to show they are not inadmissible under section 212(a)(4), 8 U.S.C. 1182(a)(4). At the time of the application for a nonimmigrant visa, the alien must demonstrate to DOS that he or she is not likely at any time in the future to become a public charge. Similarly, at the time a nonimmigrant applies for admission, he or she must demonstrate to CBP that he or she is not likely at any time in the future to become a public charge.

However, when seeking an extension of stay or change of status as a nonimmigrant student [201] or nonimmigrant exchange visitor,[202] the alien will not need to establish that he or she is not likely at any time in the future to become a public charge because those seeking extension of stay or change of status are not subject to the public charge ground of inadmissibility. However, the alien will need to demonstrate that he or she has sufficient funds to pay tuition and related costs as part of the application for extension of stay or change of status to a nonimmigrant. Further, the alien must demonstrate that he or she has not received, since obtaining the nonimmigrant status he or she seeks to extend or change and through the time of filing and adjudication, one or more public benefits as defined in the rule, for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months).

DHS disagrees that subjecting extension of stay and change of status applicants to this new condition is legally contradictory because a student's restriction on employment in the United States reduces an alien's self-sufficiency. As explained above, a student is required, as part of the eligibility for the nonimmigrant classification, to establish that he or she has sufficient funds to study in the United States; students are thus admitted with the expectation of self-sufficiency. The public benefits condition created by this rule would not be inconsistent with such expectation.

b. Workers

Comment: A commenter pointed out that the new public charge rule applies to specialty workers and their dependents who would seek admission or those who seek to change or extend their status. A commenter indicated that the new rule would impose new standards and barriers not only on foreign workers, but also on employers because of the unpredictability of the public charge determination and because wages alone would not be the determining factor. Citing to research and data on the population size and impact that the rule would have on H–2A nonimmigrant workers, several other commenters stated that H–2A nonimmigrant workers would be affected and that the rule would isolate H–2A nonimmigrant workers. One commenter, for example, also stated that the rule's criteria for factors to be considered in the totality of the circumstances test disadvantages farmworkers who seek to either apply to adjust to lawful permanent resident status or apply for or extend their nonimmigrant status. The commenter indicated that many farmworkers, domestic, and H–2A workers would find themselves determined to be a public charge due to factors beyond their control, such as low wages, poverty-level income, and lack of health insurance. Commenters stated that H–2A nonimmigrant workers undergo a public charge assessment at the consular office, and once in the United States, they are not eligible for the vast majority of public benefits but are provided housing by their employer. A commenter also stated that H–2A nonimmigrant workers are already reluctant to seek services due to fear of employer retaliation, and that this rule's chilling effect could further isolate them from the communities where they work and live. Thus, H–2A nonimmigrant workers would face delays and uncertainty in the extension of their visa status, and may become more vulnerable to recruitment fees and agent costs which, while prohibited, are a common abuse. The commenters urged DHS to withdraw the rule in its entirety.

Response: For aliens seeking to extend their stay or change their status to that of an H–2A nonimmigrant, absent any indication of an alien's receipt of the designated public benefits for more than 12 months in the aggregate in a 36-month period since obtaining the nonimmigrant status from which they seek to change, USCIS will approve the application if the alien meets the eligibility requirement for the nonimmigrant classification. Additionally, as commenters pointed out, nonimmigrants are generally ineligible for public benefits that would be considered in connection with this rule. DHS understands the concerns addressed by the commenter regarding the practices of nonimmigrant workers and potential abuses of the programs, and therefore encourages the reporting of any such abuse through the channels provided by DHS or the Department of Labor (DOL).[203]

As previously indicated, given Congress' policy statement with respect to self-sufficiency, and DHS's authority to promulgate a rule addressing public charge inadmissibility, it is reasonable for DHS to impose, as a condition of obtaining an extension of stay or change of status, the requirement that the alien demonstrate that he or she has not received public benefits as defined in the rule. DHS notes that it has removed the forward-looking aspect of the public benefits condition. This may ameliorate the consequences of the public benefits condition for certain nonimmigrants.

Comment: One commenter stated that the proposed rule would be detrimental to South Asian organizations that sponsor nonimmigrant religious workers and the rule would deem most of them inadmissible to the United States as public charges. The commenter stated that as part of a petition from, a sponsoring institution, usually a non-profit entity supported through volunteer contributions, it would provide free housing, all meals, and health insurance to the religious worker as part of the employment package and may offer a small stipend to cover incidental expenses in lieu of a salary. The commenter indicated that such an employment offer, with its mix of monetary and non-monetary compensation, might be insufficient to overcome the public charge grounds based on the totality of the

[201] *See* 8 CFR 214.1(f)(1)(B) (requiring that the student presents documentary evidence of financial support in the amount indicated on the SEVIS Form I–20 (or the Form I–20A–B/I–20ID)); 8 CFR 214.1(m)(1)(B) (requiring that student documents financial support in the amount indicated on the SEVIS Form I–20 (or the Form I–20M–N/I–20ID); *see* AFM Chapter 30.3(c)(2)(C) (applicants to change status to a nonimmigrant student must demonstrate that they have the financial resources to pay for coursework and living expenses in the United States); *see also* 22 CFR 41.61(b)(1)(ii) (requiring that F and M nonimmigrants possess sufficient funds to cover expenses while in the United States or can satisfy the consular officer that other arrangements have been made to meet those expenses).

[202] *See* 8 CFR 214.2(j)(1) (admission upon presentation of SEVIS Form DS–2019, issued by DOS); 22 CFR 41.62(b)(2) (requiring that J nonimmigrants possess sufficient funds to cover expenses or have made other arrangements to provide for expenses before DOS can approve DS–2019 and the visa). *See also* AFM Chapter 30.3(c)(2)(C) (applicant to change status to exchange visitor must show approved DS–2019 (formerly known as IAP–66).

[203] USCIS has web pages and email addresses dedicated to combating suspected H–1B and H–2B fraud or abuse. Anyone, including both U.S. and foreign workers who suspect they or others may be the victim of fraud or abuse, can email USCIS to submit tips, alleged violations, and other relevant information. *See* USCIS, Report Labor Abuses, *https://www.uscis.gov/working-united-states/information-employers-employees/report-labor-abuses* (last visited May 8, 2019).

circumstances test proposed in the NPRM.

Response: For aliens seeking to extend their stay or change their status to that of religious workers, absent any indication of an alien's receipt of the designated public benefits for more than 12 months in the aggregate in a 36-month period, USCIS will approve the application if the alien meets the eligibility requirement for the nonimmigrant classification. Additionally, as commenters pointed out, nonimmigrants are generally ineligible for public benefits that would be considered in connection with this rule.

As previously indicated, given Congress' policy statement with respect to self-sufficiency, and DHS's authority to promulgate a rule addressing public charge inadmissibility, it is reasonable for DHS to impose, as a condition of obtaining an extension of stay or change of status, the requirement that the alien demonstrate that he or she has not received public benefits as defined in the rule. DHS notes that it has removed the forward-looking aspect of the public benefits condition. This may ameliorate the consequences of the public benefits condition for certain nonimmigrants.

DHS acknowledges that, once the rule is effective, certain religious workers seeking admission to the United States as nonimmigrants could be impacted by this rule. As part of the determination of whether any alien is likely at any time in the future to become a public charge, DHS will consider whether the alien has sufficient assets and resources for the purpose of his or her stay in the United States upon admission.[204] DHS believes that this regulation, and other provisions of the INA and implementing regulations, can be administered consistently with the Religious Freedom Restoration Act of 1993 (RFRA).[205] As DHS has noted previously, ''[a]n organization or individual who believes that the RFRA may require specific relief from any provision of this regulation may assert such a claim at the time they petition for benefits.'' [206] Similarly, DHS acknowledges that any individual or organization who identifies a substantial burden on his, her, or an organization's exercise of religion such that the RFRA may require specific relief may assert such a claim.[207] Note, the RFRA does not create a wholesale ''exemption'' to a generally applicable regulation; rather, it permits an applicant to seek specific relief which may or may not be complied with. Whether the RFRA applies to a given applicant is a case-by-case determination.[208] Therefore, for extension of stay and change of status purposes, DHS would still apply the public benefit condition to religious workers and review each case and each request individually.

With respect to admission and adjustment of status, the fact that the alien has an employment offer to work in the United States as well as monetary and non-monetary compensation are positive factors that generally indicate that the alien has sufficient assets and resources to be self-sufficient while present in the United States.[209] As previously noted, the public charge determination is an assessment considering all statutory mandated factors in the totality of the circumstances and that one factor alone is not outcome determinative. Separately, if an individual is required to obtain a visa from the DOS to facilitate entry into the United States, the inadmissibility determination with respect to whether to issue a visa is in the jurisdiction of DOS.

d. Compact of Free Association Migrants

Comment: Several commenters addressed Compact of Free Association (COFA) migrants from the Republic of the Marshall Islands, Federated States of Micronesia and the Republic of Palau, who are able to reside in the United States as nonimmigrants under treaty obligations. Commenters stated that while COFA migrants are not eligible for many federal public benefits, some do participate in state and local programs, especially health insurance, and COFA migrant children and pregnant women are eligible for Medicaid. Commenters stated that workers may either disenroll from these types of programs because of the applicability to nonimmigrants seeking admission or be blocked from entering the United States. One commenter stated that ''[t]his rule could be used to deny COFA entry and ability to live in the [United States] thereby abandoning our Nation's commitment to our Pacific allies, including the more than 61,000 COFA persons currently residing in the United States.''

Response: DHS appreciates the comments on the impact of the rule on COFA migrants and appreciates the continued relationship between COFA nations and the United States. Under the agreements and resulting regulations, citizens of the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau may enter into the United States as nonimmigrants, lawfully engage in employment, and establish residence in the United States without regard to certain grounds of inadmissibility.[210] Certain COFA citizens are subject to a modified version of the public charge ground of deportability, which is not directly affected by this rule.[211] But Congress did not exempt foreign nationals entering the United States under COFA from the public charge ground of inadmissibility, or otherwise modify the applicability of such ground of inadmissibility with respect to COFA migrants. And Congress expressly reiterated DHS's authority under section 214(a)(1) of the INA, 8 U.S.C. 1184(a)(1), ''to provide that admission as a nonimmigrant shall be for such time and under such conditions as the Government of the United States may by regulations prescribe.'' [212] DHS acknowledges that COFA migrants may be affected by this rulemaking when applying for admission at a port of entry

[204] *See* 8 CFR 214.2(r)(11).

[205] Public Law 103–141, sec. 3, 107 Stat. 1488, 1488 (Nov. 16, 1993).

[206] *Special Immigrant and Nonimmigrant Religious Workers,* 73 FR 72276, 72283 (2008) codified at 8 CFR pts. 204, 214, 299.

[207] Note that individuals ''located outside sovereign United States territory at the time their alleged RFRA claim arose'' are not ''person[s]'' within the meaning of RFRA. *Rasul* v. *Myers,* 512 F.3d 644, 672 (D.C. Cir.), *cert. granted, judgment vacated on other grounds,* 555 U.S. 1083 (2008).

[208] See generally *Federal Law Protections for Religious Liberty,* 82 FR 49668, 49669 (Oct. 26, 2017) from DOJ.

[209] Regulations that permit certain religious workers to self-support, 8 CFR 214.2(r)(11)(ii), require submission of ''verifiable evidence acceptable to USCIS'' that document ''the sources of self-support.'' These sources of self-support are a positive factor in the public charge determination. Additionally, as noted above, any individual or organization who identifies a substantial burden on his, her, or an organization's exercise of religion such that the RFRA may require specific relief from any provision of this rule may assert such a claim. Separately, as noted in the preamble of a different rule, ''self-supporting religious workers who are not eligible for admission to the United States as R–1 nonimmigrant religious workers may pursue admission in the B–1 classification.'' *Special Immigrant and Nonimmigrant Religious Workers,* 73 FR 72282 (2008) codified at 8 CFR pts. 204, 214, 299.

[210] Under these compacts, foreign nationals falling under COFA are able to enter without regard to inadmissibility under INA section 212(a)(5) and (7)(B)(i)(II), 8 U.S.C. 1182(a)(5) and (7)(B)(i)(II). *See* Compact of Free Association Amendment Act of 2003, Public Law 108–188, 117 Stat. 2720 (Dec. 17, 2003); *see also* Compact Free Association Approval Act, Public Law 99–658, 100 Stat. 3672 (Nov. 14, 1986) (regarding the Republic of Palau); *see also* 8 CFR 212.1(d).

[211] *See* Public Law 108–188, 117 Stat. 2720, 2762, 2800 (Dec. 17, 2003) (providing that with respect to citizens of the Federated States of Micronesia and the Republic of the Marshall Islands, ''section 237(a)(5) of [the INA] shall be construed and applied as if it reads as follows: 'any alien who has been admitted under the Compact, or the Compact, as amended, who cannot show that he or she has sufficient means of support in the United States, is deportable'''); 8 CFR 214.7(e)(1).

[212] *See* Public Law 108–188, 117 Stat. 2720, 2762, 2800 (Dec. 17, 2003).

or when applying for adjustment of status before USCIS, but respectfully submits that Congress never exempted COFA nonimmigrants from the public charge ground of inadmissibility.

DHS notes, however, that because COFA migrants are not required to obtain an extension of their nonimmigrant stay to remain in the United States pursuant to COFA, such nonimmigrants are unlikely to be affected by public benefits condition applicable to extension of stay applications. In addition, as noted elsewhere in this rule, to the extent that COFA migrant children under 21 and pregnant women receive Medicaid, such receipt would not be considered under this rule.

3. Exemptions and Waivers With Respect to the Rule Generally

a. General Comments

Comment: Many commenters supported the exemptions proposed in the NPRM, but a few of the commenters suggested that exemptions be clearly communicated. Some commenters requested that the discussion of exemptions should be moved earlier in the regulation or included in the executive summary of the preamble, to avoid any confusion. Other commenters expressed their support for the exemptions and waivers but indicated that DHS should ensure that immigrant communities and service providers be made aware of these exemptions.

Many commenters expressed concern about the rule's impact on the vulnerable populations specifically excluded from public charge requirements, such as refugees, asylum seekers, victims of trafficking, and VAWA petitioners, who may avoid applying for or accepting any public benefits for which they qualify, to avoid any negative impact on the adjudication of their benefit requests and for fear of future repercussions. One commenter indicated that the exemptions for asylees and refugees appear to be based on their status at the time of admission or grant of status but do not apply to those whose application for asylum or refugee status is pending and who may be eligible for public benefits during that period.

Multiple commenters stated that while the proposed rule exempts VAWA petitioners and U nonimmigrant status, the exemptions will not protect a large number of victims from the detrimental effects of the public charge rule since there are many victims of domestic violence and sexual assaults that seek status in other immigration categories. While a commenter agreed with the proposed rule's intention to streamline all abused-spouse applications under the VAWA umbrella, the commenter said USCIS and DHS must ensure there is no negative impact to survivors who choose to seek adjustment of status. A few commenters specifically stated that human trafficking survivors would be negatively impacted by the significant delays and increased adjudication expenses. Other commenters expressed concerns about permitting refugees and asylees to continue to receive healthcare while excluding foreign nationals who have immigrated here with the proper documentation (*i.e.,* legally) and are going through the process to obtain permanent residency here in the United States. These commenters said that this is logical fallacy, at best, and at worst, it is unjustified discrimination.

Response: DHS believes that the current organization of the regulations and exemptions clearly communicates who is exempt from the public charge ground of inadmissibility and who may be eligible for a waiver of the inadmissibility ground. DHS has also added the summary table in subsection III.F.4 below. DHS declines to implement the suggestions for reorganizing the final rule because the current organization sufficiently addresses visibility.

DHS does not agree that the rule should be more limited in scope and not consider public benefits as part of the public charge inadmissibility determination. The purpose of this rule is to implement the public charge ground of inadmissibility consistent with the principles of self-sufficiency set forth by Congress, and to minimize the incentive of aliens to attempt to immigrate to, or to adjust status in, the United States due to the availability of public benefits.[213]

DHS disagrees with the commenters who indicated that this rule would negatively impact refugees, asylum seekers, victims of trafficking, and VAWA self-petitioners and that the exemptions should be broader. As noted in the NPRM and previous sections in this final rule, the public charge ground of inadmissibility does not generally apply to these populations. Congress expressly exempted refugees, asylees, and applicants for adjustment based on refugee or asylee status from the public charge inadmissibility ground.[214] Therefore, if an individual has a pending application for asylum, the individual will not be assessed for public charge for purposes of the asylum application and obtaining asylee status. Refugees who are seeking admission to the United States are not subject to public charge grounds of inadmissibility and DHS will not determine whether they may be likely to become a public charge in the United States as part of the refugee admission. Similarly, refugees or asylees seeking adjustment based on their refugee or asylee status, are not subject to the public charge inadmissibility ground, and therefore, the use of public benefits is not considered. Therefore, DHS believes that the commenters' concerns regarding the rule's impact on asylees and refugees are sufficiently addressed.

Similarly, applicants for T nonimmigrant visas are also generally exempt from the public charge inadmissibility ground,[215] and, as established below, DHS also agrees with the commenters that T nonimmigrants applying for adjustment of status should generally be exempt from public charge.[216] Additionally, Congress generally exempted VAWA self-petitioners from the public charge ground of inadmissibility.[217] Also, in response to comments and for reasons explained in the section addressing public benefits, DHS has amended 8 CFR 212.21(b) by providing that public benefits received by those who are in a status exempted from public charge will not be considered in a subsequent adjudication of a benefit that does subject the alien to the public charge ground of inadmissibility. This step should further alleviate concerns that a person in one of the listed categories would be subject to the public charge ground.

DHS also disagrees that this rule discriminates against aliens who are not asylees or refugees. Congress, in PRWORA, made the decision as to which noncitizens are eligible to apply for and receive certain public benefits. Congress decided that asylees and refugees should be eligible to apply for public benefits, and DHS does not have the authority to include or exclude any groups from the receipt of public benefits.

Comment: A commenter stated the rule should exempt people with disabilities and their families, stating many of these families come to the United States in order to receive adequate medical care. Commenters opposed including immigrants with

[213] *See* 8 U.S.C. 1601.

[214] *See* INA sections 207, 208, and 209; 8 U.S.C. 1157, 1158, and 1159.

[215] *See* INA sections 101(a)(15)(T) and 212(d)(13)(A), 8 U.S.C. 1101(a)(15)(T) and 1182(d)(13)(A).

[216] *See* INA sections 101(a)(15)(T) and 245(l)(2), 8 U.S.C. 1101(a)(15)(T) and 1255(l)(2).

[217] *See* INA section 212(a)(4)(E)(i), 8 U.S.C. 1182(a)(4)(E)(i).

disabilities in the proposed rule because disability is one of the strongest known factors that affect a household's food security and housing instability. Some commenters said DHS should make an exception for pregnant women. Another commenter asked that DHS provide more exemptions and waivers, suggesting that the rule should be narrowed to only apply to those seeking entry into the United States initially or to provide extra protection to those in the United States to lessen the fears of the proposed rule's negative effects.

Response: Congress generally specifies, in legislation, to whom grounds of inadmissibility apply and which classes of aliens are exempt from public charge. DHS understands that individuals with disabilities and pregnant women may be affected by this rule. However, Congress did not provide an exemption for individuals with disabilities or pregnant women in the statute.[218]

Additionally, DHS cannot limit the application of the ground of inadmissibility in a matter so that it only applies to those seeking entry into the United States or so that DHS provides extra protections because Congress, in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) specified that the ground of inadmissibility applies to those seeking a visa, admission to the United States, or adjustment of status in the United States. Classes of aliens exempt from the public charge ground of inadmissibility are listed in 8 CFR 212.23. Certain aspects of this rule limit some of the rule's effects, such as by relying on an exhaustive list of non-cash benefits, and excluding consideration of certain benefits for certain populations or circumstances. DHS believes that this is sufficient.

Comment: A commenter recommended adding exemptions from the public charge ground of inadmissibility for those who have been certified for benefits under the authorization of another person, such as the head of household or guardian. The commenter reasoned that the dependents may not have been aware that this occurred or even that they receive a benefit.

Response: DHS disagrees that it should exempt from the public charge ground of inadmissibility those who have been certified for benefits under the authorization of another, such as the head of household or guardian, if the beneficiary is an alien subject to the public charge ground of inadmissibility. In general, Congress has the authority to legislate which classes of aliens should be subject to public charge ground of inadmissibility and which are exempt. Congress did not provide an exemption from the public charge ground of inadmissibility for aliens seeking a visa, admission, or adjustment of status and who may have been certified for benefits under the authorization of another, such as the head of household or the guardian who applied on the alien's behalf. DHS acknowledges that those dependents who are certified for or receiving public benefits under the authorization of another, such as the head of the household or the guardian, may be unaware of the receipt of public benefits but will, once the rulemaking is effective, may be impacted by such receipt of public benefits, if they are subject to the public charge ground of inadmissibility.

After having reviewed the comments, however, DHS has decided to provide additional clarification regarding such matters. As explained in detail in the public benefits section in this preamble, DHS has added a new definition of ''receipt of public benefits'' to section 212.21(e) to clarify that DHS will only consider the alien to have received a public benefit if the alien is a named beneficiary of the benefit. An alien does not receive a benefit merely by virtue of having applied or been certified for such benefit, and has not received a public benefit if the alien acted not on his or her own behalf but on behalf of another person. Therefore, if an alien is the person receiving benefits on behalf of another (for instance as a parent, legal guardian) the alien will not be considered to have received, been certified for, or applied for such public benefit.

b. Special Immigrant Juvenile

Comment: A commenter stated that the proposed rule would conflict with the purpose of Special Immigrant Juvenile (SIJ) status, asserting that the purpose of the status is to allow children to thrive in the United States and that children are not responsible for their circumstances. Although SIJ recipients are statutorily exempt from inadmissibility on public charge grounds, this rule would still affect SIJ youth indirectly because of its scope, secondary effects on families, and potential for confusion. Many of these youth live in homes with U.S. citizen or permanent resident adults or siblings who would be entitled to benefits but may be deterred from accessing them because of a fear of how it will affect the SIJ youth or other family members.

Response: DHS disagrees that this rule conflicts with the SIJ program. As stated in the proposed rule, aliens applying for adjustment of status based on an SIJ determination are exempt from the public charge inadmissibility ground. If aliens who are not subject to the public charge ground of inadmissibility choose to disenroll from or forego public benefit receipt based on this rule, then the decision to disenroll from or forego enrollment is unwarranted. The NPRM provided an exhaustive list of individuals who are exempt from the public charge ground of inadmissibility, and this final rule retains that list of exemptions. DHS will not consider receipt of public benefits by aliens exempt from the public charge ground inadmissibility, even if the exempted alien has an alien family member who is not exempt. DHS notes that this rule also categorically exempts receipt of Medicaid by children under the age of 21, which should reduce the potential for confusion.

c. Certain Employment Based Preference Categories, or National Interest Waiver

Comment: One commenter requested that individuals applying for lawful permanent resident status via approved EB–1A (extraordinary ability alien), EB–1B (outstanding researcher or scientist), or National Interest Waiver (NIW) petitions be added to the list of those exempted from the rule. The commenter stated that the vast majority of these individuals may need to resort to using the designated benefits, and it would be completely contrary to the intent of Congress in passing the EB–1A, EB–1B and NIW statutes to deny scientific researchers green cards who would otherwise be benefiting the lives of literally millions of U.S. citizens.

Response: DHS disagrees that this rule is contrary to congressional intent in passing the EB–1A, EB–1B and NIW statutes. Congress did not exempt employment based EB–1A or EB–1B categories, or those seeking an NIW, from the public charge ground of inadmissibility.[219] DHS neither has the

[218] *See* INA sections 212(a)(4), 8 U.S.C. 1182(a)(4).

[219] *See* INA section 203(b)(1)(A), 8 U.S.C. 1153(b)(1)(A) (aliens with extraordinary ability) or INA section 203(b)(1)(B), 8 U.S.C. 1153(b)(1)(B) (outstanding professors and researchers). *See* INA section 203(b)(2), 8 U.S.C. 1153(b)(2) (aliens who are members of the professions holding advance degrees or aliens of exceptional ability who are seeking a waiver of the job over in the national interest); *see also* comment USCIS 2010–0012–31111. The commenter explained that the work these individuals perform is of great importance to the United States and have a profound impact on the U.S. economies. However, the commenter indicated, a vast majority of these individuals who are conducting scientific research earn low salaries below the 250% threshold and may need to resort to using these types of benefits the proposed regulation is seeking to prohibit, especially for their U.S. citizen children. The commenter indicated that it would be contrary to congressional intent to apply public charge to these workers.

authority to exempt an applicant or a group of applicants for admission or adjustment of status from the public charge ground of inadmissibility where Congress has not already done so,[220] nor has the authority to ignore the congressionally-mandated exemptions to the public charge ground of inadmissibility. Because Congress has expressly exempted asylees and refugees from the public charge inadmissibility ground, DHS cannot remove this exemption. Further, because Congress did not specifically exempt EB–1A or EB–1B workers, or those with NIWs, from the public charge ground of inadmissibility, DHS may not create an exemption for them in this rule.[221]

d. Violence Against Women Act, T, and U

Comment: A commenter provided the statutory amendment history of 8 U.S.C. Section 1641, and stated that VAWA, T, and U visa victims and all other immigrants covered by 8 U.S.C. 1641(c) cannot be subject to public charge under federal statutes. Another commenter indicated that the NPRM incorrectly applies the public charge ground of inadmissibility to applications for adjustment of status and extension of stay filed by T nonimmigrants. The commenter noted that both T nonimmigrant status seekers and T nonimmigrant status holders are exempt from the public charge ground of inadmissibility. The commenter also indicated that proposed 8 CFR 212.23(a)(17) should be amended to conform to section 804 of VAWA 2013,[222] exempting T nonimmigrants seeking to adjust status to lawful permanent residence or to extend status from the public charge ground of inadmissibility. The commenter indicated that section 804 of VAWA 2013, granted the same exemptions from the public charge ground of inadmissibility to all foreign national victims who are ''qualified aliens'' under section 431(c) of PRWORA, 8 U.S.C. 1641(c), including T nonimmigrant status holders.[223]

Response: DHS agrees that qualified aliens under 8 U.S.C. 1641(c) (certain battered aliens as qualified aliens) are generally not subject to the public charge inadmissibility ground. Section 212(a)(4)(E)(iii) of the INA, 8 U.S.C. 1182(a)(4)(E)(iii), specifically excludes such individuals from the public charge ground.[224] VAWA 2013, which added section 212(a)(4)(E)(iii) of the INA, 8 U.S.C. 1182(a)(4)(E)(iii), specifically excludes individuals such as qualified aliens described in 8 U.S.C. 1641(c) (including T nonimmigrants and certain battered spouses and children of U.S. citizens), VAWA self-petitioners, and U nonimmigrants from sections 212(a)(4)(A), (B), and (C) of the INA, 8 U.S.C. 1182(a)(4)(A), (B), and (C).

Congress, however, did not include paragraph (D) among the exemptions in section 212(a)(4)(E) of the INA, 8 U.S.C. 1182(a)(4)(E). We must presume that Congress acted intentionally in requiring all aliens described in paragraph (D) to file the requisite affidavit of support, even if they are described in paragraph (E). The law does not permit DHS to add language to the statute. *See, e.g., Lamie* v. *U.S. Tr.,* 540 U.S. 526, 538 (2004) (counseling against interpretative methodologies that yield ''not . . . a construction of [a] statute, but, in effect, an enlargement of it by the court, so that what was omitted, presumably by inadvertence, may be included within its scope''); *Yith* v. *Nielsen,* 881 F.3d 1155, 1164 (9th Cir. 2018) (''It is never our job to rewrite a constitutionally valid statutory text. Indeed it is quite mistaken to assume that whatever might appear to further the statute's primary objective must be the law.'' (citations, quotation marks, and alterations omitted)). Accordingly, in the unlikely event that an alien described in paragraph (E) is seeking admission or adjustment of status based on an immigrant visa issued under section 203(b) of the INA, 8 U.S.C. 1153(b), that individual must comply with the affidavit of support requirement in section 213A of the INA, 8 U.S.C. 1183a. Such individuals, however, would not need to demonstrate, as set forth in paragraphs 212(a)(4)(A) and (B), 8 U.S.C. 1182(A) and (B), that he or she is not likely at any time to become a public charge. Those applicants would not need to submit Form I–944. As such, such applicants would only have to submit a sufficient affidavit of support described in section 213A of the INA, 8 U.S.C. 1183a.

For the reasons stated above, DHS is amending proposed 8 CFR 212.23(a)(18), (19), (20), (21), and 8 CFR 212.23(b) in this final rule to clarify that aliens exempt under section 212(a)(4)(E) of the INA, 8 U.S.C. 1182(a)(4)(E), that are adjusting status based on an employment-based petition subject to section 212(a)(4)(D) of the INA, 8 U.S.C. 1182(a)(4)(D), that requires the execution of an affidavit of support as described in section 213A of the Act, 8 U.S.C. 1183a, are not exempt from the entirety of section 212(a)(4) of the INA, 1182(a)(4), as they are still subject to section 212(a)(4)(D) of the INA, 8 U.S.C. 1182(a)(4)(D).

Applicants seeking T nonimmigrant status, T nonimmigrants applying for adjustment of status, and T nonimmigrants seeking another immigration benefit that requires admissibility, are generally exempt from the public charge ground of inadmissibility under section 212(a)(4)(E) of the Act, 8 U.S.C. 1182(a)(4)(E). In accordance with section 804 of the VAWA 2013,[225] which added new section 212(a)(4)(E) of the Act, 8 U.S.C. 1182(a)(4)(E), individuals who have been granted T nonimmigrant status or have a pending application that sets forth a prima facie case for eligibility for T nonimmigrant status are generally exempt from the public charge inadmissibility determination.

Notwithstanding these changes, VAWA 2013 did not amend section 245(l)(2) of the Act, 8 U.S.C. 1255(l)(2),[226] which provides that DHS may waive the application of the public charge ground of inadmissibility if it is in the national interest to do so for a T nonimmigrant seeking to adjust status to lawful permanent residence under section 245(l) of the Act, 8 U.S.C. 1255(l). DHS concludes, however, that the VAWA 2013 amendments, which postdated the enactment of section 245(l)(2) of the Act, 8 U.S.C. 1255(l)(2),

[220] As explained in the NPRM, DHS derives its statutory authority for this rule and its authority to promulgate regulation based on section 102 of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, 2142–44 (Nov. 25, 2002) (codified at 6 U.S.C. 112) and INA section 103, 8 U.S.C. 1103, as well as INA section 212(a)(4), 8 U.S.C. 1182 and the relevant statutory provisions governing immigration benefits. *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51124 (proposed Oct. 10, 2018).

[221] Providing for an exemption where Congress does not expressly authorize one, as it does for other immigration benefits applicants under the INA, would be beyond the scope of DHS's authority. *See Andrus* v. *Glover Const. Co.,* 446 U.S. 608, 616–17 (1980) (''Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of a contrary legislative intent.'').

[222] *See* Public Law 113–4 (March 7, 2013).

[223] The commenter indicated that DHS correctly recognized the full extent of exceptions that the same provisions made for VAWA-self petitioners, U visa applicants, and U visa holders for purposes of lawful permanent residency.

[224] While INA section 212(a)(4)(E)(iii), 8 U.S.C. 1182(a)(4)(E)(iii), excludes qualified aliens under 8 U.S.C. 1641(c) from public charge, that exclusion does not apply to the separate category of ''qualified aliens'' described in 8 U.S.C. 1641(b) who are subject to public charge unless otherwise subject to an exception.

[225] *See* Public Law 113–4, 127 Stat 54 (Mar. 7, 2013).

[226] *See* INA section 245(l), 8 U.S.C. 1255(l), which was created by the Victims of Trafficking and Violence Protection Act of 2000, Public Law 106–386, 114 Stat. 1464 (Oct. 8, 2000).

are controlling. That is, DHS has determined that T nonimmigrants seeking to adjust status under section 245(a) of the Act, 8 U.S.C. 1255(a) (with a limited exception) and section 245(l) of the Act, 8 U.S.C. 1255(l) are not subject to the public charge ground of inadmissibility for purposes of establishing eligibility for adjustment of status. However, for this exemption from public charge to apply, the T nonimmigrant must hold and be in valid T nonimmigrant status at the time the Form I–485 is properly filed in compliance with 8 CFR 103.2(a)(7) and throughout the pendency of an application.[227] For the reasons stated above, DHS is amending proposed 8 CFR 212.23(a)(17) in this final rule to clarify that T nonimmigrants seeking any immigration benefit subject to section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4)—except those described in section 212(a)(4)(D) of the Act, 8 U.S.C. 1182(a)(4)(D), who must file an affidavit of support—are exempt from the public charge ground of inadmissibility, provided that the T nonimmigrant seeking the immigration benefit is in valid T nonimmigrant status at the benefit request is properly filed with USCIS and at the time the benefit request is adjudicated.[228] As section 212(a)(4)(E) of the Act, 8 U.S.C. 1182(a)(4)(E), is an additional authority for exempting T nonimmigrants, DHS has revised the authority for the exemption to refer to sections 212(a)(4)(E) and 212(d)(13)(A) of the Act, 8 U.S.C. 1182(a)(4)(E), (d)(13)(A).[229] Additionally, based on the same rationale provided above, DHS is also modifying current 8 CFR 212.18(b)(2) and 8 CFR 245.23(c)(3) to accurately reflect changes codified by Congress in 2013 in relation to those having a pending prima facie case for status under section 101(a)(15)(T) of the Act, 8 U.S.C. 1101(a)(15)(T), or is in valid T nonimmigrant status at the time of filing for an immigration benefit, and to clarify that these individuals—with the limited exception described in INA 212(a)(4)(D), 8 U.S.C. 1182(a)(4)(D)—are not subject to the public charge ground of inadmissibility. As discussed further under the PRA section of this final rule, DHS is also making conforming changes to the Form I–601 instructions.

Individuals seeking U nonimmigrant status and U nonimmigrants seeking adjustment of status on account of their U nonimmigrant status are generally exempt from the public charge ground.[230] In accordance with section 804 of the VAWA 2013,[231] which added new section 212(a)(4)(E) of the Act, 8 U.S.C. 1182(a)(4)(E), an individual who is an applicant for, or is granted U nonimmigrant status is exempt from the public charge ground of inadmissibility.[232] However, for this exemption from public charge to apply, the U nonimmigrant must hold and be in valid U nonimmigrant status at the time the Form I–485 is properly filed in compliance with 8 CFR 103.2(a)(7) and throughout the pendency of an application.[233] Therefore, DHS clarified in this final rule that these individuals are not subject to the public charge ground of inadmissibility when seeking an immigration benefit,[234] to accurately reflect changes enacted by Congress in VAWA 2013. Additionally, VAWA self-petitioners are generally exempt from the public charge ground of inadmissibility.[235] Similar to T nonimmigrants (and as described above), U nonimmigrants and VAWA self-petitioners who are adjusting status under an employment-based category that is required to execute an affidavit of support described in section 213A, 8 U.S.C. 1183a, under 212(a)(4)(D) of the INA, 8 U.S.C. 1182(a)(4)(D), must still execute that affidavit of support to overcome the public charge ground of inadmissibility.

4. Summary of Applicability, Exemptions, and Waivers

The following tables provide a summary of all nonimmigrant and immigrant classification and whether they are subject to the public charge inadmissibility determination and submit an I–944 or are subject to the public benefit condition for extension of stay and change of status nonimmigrants.

TABLE 2—SUMMARY OF NONIMMIGRANT CATEGORIES SUBJECT TO PUBLIC BENEFITS CONDITION

Category	Eligible to apply for extension of stay (*i.e.,* may file Form I–129 or Form I–539) *	Eligible to apply for change of status (*i.e.,* may file Form I–129 or I–Form 539) *	Subject to public benefit condition under proposed 8 CFR 214.1(a)(3)(iv), 214.1(a)(4)(iv); 248.1(c)(4)
A–1—Ambassador, Public Minister, Career Diplomat or Consular Officer, or Immediate Family; A–2—Other Foreign Government Official or Employee, or Immediate Family; INA 101(a)(15)(A), 22 CFR 41.21.	No. Not applicable as admitted for Duration of Status, 8 CFR 214.1(c)(3)(v).	Yes. Files I–539, 8 CFR 248.1(a).	No. INA 102; 22 CFR 41.21(d).
A–3—Attendant, Servant, or Personal Employee of A–1 or A–2, or Immediate Family; INA 101(a)(15)(A), 22 CFR 41.21.	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes. INA 102; 22 CFR 41.21(d)(3).
B–1—Temporary Visitor for Business; B–2—Temporary Visitor for Pleasure; * not admitted under Visa Waiver Program; INA 101(a)(15)(B).	Yes. Files Form I–539, 8 CFR 214.1(c)(2), 8 CFR 214.2(b)(1).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes.

[227] *See* 8 CFR 103.2(b)(1) (an applicant or petitioner must establish that he or she is eligible for the requested benefits at the time of filing and the benefit request and must continue to be eligible through adjudication); *see also Matter of Alarcon,* 20 I&N Dec. 557, 562 (BIA 1992) (''an application for admission to the United States is a continuing application, and admissibility is determined on the basis of the facts and the law at the time the application is finally considered'').

[228] *See* 8 CFR 212.23(a)(17) and (18).

[229] *See also* INA section 212(s), 8 U.S.C. 1182(s) (excluding from the public charge determination consideration of benefits received by those eligible to receive benefits under 8 U.S.C. 1641(c)).

[230] *See* 8 CFR 212.23(a)(18).

[231] *See* Public Law 113–4, 127 Stat 54 (Mar. 7, 2013).

[232] *See* INA sections 212(a)(4)(E)(ii), 8 U.S.C. 1182(a)(4)(E)(ii), which exclude from public charge determinations an applicants for, or individuals granted, nonimmigrant status under section 1101(a)(15)(U).

[233] *See* 8 CFR 103.2(b)(1) (An applicant or petitioner must establish that he or she is eligible for the requested benefits at the time of filing and the benefit request and must continue to be eligible through adjudication). *See also Matter of Alarcon,* 20 I&N Dec. 557, 562 (BIA 1992) (''an application for admission to the United States is a continuing application, and admissibility is determined on the basis of the facts and the law at the time the application is finally considered.'').

[234] *See* 8 CFR 212.23(a)(19).

[235] *See* 8 CFR 212.23(a)(21).

TABLE 2—SUMMARY OF NONIMMIGRANT CATEGORIES SUBJECT TO PUBLIC BENEFITS CONDITION—Continued

Category	Eligible to apply for extension of stay (*i.e.,* may file Form I–129 or Form I–539) *	Eligible to apply for change of status (*i.e.,* may file Form I–129 or I–Form 539) *	Subject to public benefit condition under proposed 8 CFR 214.1(a)(3)(iv), 214.1(a)(4)(iv); 248.1(c)(4)
C–1—Alien in Transit; C–1/D—Combined Transit and Crewmember Visa; INA 101(a)(15)(C) and (D), INA 212(d)(8).	No. 8 CFR 214.1(c)(3)(ii)	No. 8 CFR 248.2(a)(2), except for change to T and U, 8 CFR 248.2(b) using Form I–914 or I–918.	Not Applicable as not eligible for extension of stay or change of status.
C–2—Alien in Transit to United Nations Headquarters District Under Section 11.(3), (4), or (5) of the Headquarters Agreement; INA 101(a)(15)(C) and (D), INA 212(d)(8).	No. Not applicable as admitted for Duration of Status. 8 CFR 214.1(c)(3)(ii).	No, 8 CFR 248.2(a)(2), except for change to T and U, 8 CFR 248.2(b) using Form I–914 or I–918.	No. 22 CFR 41.21(d).
C–3—Foreign Government Official, Immediate Family, Attendant, Servant or Personal Employee, in Transit; INA 101(a)(15)(C) and (D), INA 212(d)(8).	No. 8 CFR 214.1(c)(3)(ii)	No, 8 CFR 248.2(a)(2), except for change to T and U, 8 CFR 248.2(b) using Form I–914 or I–918.	No. 22 CFR 41.21(d).
CW–1—Commonwealth of Northern Mariana Islands Transitional Worker Section 6(d) of Public Law 94–241, as added by Section 702(a) of Public Law 110–229. 8 CFR 214.2(w).	Yes. Files Form I–129CW, 8 CFR 214.1(c)(2) and 8 CFR 214.2(w)(17).	Yes. Files Form I–129CW, 8 CFR 248.1(a); 8 CFR 214.2(w)(18).	Yes.
CW–2—Spouse or Child of CW–1	Yes. Files Form I–539, 8 CFR 214.1(c)(2) and 8 CFR 214.2(w)(17)(v).	Yes. Files Form I–539, 8 CFR 248.1(a); 8 CFR 214.2(w)(18).	
D—Crewmember (Sea or Air); D–2—Crewmember departing from a different vessel than one of arrival; INA 101(a)(15)(D).	No. 8 CFR 214.1(c)(3)(iii)	No, 8 CFR 248.2(a)(2), except for change to T and U, 248.2(b) using Form I–914 or Form I–918.	Yes.
E–1, E–2—Treaty Trader (Principal); INA 101(a)(15)(E).	Yes. Files Form I–129, 8 CFR 214.1(c)(1); 8 CFR 214.2(e)(20).	Yes, Files Form I–129, 8 CFR 248.1(a), 8 CFR 214.2(e)(21)(i).	Yes.
E–1, E–2—Treaty Trader, Spouse or Child; INA 101(a)(15)(E).	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539, 8 CFR 214.2(e)(21)(ii),.	Yes.
E–2–CNMI—Commonwealth of Northern Mariana Islands Investor (Principal) Section 6(c) of Public Law 94–241, as added by Section 702(a) of Public Law 110–229.8 CFR 214.2(e)(23).	Yes. Files Form I–129, 8 CFR 214.2(e)(23)(xii).	Yes. Files Form I–129, 8 CFR 248.1(a), 8 CFR 214.2(e)(23)(xiii).	Yes.
E–2–CNMI—Commonwealth of Northern Mariana Islands Investor, Spouse or Child Section 6(c) of Public Law 94–241, as added by Section 702(a) of Public Law 110–229. 8 CFR 214.2(e)(23)(x).	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes.
E–3—Australian Treaty Alien coming to the United States Solely to Perform Services in a Specialty Occupation.	Yes. Files Form I–129, 8 CFR 214.1(c)(1) and (2).	Yes. Files Form I–129, 8 CFR 248.1(a).	Yes.
E–3D—Spouse or Child of E–3; E–3R—Returning E–3; INA 101(a)(15)(E)(iii).	Yes. Files I–539, 8 CFR 214.1(c)(1) and (2).	Yes. Files I–539, 8 CFR 248.1(a).	Yes.
F–1—Student in an academic or language training program (principal); INA 101(a)(15)(F).	Yes, only if the F–1 requesting reinstatement to F–1 status or if the F–1 received a date-specific admission to attend high school and is now seeking an extension to D/S to attend college. 8 CFR 214.1(c)(3)(v); 8 CFR 214.2(f)(7); 8 CFR 214.2(f)(16).	Yes. Files Form I–539, 8 CFR 248.1(a),.	Yes.
F–2—Spouse or Child of F–1; INA 101(a)(15)(F).	No, not applicable as admitted for Duration of Status. 8 CFR 214.1(c)(3)(v); 8 CFR 214.2(f)(3).	Yes. Files Form I–539, 8 CFR 214.2(f)(3).	Yes.

TABLE 2—SUMMARY OF NONIMMIGRANT CATEGORIES SUBJECT TO PUBLIC BENEFITS CONDITION—Continued

Category	Eligible to apply for extension of stay (*i.e.,* may file Form I–129 or Form I–539) *	Eligible to apply for change of status (*i.e.,* may file Form I–129 or I–Form 539) *	Subject to public benefit condition under proposed 8 CFR 214.1(a)(3)(iv), 214.1(a)(4)(iv); 248.1(c)(4)
G–1—Principal Resident Representative of Recognized Foreign Government to International Organization, Staff, or Immediate Family; G–2—Other Representative of Recognized Foreign Member Government to International Organization, or Immediate Family; G–3—Representative of Nonrecognized or Nonmember Foreign Government to International Organization, or Immediate Family; G–4—International Organization Officer or Employee, or Immediate Family; INA 101(a)(15)(G).	No, not applicable as admitted for Duration of Status 8 CFR 214.1(c)(3)(v).	Yes. Files Form I–539, 8 CFR 248.1(a).	No. 22 CFR 41.21(d).
G–5—Attendant, Servant, or Personal Employee of G–1 through G–4, or Immediate Family.	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes.
H–1B—Alien in a Specialty Occupation, Fashion Models of Distinguished Merit and Ability, and workers performing services of exceptional merit and ability relating to a Department of Defense (DOD) cooperative research and development project; INA 101(a)(15)(H)(i)(b); Section 222 of Pub. L. 101–649.	Yes. Files Form I–129, 8 CFR 214.1(c)(1).	Yes. Files Form I–129.8 CFR 248.1(a).	Yes.
H–1B1—Chilean or Singaporean National to Work in a Specialty Occupation; INA 101(a)(15)(H)(i)(b1).	Yes. Files Form I–129, 8 CFR 214.1(c)(1).	Yes. Files Form I–129. 8 CFR 248.1(a).	Yes.
H–1C [236]—Nurse in health professional shortage area; INA 101(a)(15)(H)(i)(c).	Yes. Filed Form I–129, 8 CFR 212.2(h)(4)(v)(E).	Yes. Filed Form I–129, 8 CFR 212.2(h)(4)(v)(E).	Yes.
H–2A—Temporary Worker Performing Agricultural Services Unavailable in the United States; INA 101(a)(15)(H)(ii)(a).	Yes. Files Form I–129, 8 CFR 214.1(c)(1).	Yes. Files Form I–129	Yes.
H–2B—Temporary Worker Performing Other Services Unavailable in the United States; INA 101(a)(15)(H)(ii)(b).	Yes. Files Form I–129, 8 CFR 214.1(c)(1).	Yes. Files Form I–129	Yes.
H–3—Trainee; INA 101(a)(15)(H)(iii)	Yes. Files Form I–129, 8 CFR 214.1(c)(1).	Yes. Files Form I–539	Yes.
H–4—Spouse or Child of Alien Classified H1B/B1/C, H2A/B, or H–3; INA 101(a)(15)(H)(iv).	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539. 8 CFR 248.1(a).	Yes.
I—Representative of Foreign Information Media, Spouse and Child; INA 101(a)(15)(I).	No, not applicable as admitted for Duration of Status 8 CFR 214.1(c)(3)(v).	Yes. Files Form I–539	Yes.
J–1—Exchange Visitor; J–2—Spouse or Child of J1; INA 101(a)(15)(J).	No, not applicable, as generally admitted for Duration of Status [237] 8 CFR 214.1(c)(3)(v).	Yes, subject to receiving a waiver of the foreign residence requirement, if necessary, Files I–539. 8 CFR 248.2(a)(4); may apply for change to T and U, using for Form I–914 or I–918, 8 CFR 248.2(b).	Yes.
K–1—Fiance(e) of United States Citizen; K–2—Child of Fiance(e) of U.S. Citizen; INA 101(a)(15)(K).	No. 8 CFR 214.1(c)(3)(iv)	No. 8 CFR 248.2(a)(2) except for change to T and U, 248.2(b) using Form I–914 or I–918.	Not Applicable.
K–3—Spouse of U.S. Citizen awaiting availability of immigrant visa; K–4—Child of K–3; INA 101(a)(15)(K).	Yes. Files Form I–539, 8 CFR 214.1(c)(2) and 8 CFR 214.2(k)(10).	No. 8 CFR 248.2(2) except for change to T and U, 248.2(b) using Form I–914 or I–918.	Yes.
L–1—Intracompany Transferee (Executive, Managerial, and Specialized Knowledge Personnel Continuing Employment with International Firm or Corporation); INA 101(a)(15)(L).	Yes. Files Form I–129, 8 CFR 214.1(c)(1).	Yes. Files Form I–129, 8 CFR 248.1(a).	Yes.
L–2—Spouse or Child of Intracompany Transferee.	Yes. Files I–539 8 CFR 214.1(c)(1) and (2).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes.
M–1—Vocational Student or Other Non-academic Student; INA 101(a)(15)(M).	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539. Not eligible if requesting F–1, 8 CFR 248.1(c)(1).	Yes.

TABLE 2—SUMMARY OF NONIMMIGRANT CATEGORIES SUBJECT TO PUBLIC BENEFITS CONDITION—Continued

Category	Eligible to apply for extension of stay (*i.e.,* may file Form I–129 or Form I–539) *	Eligible to apply for change of status (*i.e.,* may file Form I–129 or I–Form 539) *	Subject to public benefit condition under proposed 8 CFR 214.1(a)(3)(iv), 214.1(a)(4)(iv); 248.1(c)(4)
M–2—Spouse or Child of M–1; INA 101(a)(15)(M).	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539	Yes.
N–8—Parent of an Alien Classified SK3 (Unmarried Child Employee of International Organization) or SN–3; N–9—Child of N–8 or of SK–1 (Retired Employee International Organization), SK–2 (Spouse), SK–4 (surviving spouse), SN–1 (certain retired NATO 6 civilian employee), SN–2 (spouse) or SN–4 (surviving spouse); INA 101(a)(15)(N).	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539, 8 CFR 248.1(e).	Yes.
NATO–1—Principal Permanent Representative of Member State to NATO (including any of its Subsidiary Bodies) Resident in the U.S. and Resident Members of Official Staff; Secretary General, Assistant Secretaries General, and Executive Secretary of NATO; Other Permanent NATO Officials of Similar Rank, or Immediate Family Art. 12, 5 UST 1094; Art. 20, 5 UST 1098.	No, not applicable as admitted for Duration of Status 8 CFR 214.1(c)(3)(v).	Yes. Files Form I–539, 8 CFR 248.1(a).	No. INA 102; 22 CFR 41.21(d).
NATO–2—Other Representative of member state to NATO (including any of its Subsidiary Bodies) including Representatives, Advisers, and Technical Experts of Delegations, or Immediate Family; Dependents of Member of a Force Entering in Accordance with the Provisions of the NATO Status-of-Forces Agreement or in Accordance with the provisions of the ''Protocol on the Status of International Military Headquarters''; Members of Such a Force if Issued Visas Art. 13, 5 UST 1094; Art. 1, 4 UST 1794; Art. 3, 4 UST 1796.	No, not applicable as admitted for Duration of Status 8 CFR 214.1(c)(3)(v).	Yes. Files Form I–539, 8 CFR 248.1(a).	No. INA 102; 22 CFR 41.21(d).
NATO–3—Official Clerical Staff Accompanying Representative of Member State to NATO (including any of its Subsidiary Bodies), or Immediate Family Art. 14, 5 UST 1096.	No, not applicable as admitted for Duration of Status 8 CFR 214.1(c)(3)(v).	Yes. Files Form I–539, 8 CFR 248.1(a).	No. INA 102; 22 CFR 41.21(d).
NATO–4—Official of NATO (Other Than Those Classifiable as NATO1), or Immediate Family Art. 18, 5 UST 1098.	No, not applicable as admitted for Duration of Status 8 CFR 214.1(c)(3)(v).	Yes. Files Form I–539, 8 CFR 248.1(a).	No. INA 102; 22 CFR 41.21(d).
NATO–5—Experts, Other Than NATO Officials Classifiable Under NATO 4, Employed in Missions on Behalf of NATO, and their Dependents Art. 21, 5 UST 1100.	No, not applicable as admitted for Duration of Status 8 CFR 214.1(c)(3)(v).	Yes. Files Form I–539, 8 CFR 248.1(a).	No. INA 102; 22 CFR 41.21(d).
NATO–6—Member of a Civilian Component Accompanying a Force Entering in Accordance with the Provisions of the NATO Status-of-Forces Agreement; Member of a Civilian Component Attached to or Employed by an Allied Headquarters Under the ''Protocol on the Status of International Military Headquarters'' Set Up Pursuant to the North Atlantic Treaty; and their Dependents Art. 1, 4 UST 1794; Art. 3, 5 UST 877.	No, not applicable as admitted for Duration of Status 8 CFR 214.1(c)(3)(v).	Yes. Files Form I–539, 8 CFR 248.1(a).	No. INA 102; 22 CFR 41.21(d).
NATO 7—Attendant, Servant, or Personal Employee of NATO 1, NATO 2, NATO 3, NATO 4, NATO 5, and NATO 6 Classes, or Immediate Family Arts. 12–20, 5 UST 1094–1098.	Yes. Files Form I–539, 8 CFR 214.2(s)(1)(ii)..	Yes. Files Form I–539, 8 CFR 248.1(a).	No. INA 102; 22 CFR 41.21(d).

TABLE 2—SUMMARY OF NONIMMIGRANT CATEGORIES SUBJECT TO PUBLIC BENEFITS CONDITION—Continued

Category	Eligible to apply for extension of stay (*i.e.,* may file Form I–129 or Form I–539) *	Eligible to apply for change of status (*i.e.,* may file Form I–129 or I–Form 539) *	Subject to public benefit condition under proposed 8 CFR 214.1(a)(3)(iv), 214.1(a)(4)(iv); 248.1(c)(4)
O–1—Alien with Extraordinary Ability in Sciences, Arts, Education, Business or Athletics or Extraordinary Achievement in the Motion Picture or Television Industry; O–2—Essential Support Workers Accompanying and Assisting in the Artistic or Athletic Performance by O–1 INA 101(a)(15)(O).	Yes. Files Form I–129, 8 CFR 214.1(c)(1).	Yes. Files Form I–129, 8 CFR 248.1(a).	Yes.
O–3—Spouse or Child of O–1 or O–2 INA 101(a)(15)(O).	Yes. Files Form I–539, 8 CFR 214.1(c)(1) and (2).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes.
P–1—Internationally Recognized Athlete or Member of Internationally Recognized Entertainment Group; P–2—Artist or Entertainer in a Reciprocal Exchange Program; P–3—Artist or Entertainer in a Culturally Unique Program INA 101(a)(15)(P); P–1S/P–2S/P–3S—Essential Support Workers 8 CFR 214.2(p).	Yes. Files Form I–129, 8 CFR 213.1(c)(3)(i).	Yes. Files Form I–129, 8 CFR 248.1(a).	Yes.
P–4—Spouse or Child of P–1, P–2, or P–3; INA 101(a)(15)(P).	Yes. Files Form I–539, 8 CFR 214.1(c) (1) and (2).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes.
Q–1—Participant in an International Cultural Exchange Program; INA 101(a)(15)(Q)(i).	Yes. Files Form I–129, 8 CFR 213.1(c)(3)(i).	Yes. Files Form I–129, 8 CFR 248.1(a).	Yes.
R–1—Alien in a Religious Occupation; INA 101(a)(15)(R).	Yes. Files Form I–129, 8 CFR 213.1(c)(3)(i).	Yes. Files Form I–129, 8 CFR 248.1(a).	Yes.
R–2—Spouse or Child of R–1; INA 101(a)(15)(R).	Yes. Files Form I–539, 8 CFR 214.1(c)(1) and (2).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes.
S–5—Certain Aliens Supplying Critical Information Relating to a Criminal Organization or Enterprise; S–6—Certain Aliens Supplying Critical Information Relating to Terrorism; S–7—Qualified Family Member of S–5 or S–6 INA 101(a)(15)(S).	No. 8 CFR 213.1(c)(3)(vi)	No. 8 CFR 248.2(2) except for change to T and U, 248.2(b) using Form I–914 or I–918.	Yes.
T–1—Victim of a severe form of trafficking in persons; INA 101(a)(15)(T).	Yes. Files Form I–539. INA § 214(o)(7)(B); 8 CFR 214.11(l)(1) and (2); 8 CFR 214.1(c)(2).	Yes. Files Form I–539, 8 CFR 248.1(a).	No.
T–2—Spouse of T–1; T–3—Child of T–1; T–4—Parent of T–1 under 21 years of age; T–5—Unmarried Sibling under age 18 of T–1; T–6—Adult or Minor Child of a Derivative Beneficiary of a T–1; INA 101(a)(15)(T).	Yes. Files Form I–539. INA 214(o)(7)(B); 8 CFR 214.1(c)(2).	Yes. Files Form Files I–539, 8 CFR 248.1(a).	No.
TN—NAFTA Professional; INA 214(e)(2) ..	Yes. Files Form I–129, 8 CFR 214.1(c)(1).	Yes. Files Form Files I–129, 8 CFR 248.1(a).	Yes.
TD—Spouse or Child of NAFTA Professional; INA 214(e)(2).	Yes. Files Form I–539, 8 CFR 214.1(c)(2).	Yes. Files Form I–539, 8 CFR 248.1(a).	Yes.
U–1—Victim of criminal activity; U–2—Spouse of U–1; U–3—Child of U–1; U–4—Parent of U–1 under 21 years of age; U–5—Unmarried Sibling under age 18 of U–1 under 21 years of age; INA 101(a)(15)(U).	Yes. Files Form I–539, 8 CFR 214.1(c)(2); 8 CFR 214.14(g)(2).	Yes. Files Form I–539, 8 CFR 248.1(a).	No.
V–1—Spouse of a Lawful Permanent Resident Alien Awaiting Availability of Immigrant Visa; V–2—Child of a Lawful Permanent Resident Alien Awaiting Availability of Immigrant Visa; V–3—Child of a V–1 or V–2 INA 101(a)(15)(V)(i) or INA 101(a)(15)(V)(ii); INA 203(d).	Yes. Files Form I–539, 8 CFR 214.1(c)(2); 8 CFR 214.15(g)(3).	Yes. Files Form I–539, 8 CFR 248.1(a); 214.15(g)(3).	Yes.

TABLE 2—SUMMARY OF NONIMMIGRANT CATEGORIES SUBJECT TO PUBLIC BENEFITS CONDITION—Continued

Category	Eligible to apply for extension of stay (*i.e.,* may file Form I–129 or Form I–539) *	Eligible to apply for change of status (*i.e.,* may file Form I–129 or I–Form 539) *	Subject to public benefit condition under proposed 8 CFR 214.1(a)(3)(iv), 214.1(a)(4)(iv); 248.1(c)(4)
W–B—Visa Waiver for visitor for business; W–T—visitor for pleasure, Visa Waiver Program; INA 217.	No. 8 CFR 214.1(c)(3)(i) and 214.1(c)(3)(viii).	No, except for change to T and U, using Form I–914 or I–918; INA 248.2(b).	Not Applicable.

* Includes questions on Form I–129 and Form I–539 about receipt of public benefits since the nonimmigrant status was approved. Whether the alien must file and I–129 or an I–539 depends on the status the alien is applying to change to or extend. If more than one person is applying using the I–539 application, the Form I–539A, Supplemental Information for Application to extend/Change Nonimmigrant Status, is submitted to provide all of the requested information for each additional applicant listed.

TABLE 3—APPLICABILITY OF INA 212(a)(4) TO FAMILY-BASED ADJUSTMENT OF STATUS APPLICATIONS [238]

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A and Form I–864, affidavit of support under section 213A of the INA, required or exempt?
Immediate Relatives of U.S. citizens including spouses, children and parents [239].	Yes. INA 212(a)(4)	Required. INA 212(a)(4)(C).
Family-Based First Preference: Unmarried sons/daughters of U.S. citizens and their children [240].	Yes. INA 212(a)(4)	Required. INA 212(a)(4)(C).
Family-Preference Second: Spouses, children, and unmarried sons/daughters of alien residents [241].	Yes. INA 212(a)(4)	Required. INA 212(a)(4)(C).
Family Preference Third: Married sons/daughters of U.S. citizens and their spouses and children [242].	Yes. INA 212(a)(4)	Required. INA 212(a)(4)(C).
Family Preference Fourth: Brothers/sisters of U.S. citizens (at least 21 years of age) and their spouses and children [243].	Yes. INA 212(a)(4)	Required. INA 212(a)(4)(C).
Fiancé, * admitted as nonimmigrant K–1/K2 [244]	Yes. INA 212(a)(4)	Required. INA 212(a)(4)(C).
Amerasians based on preference category-born between December 31, 1950 and before October 22, 1982 [245].	Yes. INA 212(a)(4)	Exempt. Amerasian Act, Public Law 97–359 (Oct. 22, 1982).

[236] This classification can no longer be sought as of December 20, 2009. See the Nursing Relief for Disadvantaged Areas Reauthorization Act of 2005, Public Law 109–423.

[237] J nonimmigrant who are admitted for a specific time period are not eligible for an extension of stay.

[238] Applicants who filed a Form I–485 prior to December 19, 1997 are exempt from the Affidavit of Support requirement. *See* Public Law 104–208, div. C., section 531(b), 110 Stat. 3009–546, 3009–675 (Sept. 30, 1996); 8 CFR 213a.2(a)(2)(i) (adjustment applicants) and 213a.2(a)(2)(ii)(B) (applicants for admission). Aliens who acquired citizenship under section 320 of the Act upon admission to the United States are exempt from submitting an affidavit of support. *See* 8 CFR 213a.2(a)(2)(ii)(E); Child Citizenship Act, Public Law 106–395, section 101, 114 Stat. 1631, 1631 (Oct. 30, 2000) (amending INA section 320). In addition, the surviving spouses, children, and parents of a deceased member of the military who obtain citizenship posthumously are exempt from a public charge determination. *See* National Defense Authorization Act For Fiscal Year 2004, Public Law 108–136, section 1703(e), 117 Stat. 1392, 1695 (Nov. 24, 2003). An alien who meets the conditions of new 8 CFR 212.23(a)(18), (19), (20), or (21) (*e.g.,* certain T nonimmigrants, U nonimmigrants, and VAWA self-petitioners) are exempt from the public charge inadmissibility ground and the affidavit of support requirement, and therefore do not need to File Form I–944 or Form I–864 regardless of what category the alien adjusts under.

[239] Including the following categories: IR–6 Spouses; IR–7 Children; CR–7 Children, conditional; IH–8 Children adopted abroad under the Hague Adoption Convention; IH–9 Children coming to the United States to be adopted under the Hague Adoption Convention; IR–8 Orphans adopted abroad; IR–9 Orphans coming to the United States to be adopted; IR–0 Parents of adult U.S. citizens. Note children adopted abroad generally do not apply for adjustment of status.

[240] Including the following categories: A–16 Unmarried Amerasian sons/daughters of U.S. citizens; F–16 Unmarried sons/daughters of U.S. citizens; A–17 Children of A–11 or A–16; F–17 Children of F–11 or F–16; B–17 Children of B–11 or B–16.

[241] Including the following categories: F–26 Spouses of alien residents, subject to country limits; C–26 Spouses of alien residents, subject to country limits, conditional; FX–6 Spouses of alien residents, exempt from country limits; CX–6 Spouses of alien residents, exempt from country limits, conditional; F–27 Children of alien residents, subject to country limits; C–28 Children of C–26, or C–27, subject to country limits, conditional; B–28 Children of B–26, or B–27, subject to country limits; F–28 Children of F–26, or F–27, subject to country limits; C–20 Children of C–29, subject to country limits, conditional; B–20 Children of B–29, subject to country limits; F–20 Children of F–29, subject to country limits; C–27 Children of alien residents, subject to country limits, conditional; FX–7 Children of alien residents, exempt from country limits; CX–8 Children of CX–7, exempt from country limits, conditional; FX–8 Children of FX–7, or FX–8, exempt from country limits; CX–7 Children of alien residents, exempt from country limits, conditional; F–29 Unmarried sons/daughters of alien residents, subject to country limits; C–29 Unmarried children of alien residents, subject to country limits, conditional.

[242] Including the following categories: A–36 Married Amerasian sons/daughters of U.S. citizens; F–36 Married sons/daughters of U.S. citizens; C–36 Married sons/daughters of U.S. citizens, conditional; A–37 Spouses of A–31 or A–36; F–37 Spouses of married sons/daughters of U.S. citizens; C–37 Spouses of married sons/daughters of U.S. citizens, conditional; B–37 Spouses of B–31 or B–36; A–38 Children of A–31 or A–36, subject to country limits; F–38 Children of married sons/daughters of U.S. citizens; C–38 Children of C–31 or C–36, subject to country limits, conditional; B–38 Children of B–31 or B–36, subject to country limits.

[243] Includes the following categories: F–46 Brothers/sisters of U.S. citizens, adjustments; F–47 Spouses of brothers/sisters of U.S. citizens, adjustments; F–48 Children of brothers/sisters of U.S. citizens, adjustments.

[244] Includes the following categories: CF–1 Spouses, entered as fiance(e), adjustments conditional; IF–1 Spouses, entered as fiance(e), adjustments.

[245] Includes the following categories: Immediate Relative AR–6 Children, Amerasian, First Preference: A–16 Unmarried Amerasian sons/daughters of U.S. citizens; Third Preference A–36 Married Amerasian sons/daughters of U.S. citizens; See INA 204(f). Note that this program does not have a specific sunset date and technically applicants could apply but should have already applied.

TABLE 3—APPLICABILITY OF INA 212(a)(4) TO FAMILY-BASED ADJUSTMENT OF STATUS APPLICATIONS [238]—Continued

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A and Form I–864, affidavit of support under section 213A of the INA, required or exempt?
Amerasians, born in Vietnam between 1/1/62–1/1/76. Immediate Relative: AM–6, AR–6 Children; Amerasians under Amerasian Homecoming Act, Public Law 100–202 (Dec. 22, 1987) [246]—born between 1/1/1962–1/1/1976.	No. (I–360 and adjustment) Section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1988, Public Law 100–202.	Exempt. Section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1988, Public Law 100–202.
IW–6 Spouses, widows or widowers	Yes. INA 212(a)(4)	Exempt. 8 CFR 204.2 and 71 FR 35732.
Immediate Relative VAWA applicant, including spouses and children [247].	No. INA 212(a)(4)(E)	Exempt. INA 212(a)(4)(E).
First Preference VAWA, B–16 Unmarried sons/daughters of U.S. citizens, self-petitioning; B–17 Children of B–16.	No. INA 212(a)(4)(C)(i)	Exempt. INA 212(a)(4)(C)(i).
Second Preference VAWA applicant, including spouses and children [248].	No. INA 212(a)(4)(C)(i)	Exempt. INA 212(a)(4)(C)(i).
Third Preference VAWA. Married son/daughters of U.S. citizen, including spouses and children [249].	No. INA 212(a)(4)(C)(i)	Exempt. INA 212(a)(4)(C)(i).

* If found inadmissible based on the public charge ground, USCIS, at its discretion, may permit the alien to post a public charge bond (Form I–945). A public charge bond may be cancelled (Form I–356) upon the death, naturalization (or otherwise obtaining U.S. citizenship), permanent departure of the alien, or otherwise as outlined in proposed 8 CFR 213.1(g), if the alien did not receive any public benefits as defined in the proposed rule.

TABLE 4—APPLICABILITY OF INA 212(a)(4) TO EMPLOYMENT-BASED ADJUSTMENT OF STATUS APPLICATIONS [250]

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A, and Form I–864, Affidavit of Support under section 213A of the INA, required or exempt?
First Preference: Priority workers [251]	Yes, in general.[252] INA 212(a)(4)	Exempt, unless qualifying relative or entity in which such relative has a significant ownership interest (5% or more) [253] in filed Form I–140. INA 212(a)(4)(D), 8 CFR 213a.
Second Preference: Professionals with advanced degrees or aliens of exceptional ability [254].	Yes in general.[255] INA 212(a)(4)	Exempt, unless qualifying relative or entity in which such relative has a significant ownership interest (5% or more) in filed Form I–140. INA 212(a)(4)(D), 8 CFR 213a.

[246] Includes the following categories: AM–1 principal (born between 1/1/1962–1/1/1976); AM–2 Spouse, AM–3 child; AR–1 child of U.S. citizen born Cambodia, Korea, Laos, Thailand, Vietnam. Note that this program does not have a specific sunset date and technically applicants could apply but should have already applied.

[247] Includes the following categories: IB–6 Spouses, self-petitioning; IB–7 Children, self-petitioning; IB–8 Children of IB–1 or IB–6; IB–0 Parents battered or abused, of U.S. citizens, self-petitioning.

[248] Includes the following categories: B–26 Spouses of alien residents, subject to country limits, self-petitioning; BX–6 Spouses of alien residents, exempt from country limits, self-petitioning; B–27 Children of alien residents, subject to country limits, self-petitioning; BX–7 Children of alien residents, exempt from country limits, self-petitioning; BX–8 Children of BX–6, or BX–7, exempt from country limits; B–29 Unmarried sons/daughters of alien residents, subject to country limits, self-petitioning.

[249] Includes the following categories: B–36 Married sons/daughters of U.S. citizens, self-petitioning B–37 Spouses of B–36, adjustments; B–38 Children of B–36, subject to country limits; Third Preference VAWA; B–36 Married sons/daughters of U.S. citizens, self-petitioning; B–37 Spouses of B–36, adjustments B–38 Children of B–36, subject to country limits; Third Preference VAWA; B–37 Spouses of B–36, adjustments; B–38 Children of B–36, subject to country limits.

[250] An alien who meets the conditions of new 8 CFR 212.23(a)(18), (19), (20), or (21) (*e.g.,* certain T nonimmigrants, U nonimmigrants, and VAWA self-petitioners) are exempt from the public charge inadmissibility ground and the affidavit of support requirement, and therefore do not need to File Form I–944 or Form I–864 regardless of what category the alien adjusts under.

[251] Includes the following categories: E–16 Aliens with extraordinary ability; E–17 Outstanding professors or researchers; E–18 Certain Multinational executives or managers; E–19 Spouses of E–11, E–12, E–13, E–16, E–17, or E–18; E–10 Children of E–11, E–12, E–13, E–16, E–17, or E–18.

[252] If the alien is adjusting based on an employment-based petition where the petition is filed by either a qualifying relative, or an entity in which such relative has a significant ownership interest (5% or more), and the alien, at both the time of filing and adjudication of the Form I–485, also falls under a category exempted under INA section 212(a)(4)(E), 8 U.S.C. 1182(a)(4)(E), (*e.g.,* T nonimmigrants, U nonimmigrants, and VAWA self-petitioners) the alien does not need to file Form I–944 (but is still required to file Form I–864).

[253] Relative means a husband, wife, father, mother, child, adult son, adult daughter, brother, or sister. Significant ownership interest means an ownership interest of five percent or more in a for-profit entity that filed an immigrant visa petition to accord a prospective employee an immigrant status under section 203(b) of the Act. *See* 8 CFR.213a.1.

[254] Includes the following categories: E–26 Professionals holding advanced degrees; ES–6 Soviet scientists E–27 Spouses of E–21 or E–26; E–28 Children of E–21 or E–26.

[255] If the alien is adjusting based on an employment-based petition where the petition is filed by either a qualifying relative, or an entity in which such relative has a significant ownership interest (five percent or more), and the alien, at both the time of filing and adjudication of the Form I–485, also falls under a category exempted under INA section 212(a)(4)(E), 8 U.S.C. 1182(a)(4)(E), (*e.g.,* T nonimmigrants, U nonimmigrants, and VAWA self-petitioners) the alien does not need to file Form I–944 (but is still required to file Form I–864).

TABLE 4—APPLICABILITY OF INA 212(a)(4) TO EMPLOYMENT-BASED ADJUSTMENT OF STATUS APPLICATIONS [250]—Continued

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A, and Form I–864, Affidavit of Support under section 213A of the INA, required or exempt?
Third: Skilled workers, professionals, and other workers [256]	Yes in general.[257] INA 212(a)(4)	Exempt, unless qualifying relative or entity in which such relative has a significant ownership interest (5% or more) in filed Form I–140. INA 212(a)(4)(D), 8 CFR 213a.
Fifth: I–526 Immigrant Petition by Alien Entrepreneur (EB–5) INA 203(b)(5), 8 CFR 204.6 [258].	Yes. INA 212(a)(4)	Not Applicable.[259]

* If found inadmissible based on the public charge ground, USCIS, at its discretion, may permit the alien to post a public charge bond (Form I–945). A public charge bond may be cancelled (Form I–356) upon the death, naturalization (or otherwise obtaining U.S. citizenship), permanent departure of the alien, or upon the fifth year of the alien's anniversary of the adjustment of status, or, if the alien, following the initial grant of lawful permanent resident status, obtains a status that is exempt from the public charge ground of inadmissibility, and provided that the alien did not receive any public benefits as defined in the proposed rule.

TABLE 5—APPLICABILITY OF INA 212(*a*)(4) TO SPECIAL IMMIGRANT ADJUSTMENT OF STATUS APPLICATION

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A, and Form I–864, Affidavit of Support under section 213A of the INA, required or exempt?
Special Immigrant (EB–4)—Religious Workers. 8 CFR 204.5(m); INA 101(a)(27)(C) [260].	Yes. INA 212(a)(4)	Not Applicable.[261]
Special Immigrant (EB–4)—International employees of U.S. government abroad. INA 101(a)(27)(D), 22 CFR 42.32(d)(2) [262].	Yes. INA 212(a)(4)	Not Applicable.[263]
Special Immigrant (EB–4)—Employees of Panama Canal. 22 CFR 42.32(d)(3); INA 101(a)(27)(E), INA 101(a)(27)(F), and INA 101(a)(27)(G) [264].	Yes. INA 212(a)(4)	Not Applicable.[265]
Special Immigrant (EB–4)—Foreign Medical School Graduates. INA 101(a)(27)(H), INA 203(b)(4) [266].	Yes. INA 212(a)(4)	Not Applicable.[267]

[256] Includes the following categories: EX–6 Schedule—A worker; EX–7 Spouses of EX–6; EX–8 Children of EX–6; E–36 Skilled workers; E–37 Professionals with baccalaureate degrees; E–39 Spouses of E–36, or E–37; E–30 Children of E–36, or E–37; EW–8 Other workers; EW–0 Children of EW–8; EW–9 Spouses of EW–8; EC–6 Chinese Student Protection Act (CSPA) principals; EC–7 Spouses of EC–6; EC–8 Children of EC–6.

[257] If the alien is adjusting based on an employment-based petition where the petition is filed by either a qualifying relative, or an entity in which such relative has a significant ownership interest (5% or more), and the alien, at both the time of filing and adjudication of the Form I–485, also falls under a category exempted under INA section 212(a)(4)(E), 8 U.S.C. 1182(a)(4)(E), (*e.g.,* T nonimmigrants, U nonimmigrants, and VAWA self-petitioners) the alien does not need to file Form I–944 (but is still required to file Form I–864).

[258] Includes the following categories: C–56 Employment creation, not in targeted area, adjustments, conditional E–56 Employment creation; I–56 Employment creation, targeted area, pilot program, adjustments, conditional; T–56 Employment creation, targeted area, conditional; R–56 Investor pilot program, not targeted, conditional; C–57 Spouses of C–51 or C–56, conditional; E–57 Spouses of E–51 or E–56; I–57 Spouses of I–51 or I–56, conditional; T–57 Spouses of T–51 or T–56, conditional; R–57 Spouses of R–51 or R–56, conditional; C–58 Children of C–51 or C–56, conditional; E–58 Children of E–51 or E–56; I–58 Children of I–51 or I–56, conditional; T–58 Children of T–51 or T–56, conditional; R–58 Children of R–51 or R–56, conditional.

[259] EB–5 applicants are Form I–526, Immigrant Petition by Alien Entrepreneur, self-petitioners. The regulation at 8 CFR 213a.1 relates to a person having ownership interest in an entity filing for a prospective employee and therefore the requirements for an affidavit of support under INA section 212(a)(4)(D) is inapplicable.

[260] Includes the following categories: SD–6 Ministers; SD–7 Spouses of SD–6; SD–8 Children of SD–6; SR–6 Religious workers; SR–7 Spouses of SR–6; SR–8 Children of SR–6.

[261] For this category, although the applicants are subject to public charge under INA section 212(a)(4), the employers (for example, a religious institution), would generally not be a relative of the alien or a for-profit entity and therefore the requirements for an affidavit of support under INA section 212(a)(4)(D) is inapplicable.

[262] Includes the following categories: SE–6 Employees of U.S. government abroad, adjustments; SE–7 Spouses of SE–6; SE–8 Children of SE–6. Note that this program does not have a specific sunset date and technically applicants could apply but should have already applied.

[263] For this category, although the applicants are subject to public charge under INA section 212(a)(4), the employers (for example, the U.S. armed forces), would generally not be a relative of the alien or a for-profit entity and therefore the requirements for an affidavit of support under INA section 212(a)(4)(D) is inapplicable.

[264] Includes the following categories: SF–6 Former employees of the Panama Canal Company or Canal Zone Government; SF–7 Spouses or children of SF–6; SG–6 Former U.S. government employees in the Panama Canal Zone; SG–7 Spouses or children of SG–6; SH–6 Former employees of the Panama Canal Company or Canal Zone government, employed on April 1, 1979; SH–7 Spouses or children of SH–6. Note that this program does not have a specific sunset date and technically applicants could apply but should have already applied.

[265] For this category, although the applicants are subject to public charge under INA section 212(a)(4), the employers generally would not be a relative of the alien or a for-profit entity and therefore the requirements for an affidavit of support under INA section 212(a)(4)(D) is inapplicable.

[266] Includes the following categories: SJ–6 Foreign medical school graduate who was licensed to practice in the United States on Jan. 9, 1978; SJ–7 Spouses or children of SJ–6; Note that this program does not have a specific sunset date and technically applicants could apply but should have already applied.

[267] For this category, although the applicants are subject to public charge under INA section 212(a)(4), the employers would generally not be a relative of the alien or a for-profit entity and therefore the requirements for an affidavit of support under INA section 212(a)(4)(D) is inapplicable.

TABLE 5—APPLICABILITY OF INA 212(*a*)(4) TO SPECIAL IMMIGRANT ADJUSTMENT OF STATUS APPLICATION—Continued

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A, and Form I–864, Affidavit of Support under section 213A of the INA, required or exempt?
Special Immigrant (EB–4)—Retired employees of International Organizations including G–4 International Organization Officer. International Organizations (G–4s international organization officer/Retired G–4 Employee) INA 101(a)(27)(I) and INA 101(a)(27)(L); 8 CFR 101.5; 22 CFR 42.32(d)(5); 22 CFR 41.24; 22 CFR 41.25[268] [269].	Yes. INA 212(a)(4)	Not Applicable.[270]
Special Immigrant (EB–4)—SL–6 Juvenile court dependents, adjustments.	No. SIJ are exempt under 245(h)	Not Applicable. INA 245(h).
Special Immigrant (EB–4)—U.S. Armed Forces Personnel. INA 101(a)(27)(K)[271].	Yes. INA 212(a)(4)	Not Applicable.[272]
Special Immigrant—International Broadcasters. INA 101(a)(27)(M); 8 CFR 204.13[273].	Yes. INA 212(a)(4)	Not Applicable.[274]
Special Immigrant (EB–4)—Special immigrant interpreters who are nationals of Iraq or Afghanistan[275].	No. Section 1059(a)(2) of the National Defense Authorization Act for Fiscal Year 2006, as amended; Public Law 109–163—Jan. 6, 2006, Section 1244(a)(3) of the National Defense Authorization Act for Fiscal Year 2008, as amended; Public Law 110–181 (Jan. 28, 2008) Section 602(b) of the Afghan Allies Protection Act of 2009, as amended section (a)(2)(C), Public Law 111–8 (Mar. 11, 2009).	Exempt. Section 602(b)(9) of the Afghan Allies Protection Act of 2009, Title VI of Public Law 111–8, 123 Stat. 807, 809 (March 11, 2009) which states that INA 245(c)(2), INA 245(c)(7), and INA 245(c)(8) do not apply to special immigrant Iraq and Afghan nationals who were employed by or on behalf of the U.S. government (for Section 602(b) and 1244 adjustment applicants who were either paroled into the United States or admitted as nonimmigrants). See Section 1(c) of Public Law 110–36, 121 Stat. 227, 227 (June 15, 2007), which amended Section 1059(d) of the National Defense Authorization Act for Fiscal Year 2006, Public Law 109–163, 119 Stat. 3136, 3444 (January 6, 2006) to state that INA 245(c)(2), INA 245(c)(7), and INA 245(c)(8) do not apply to Iraq or Afghan translator adjustment applicants.

* If found inadmissible based on the public charge ground, USCIS, at its discretion, may permit the alien to post a public charge bond (Form I–945). A public charge bond may be cancelled (Form I–356) upon the death, naturalization (or otherwise obtaining U.S. citizenship), or permanent departure of the alien, if the alien did not receive any public benefits as defined in the proposed rule.

[268] Includes the following categories: SK–6 Retired employees of international organizations; SK–7 Spouses of SK–1 or SK–6; SK–8; Certain unmarried children of SK–6; SK–9 Certain surviving spouses of deceased international organization employees.

[269] Includes SN–6 Retired NATO–6 civilian employees; SN–7 Spouses of SN–6; SN–9; Certain surviving spouses of deceased NATO–6 civilian employees; SN–8 Certain unmarried sons/daughters of SN–6.

[270] For this category, although the applicants are subject to public charge under INA section 212(a)(4), the employers would generally not be a relative of the alien or a for-profit entity and therefore the requirements for an affidavit of support under INA section 212(a)(4)(D) is inapplicable.

[271] Includes the following categories: SM–6 U.S. Armed Forces personnel, service (12 years) after 10/1/91 SM–9 U.S. Armed Forces personnel, service (12 years) by 10/91; SM–7 Spouses of SM–1 or SM–6; SM–0 Spouses or children of SM–4 or SM–9; SM–8 Children of SM–1 or SM–6.

[272] For this category, although the applicants are subject to public charge under INA section 212(a)(4), the employers would generally not be a relative of the alien or a for-profit entity and therefore the requirements for an affidavit of support under INA section 212(a)(4)(D) is inapplicable.

[273] Includes the following categories: BC–6 Broadcast (IBCG of BBG) employees; BC–7 Spouses of BC–1 or BC–6; BC–8 Children of BC–6.

[274] For this category, although the applicants are subject to public charge under INA section 212(a)(4), the employers would generally not be a relative of the alien or a for-profit entity and therefore the requirements for an affidavit of support under INA section 212(a)(4)(D) is inapplicable.

[275] Includes the following categories: SI–6 Special immigrant interpreters who are nationals of Iraq or Afghanistan; SI–6, SI–7, SI–8—spouse and child of SI–6; SQ–6 Certain Iraqis and Afghans employed by U.S. Government SQ–6, SQ–7, SQ–8 Spouses and children of SQ–6; SI–6 Special immigrant interpreters who are nationals of Iraq or Afghanistan; SI–7 Spouses of SI–1 or SI–6; SI–8 Children of SI–1 or SI–6.

TABLE 6—APPLICABILITY OF INA 212(a)(4) TO REFUGEE, ASYLEE, AND PAROLEE ADJUSTMENT OF STATUS APPLICATIONS

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A, and Form I–864, Affidavit of Support under section 213A of the INA, required or exempt?
Asylees [276]	No. INA 209(c)	Exempt. INA 209(c).
Indochinese Parolees from Vietnam, Cambodia, and Laos. IC–6 Indochinese refugees (Public Law 95–145 of 1977). IC–7 Spouses or children of Indochinese refugees not qualified as refugees on their own.	No. Section 586, Public Law 106–429 (Nov. 6, 2000).	Exempt. Section 586, Public Law 106–429 (Nov. 6, 2000).
Polish and Hungarian Parolees (Poland or Hungary who were paroled into the United States from November 1, 1989 to December 31, 1991) [277].	No. Title VI, Subtitle D, Section 646(b), Public Law 104–208; 8 CFR 245.12.	Exempt. Title VI, Subtitle D, Section 646(b), Public Law 104–208; 8 CFR 245.12.
Refugees [278]	No. INA 207(c)(3); INA 209(c)	Exempt. INA 207; INA 209(c).
Cuban-Haitian Entrant under IRCA—CH–6, CH–7 [279]	No. Section 202, Public Law 99–603, 100 Stat. 3359 (1986) (as amended), 8 U.S.C. 1255a.	Exempt. Section 202, Public Law 99–603, 100 Stat. 3359 (1986) (as amended), 8 U.S.C. 1255a.
HRIFA—Principal HRIFA Applicant who applied for asylum before December 31, 1995 [280].	No. Section 902 Public Law 105–277, 112 Stat. 2681 (Oct. 21, 1998), 8 U.S.C. 1255.	Exempt. Section 902 Public Law 105–277, 112 Stat. 2681 (Oct. 21, 1998), 8 U.S.C. 1255.

* If found inadmissible based on the public charge ground, USCIS, at its discretion, may permit the alien to post a public charge bond (Form I–945). A public charge bond may be cancelled (Form I–356) upon the death, naturalization (or otherwise obtaining U.S. citizenship), or permanent departure of the alien, if the alien did not receive any public benefits as defined in the proposed rule.

TABLE 7—APPLICABILITY OF INA 212(a)(4) TO OTHER APPLICANTS WHO MUST BE ADMISSIBLE

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A, and Form I–864, Affidavit of Support under section 213A of the INA, required or exempt?
Diplomats Section 13	Yes. Section 13 of Public Law 85–316 (September 11, 1957), as amended by Public Law 97–116 (December 29, 1981); 8 CFR 245.3.	Exempt, by statute, as they are not listed in INA 212(a)(4) as a category that requires Form I–864.
Individuals Born in the U.S. under Diplomatic Status (NA–3) 8 CFR 101.3.	Yes. INA 212(a)(4)	Exempt. 8 CFR 101.3.
Diversity, DV–1 diversity immigrant, spouse and child	Yes. INA 212(a)(4)	Exempt, by statute, as they are not listed in INA 212(a)(4) as a category that requires Form I–864. Diversity visas are issued under INA 203(c) which do not fall under INA 212(a)(4)(C) or (D).
W–16 Entered without inspection before 1/1/82; W–26 Entered as nonimmigrant and overstayed visa before 1/1/82. Certain Entrants before January 1, 1982.	Yes. INA 212(a)(4) (except for certain aged, blind or disabled individuals as defined in 1614(a)(1) of the Social Security Act). INA 245A(b)(1)(C)(i) and (a)(4)(a))—application for adjustment 42 U.S.C. 1382c(a)(1). Special Rule for determination of public charge—See INA 245A(d)(2)(B)(iii).	Exempt, by statute as they are not listed in INA 212(a)(4) as a category that requires an Form I–864.

[276] Including the following categories: AS–6 Asylees; AS–7 Spouses of AS–6; AS–8 Children of AS–6; SY–8 Children of SY–6; GA–6 Iraqi asylees; GA–7 Spouses of GA–6; GA–8 Children of GA–6.

[277] Note that this program does not have a specific sunset date and technically applicants could apply but should have already applied.

[278] Includes the following categories: RE–6 Other refugees (Refugee Act of 1980, Public Law 96–212, 94 Stat. 102 (Mar. 17, 1980)); RE–7 Spouses of RE–6; RE–8 Children of RE–6; RE–9 Other relatives.

[279] Note that this program has a sunset date of two years after enactment, however, some cases may still be pending.

[280] Includes the following categories: 1995—HA–6 Principal HRIFA Applicant; Spouse of HA–6, HA–7 and Child of HA–6, HA–8; Unmarried Son or Daughter 21 Years of Age or Older of HA–6, HA–9 Principal HRIFA Applicant paroled into the United States before December 31, 1995- HB–6; Spouse of HB–6, HB–7; Child of HB–6, HB–8; Unmarried Son or Daughter 21 Years of Age or Older of HB–6 HB–9; Principal HRIFA Applicant who arrived as a child without parents in the United States HC–6; Spouse of HC–6, HC–7; Child of HC–6, HC–8; Unmarried Son or Daughter 21 Years of Age or Older of HC–6, HC–9; Principal HRIFA Applicant child who was orphaned subsequent to arrival in the United States HD–6, Spouse of HD–6, HD–7; Child of HD–6, HD–8; Unmarried Son or Daughter 21 Years of Age or Older of HD–6, HD–9 Principal HRIFA Applicant child who was abandoned subsequent to arrival and prior to April 1, 1998—HE–6; Spouse of HE–6, HE–7; Child of HE–6, HE–8; Unmarried Son or Daughter 21 Years of Age or Older of HE–6, HE–9. Note that this program has a sunset date of March 31, 2000; however, dependents may still file for adjustment of status.

TABLE 7—APPLICABILITY OF INA 212(a)(4) TO OTHER APPLICANTS WHO MUST BE ADMISSIBLE—Continued

Category	Subject to INA 212(a)(4) and must file Form I–944, Declaration of Self-Sufficiency? *	INA 213A, and Form I–864, Affidavit of Support under section 213A of the INA, required or exempt?
T, T–1 victim, spouse, child, parent, sibling; INA 101(a)(15)(T), INA 212(d)(13)(A).	No. INA 212(a)(4)(E).	Exempt, by statute as they are not listed in INA 212(a)(4) as a category that requires Form I–864. Adjustment of status based on T nonimmigrant status is under INA 245(l) which does not fall under INA 212(a)(4)(C) or (D).
American Indians—INA 289	No. INA 289	Exempt. INA 289.
Texas Band of Kickapoo Indians of the Kickapoo Tribe of Oklahoma, Public Law 97–429 (Jan. 8, 1983); KIC—Kickapoo Indian Citizen; KIP—Kickapoo Indian Pass.	No. Public Law 97–429 (Jan. 8, 1983).	Exempt. Public Law 97–429 (Jan. 8, 1983).
S (Alien witness or informant)	Yes, but there is a waiver available—INA 245(j); INA 101(a)(15)(S); 8 CFR 214.2(t)(2); 8 CFR 1245.11 (Waiver filed on Form I–854, Inter-Agency Alien Witness and Informant Record).	Exempt. INA 245(j); INA 101(a)(15)(S); 8 CFR 214.2(t)(2); 8 CFR 1245.11 (Waiver filed on Form I–854, Inter-Agency Alien Witness and Informant Record).
Private Immigration Bill providing for alien's adjustment of status	Dependent on the text of the Private Bill.	Dependent on the text of the Private Bill.
NACARA (202); Principal NC–6, (NC 7–9) spouse and children [281]	No. Section 202(a), Public Law 105–100, 111 Stat. 2193 (1997) (as amended), 8 U.S.C. 1255..	Exempt. Section 202(a), Public Law 105–100, 111 Stat. 2193 (1997) (as amended), 8 U.S.C. 1255.
NACARA 203; Cancellation of removal (Z–13) Battered spouses or children (Z–14) Salvadoran, Guatemalan and former Soviet bloc country nationals (Form I–881, Application for Suspension of Deportation or Special Rule Cancellation of Removal (Pursuant to Section 203 of Public Law 105–100 (NACARA)).	No. Section 203, Public Law 105–100, 111 Stat. 2193 (1997) (as amended), 8 U.S.C. 1255.	Exempt. Section 203, Public Law 105–100, 111 Stat. 2193 (1997) (as amended), 8 U.S.C. 1255.
Lautenberg, LA–6 [282]	No. Section 599E, Public Law 101–167, 103 Stat. 1195 (Nov. 21, 1989), 8 U.S.C.A. 1255.	Exempt. Section 599E, Public Law 101–167, 103 Stat. 1195 (Nov. 21, 1989), 8 U.S.C.A. 1255.
Registry, Z–66—Aliens who entered the United States prior to January 1, 1972 and who meet the other conditions.	No. INA 249 of the Act and 8 CFR part 249.	Exempt. INA 249 of the Act and 8 CFR part 249.
U, U–1 Crime Victim, spouse, children and parents, and siblings under INA 245(m).	No. INA 212(a)(4)(E).	Exempt. INA 212(a)(4)(E).
Temporary Protected Status (TPS)	No. 8 CFR 244.3(a).[283]	Exempt. 8 CFR 244.3(a).[284]

* If found inadmissible based on the public charge ground, USCIS, at its discretion, may permit the alien to post a public charge bond (Form I–945). A public charge bond may be cancelled (Form I–356) upon the death, naturalization (or otherwise obtaining U.S. citizenship), or permanent departure of the alien, if the alien did not receive any public benefits as defined in the proposed rule.

G. Definitions

1. Public Charge

Comment: A commenter stated that the lack of a public charge definition is an issue that must be resolved because immigration is an important feature of America's culture and public policy, heightening the importance of having a consistent definition.

Response: DHS agrees that it is important to define public charge in the rulemaking—public charge is a term that has appeared in U.S. Federal immigration law since at least 1882, but has never been defined by Congress or in regulation. The rule provides a definition for public charge and DHS believes that prior to this rule there has been insufficient guidance on how to determine if an alien who is applying for admission or adjustment of status is likely to become a public charge at any time in the future.

Comment: Commenters stated that the proposed definition of public charge is ''without precedent and contrary to the discretion provided to DHS under statute.'' A commenter stated that the proposed public charge definition relies on outdated case law, and that the 1999 Interim Field Guidance is preferable to the proposed rule, for three reasons. First, the commenter argued that the proposed rule undermined DHS's stated objectives, because it could stop an alien from accessing government services that would make the alien more self-sufficient. Second, the commenter argued that the proposed rule could have adverse effects on aliens whose presence in the United States is a net benefit to the U.S. Government as a consequence of their productivity, associated tax revenues, etc. And third, the commenter argued that the proposed rule would bind adjudicators to a bright-line definition of ''public charge'' that could result in harsh consequences in some cases. By contrast, in the commenter's view, the ''primarily dependent'' standard under the 1999 Interim Field Guidance provided adjudicators with more discretion. Another commenter stated that the proposed rule does not comport with the law because it is contrary to the long-established common-law definition of public charge. A commenter stated that the use of non-monetizable benefits

[281] Note that this program has a sunset date of April 1, 2000; however, some cases may still be pending.

[282] Note that this program sunset date of September 30, 2014, only applies to parole. Eligible applicants may still apply for adjustment of status.

[283] INA section 244(c)(2)(ii), 8 U.S.C. 1254a(c)(2)(ii), authorizes USCIS to waive any section 212(a) ground, except for those that Congress specifically noted could not be waived.

[284] *See* INA section 244(c)(2)(ii), 8 U.S.C. 1254a(c)(2)(ii).

for one third of the time period does not reflect ''primary dependence.''

Response: DHS disagrees that the public charge definition is contrary to the discretion provided to DHS under the INA, relies on outdated case law or is without precedent, or undermines the agency's objectives. As noted in the NPRM, DHS's authority to make public charge inadmissibility determinations and related decisions is found in several statutory provisions, including section 102 of the Homeland Security Act of 2002 (Pub. L. 107–296, 116 Stat 2135), 6 U.S.C. 112, section 103 of the Act, 8 U.S.C. 1103, as well as section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). DHS may issue regulations implementing its authority under these statutes without further congressional authorization. Additionally, as noted in the NPRM, there is a scarcity of case law specifically defining public charge.[285] The cases cited in the NPRM and in this final rule include the most recent and relevant case law discussing the term public charge and the public charge ground of inadmissibility.[286]

With respect to the argument that the public charge rule may make it more difficult for some aliens to become self-sufficient, DHS has addressed this argument at length elsewhere in this preamble. In short, and as relevant here, the fact that an alien might rely on public benefits to *become* self-sufficient in the future has no bearing on whether such alien currently is self-sufficient or currently is or is not a public charge. DHS rejects the notion that it must interpret the term ''public charge'' in such a way as to allow aliens to rely on public benefits until such time as they are self-sufficient. DHS notes that its position on this aspect of the *definition* of public charge should not be taken as a rejection of the commenters' general point that an alien's past receipt of public benefits can result in greater self-sufficiency. If an alien received public benefits in the past and such benefits helped the alien become self-sufficient, DHS agrees that the alien's current self-sufficiency is relevant to the prospective public charge inadmissibility determination, but the alien's past receipt of public benefits is relevant to assessing the likelihood of future receipt of public benefits.

With respect to the argument regarding aliens who receive the designated public benefits, but may nonetheless be a net benefit to the U.S. Government or society, neither the Act nor the case law requires DHS to weigh an alien's net impacts on government resources, such as by evaluating the potential tax receipts generated by the alien, as compared to the alien's receipt of public benefits. In addition, a definition that requires consideration of the alien's overall contributions to tax revenues, economic productivity, or society at large would be unjustifiably challenging to administer. For instance, as explained in the proposed rule, fully monetized thresholds (which would be required to make a dollars-to-dollars comparison) would not be administrable because some benefits, such as Medicaid, lack clearly monetizable value. In addition, DHS notes that taxes serve a variety of functions, and benefit the taxpayer regardless of whether she or he receives an individual, means-tested public benefit. A comparison of the alien's ''contributions'' (in the form of taxes) to the alien's ''withdrawals'' (in the form of public benefits) would therefore be incomplete, because it would not consider the other government programs and services, including national defense, infrastructure, law enforcement and emergency services, from which the alien benefits. Further, under this rule, DHS will not consider receipt of any public benefits for which the alien has paid into directly. Each of the designated benefits involves significant government subsidization. In this context, DHS does not believe that value of an alien's current or future tax contributions should ultimately have a bearing on whether the alien is a public charge.

With respect to the firmness of the definition, part of the rule's purpose is to provide a clearer definition; DHS will not institute a vague standard in order to avoid harsh consequences for some people.

Finally, as to the comment stating that the rule does not comport with the law because it is contrary to the long-standing common law definition of public charge, the commenter failed to identify any common law definition of public charge that DHS should have considered, or as the commenter stated, that DHS violated. As noted in the NPRM, DHS's definition for public charge is derived from a review of the minimal legislative history of the public charge ground of inadmissibility and the ordinary meaning of public charge. DHS's definition also relies on the limited case law addressing the definition of public charge, in which courts, in the absence of statutory definition for public charge, generally tied the definition of public charge to receipt of public benefits, without quantifying the level of public support or the type of public support required to determine that the alien is likely to become a public charge at any time in the future.

DHS notes that even if there were a clear definition for public charge grounded in case law, which there does not appear to be, agencies responsible for administering federal law generally have the authority to interpret an ambiguous statute in a different manner than the manner in which a court interpreted the statute.[287] Therefore, DHS would be within its authority to create a different definition of ''public charge.'' [288]

Comment: Commenters provided a historical overview of public charge, and asserted that expanding the definition would represent a ''radical departure'' from over 100 years of U.S. immigration policy. The commenters discussed the laws governing public charge inadmissibility and deportability, and observed that, in the past, public charge inadmissibility and associated guidance have sometimes operated to the detriment of certain vulnerable populations, including Jews, women, and people from India. The commenters stated that the change in policy—from a focus on dependence on the government by cash support for subsistence or long-term institutionalization, to a focus on a broader range of benefits—would lead to a ''general erosion'' of benefits that legal immigrants may access.

Response: While this rule expands the list of public benefits covered in the INS 1999 Interim Field Guidance and the 1999 proposed rule, DHS does not believe that the rule is inconsistent with historical practice. DHS notes that this rule is not facially discriminatory, and that DHS does not intend the rule to have a discriminatory effect based on

[285] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157–58 (proposed Oct. 10, 2018).

[286] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157–58 (proposed Oct. 10, 2018).

[287] *Nat'l Cable & Telecomms. Ass'n* v. *Brand X internet Servs.,* 545 U.S. 967, 983–84 (2005) (*Brand X*) (''Since *Chevron* teaches that a court's opinion as to the best reading of an ambiguous statute an agency is charged with administering is not authoritative, the agency's decision to construe that statute differently from a court does not say that the court's holding was legally wrong. Instead, the agency may, consistent with the court's holding, choose a different construction, since the agency remains the authoritative interpreter (within the limits of reason) of such statutes. In all other respects, the court's prior ruling remains binding law (for example, as to agency interpretations to which *Chevron* is inapplicable). The precedent has not been 'reversed' by the agency, any more than a federal court's interpretation of a State's law can be said to have been 'reversed' by a state court that adopts a conflicting (yet authoritative) interpretation of state law.'').

[288] *Brand X,* 545 U.S. at 1001 (''the Commission is free within the limits of reasoned interpretation to change course if it adequately justifies the change'').

race, gender, religion, or any other protected ground. Rather, the rule is consistent with existing precedents that have developed in the years since the earliest public charge laws, as well as Congress' codified policy statement that ''[s]elf-sufficiency has been a basic principle of United States immigration law since this country's earliest immigration laws.'' [289] As noted in the NPRM,[290] courts have consistently tied the concept of public charge to an alien's receipt of public benefits, without quantifying the level of public support or requiring a certain type of public support, and the alien's ability to be self-sufficient. DHS acknowledges that individuals may disenroll from public benefits to avoid the consequences of this rule. As previously noted, the rule aims to align the principles of self-sufficiency set forth in PRWORA[291] with the public charge inadmissibility ground.

DHS does not believe that the history of the public charge ground of inadmissibility—which Congress has consistently chosen to retain as part of our immigration laws—precludes DHS from implementing a rigorous and fair regulatory framework for public charge inadmissibility determinations. DHS notes that our immigration laws have evolved to provide greater protections to vulnerable populations. For instance, refugees and asylees are exempt from the public charge ground of inadmissibility.

Comment: One commenter stated that the proposed rule greatly expands the definition of public charge, is a departure from existing policy and creates an unworkable, overly broad definition that will be impossible to implement fairly. The commenter also asserted that experts estimated that, under the new definition, 94% of all noncitizens who entered the United States without lawful permanent resident status have at least one characteristic that DHS could potentially weigh negatively in a public charge determination under the proposed rule. Another commenter stated that taking advantage of any federal, state, or local government program should have no impact on a pathway to residency or citizenship. The commenter suggested that instead, DHS evaluate each applicant based on whether the alien is employed or is caring for a family, has a violent felony conviction, and has a sponsor (such as a family member or corporate sponsor providing support).

Response: DHS agrees that the definition of public charge in this rule is broader than the existing definition and policy. However, as noted previously, DHS believes that this expanded definition for public charge is reasonable and consistent with Congress' intent and will better ensure that aliens seeking to come to the United States temporarily or permanently are self-sufficient.[292] DHS acknowledges that the implementation of the public charge ground of inadmissibility will be a complex adjudication, but USCIS is committed to taking necessary steps to ensure consistent implementation and fair adjudication, including through the issuance of adjudicative guidance and training. As noted elsewhere in this rule, DHS believes consideration of receipt of public benefits is appropriate in determining whether an alien is likely to become a public charge in the future.

Comment: Some commenters stated that the proposed rule would exceed DHS's authority because the proposed definition is over-inclusive, encompassing a wide range of people who are substantially self-supporting and not primarily dependent upon the government to meet their basic needs. Commenters also indicated the proposal did not provide a reasoned analysis for changing the long-standing definition of public charge from being primarily dependent on the government to a determination in which a person could become a public charge based on receipt of a smaller amount of public benefits, including non-cash benefits. Commenters also stated that the NPRM would foreclose the opportunity for a hard-working, self-sufficient individual who experiences a fleeting financial hardship to become a long-term resident of the United States.

Similarly, another commenter stated that ''[t]he broader scheme of the [Immigration Act of] 1882 . . . confirms that Congress intended the term 'public charge' to refer to primary dependence on the government, not mere receipt of some public aid.'' The commenter suggested that because the Immigration Act of 1882 (1882 Act) authorized a fund ''to defray the expense of regulating immigration . . . , for the care of immigrants arriving in the United States, [and] for the relief of such as are in distress,'' [293] Congress must have anticipated that some immigrants would be in need of short-term support, without becoming a public charge.

The commenter also cited a floor statement by a member of Congress in the months preceding enactment of the 1882 Act. According to the commenter, the floor statement supported the conclusion that Congress intended for the term ''public charge'' to mean a person ''primarily if not wholly dependent on the government.'' Specifically, the member of Congress incorporated into his floor statement an 1879 resolution passed by the New York Board of Charities, which concluded that many cities and towns in Europe sent ''to this country blind, crippled, lunatic, and other infirm paupers, who ultimately become life-long dependents on our public charities''; and that many such persons ''become permanent inmates of the charitable institutions supported by the State of New York.'' [294] The resolution called on Congress to exclude such individuals from the United States and to appropriate funds for returning such individuals to their home countries. The commenter suggested that because the resolution referred to ''life-long dependents'' and ''permanent inmates,'' it is clear that Congress intended for the term ''public charge'' to refer to primary dependence on the Government for support.

Response: DHS rejects the notion that the public charge definition violates the law or is over-inclusive. DHS acknowledges that this is a change that likely will increase the number of individuals who will be deemed inadmissible or ineligible for adjustment of status based on the public charge ground. DHS disagrees, however, with the assertion that it did not provide a reasoned explanation why the prior standard is insufficient, why the change is necessary, and why non-cash benefits are included in the new public charge determinations. Longstanding agency practice and policy,[295] while generally accorded some weight, is not controlling or unalterable.[296] DHS provided

[289] 8 U.S.C. 1601(1).

[290] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51158 (proposed Oct. 10, 2018).

[291] *See* 8 U.S.C. 1601.

[292] *Brand X,* 545 U.S. at 1001 (''the Commission is free within the limits of reasoned interpretation to change course if it adequately justifies the change'').

[293] Immigration Act of 1882, 22 Stat. 214 (Aug. 3, 1882).

[294] *See* 13 Cong. Rec. 5109–10 (June 19, 1882) (Statement of Rep. John Van Voorhis).

[295] As of the date of the effective rule, the agency practice had not been codified in agency regulations as the NPRM published in May 1999 was never finalized. As explained in the NPRM, the agency also issued interim Field Guidance on Deportability and Inadmissibility on Public Charge Grounds, in which it detailed its policy. *See* 64 FR 28689 (May 26, 1999). *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51133 (proposed Oct. 10, 2018).

[296] *See, e.g., Judulang* v. *Holder,* 565 U.S. 42, 62 (2011) (indicating that longevity is ''a slender reed

detailed reasoning why the changes are necessary in the NPRM. As explained in the NPRM, although the primarily dependence (more-than-50-percent dependence) on public assistance standard creates a bright line rule, it is possible and likely probable that many individuals whose receipt of public benefits falls below that standard lack self-sufficiency.[297] Because of the nature of the benefits that would be considered under this rule—*i.e.,* cash benefits for income maintenance and non-cash benefits for basic living needs such as food and nutrition, housing, and healthcare, that account for significant public expenditures on non-cash benefits [298]—DHS believes that receipt of such benefits for more than 12 months within any 36-month period is sufficient to render a person a public charge.[299] This is because an individual with limited means to satisfy basic living needs who uses government assistance to fulfill such needs for that duration of time relies on such assistance to such an extent that the person is not self-sufficient.[300] Given that neither the wording of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), nor case law examining public charge inadmissibility, mandates the ''primarily dependent'' standard, and in light of Congress' unequivocal policy goal articulated in PRWORA, DHS has concluded that the ''primarily dependent'' standard is not the only permissible interpretation of what it means to be a public charge, and is in fact suboptimal when considered in relation to the goals of the INA and PRWORA.[301]

With respect to the commenter's arguments about the Immigration Act of 1882, the conclusions that the commenter draws from the funding mechanism in that Act appear to be largely unsupported. The commenter assumes, without articulating any basis for the assumption, that under the Immigration Act of 1882 aliens who received assistance through the fund could not also be public charges. DHS has no reason to believe that assumption is correct. But even if the Immigration Act of 1882 could be read as suggesting that an alien can rely on public funds for support without becoming a public charge, DHS is unaware of any binding case law requiring DHS to interpret the term ''public charge'' in this manner. And regardless, Congress has since amended the public charge ground of inadmissibility multiple times over the course of more than a century.

With respect to the New York State Board of Charities resolution referenced by the commenter, DHS notes that the resolution does not use the term ''public charge'' or implicitly define such term. DHS does not find the resolution or the surrounding floor statement particularly instructive for purposes of this rulemaking; they originate in a different historical context that preceded multiple modifications to and re-enactments of the public charge ground of inadmissibility in the 140 years since the passage of the 1879 resolution.[302]

Comment: A commenter stated that DHS's rationale for why the public charge definition is consistent with more than 40 years of case law—and specifically, DHS's citation of *Matter of Vindman* and *Matter of Harutunian* [303]—did not withstand scrutiny because these cases involved the receipt of cash benefits by the elderly, unemployed and unsponsored applicants, and therefore bears no relevance to the broad population affected by this rule. One commenter asserted that the cases cited do not support the proposed definition, and stated that the citation to these cases indicates that this rule is haphazardly put together and poorly researched.

Response: DHS rejects the notion that the case law cited does not support DHS's public charge definition. In particular, DHS disagrees that the case law cited in support of the public charge definition, and particularly *Vindman* and *Harutunian,*[304] bears no relevance to the population affected by this rule because the facts of *Vindman* and *Harutunian* were limited to cash assistance and elderly, unemployed, or unsponsored applicants. DHS cited these decisions to establish that its proposed regulation is consistent with case law. Absent a clear statutory or regulatory definition, some courts and administrative authorities have tied public charge to the receipt of public benefits.[305] DHS does not believe that *Vindman* or *Harutunian* specifically limited the general understanding of public charge to only those who are ''elderly, unemployed or unsponsored'' aliens. Both decisions were based on the understanding that Congress intended to exclude those who were unable to support themselves and who received public benefits.[306] Additionally, Congress later amended the law to specifically require sponsorship (by requiring an affidavit of support for some immigrants or considering an affidavit of support for others) as part of the public charge determination, and also codified statutory minimum factors to consider (including age, financial status, and education and skills). Therefore, DHS finds the commenters' assertion that DHS's reasoning does not withstand scrutiny for those non-elderly, employed, and sponsored aliens unpersuasive.

Comment: One commenter stated that the proposed public charge definition is nonsensical because DHS has asserted that legislative history and case law support the definition but has also noted that legislative history and case law on the subject are scarce.

Response: DHS does not believe that the public charge definition is nonsensical. While the case law and legislative history regarding the meaning of public charge is minimal, it is not non-existent. As outlined in the NPRM, DHS carefully analyzed the available legislative history and case law as part of this rulemaking.

Comment: A commenter indicated that DHS ignored Second Circuit case

to support a significant government policy''); *see Chevron, USA, Inc* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837, 863 (1984) (indicating that to engage in informed rulemaking, the agency must consider varying interpretations and the wisdom of its policy on a continuing basis and establish a reasonable choice); *United States* v. *Nat'l Ass'n of Sec. Dealers, Inc.,* 422 U.S. 694, 719 (1975) (longstanding interpretations by an agency are entitled to considerable weight but are not controlling).

[297] *See* Inadmissibility on Public Charge Grounds, 53 FR 51114, 51164 (proposed Oct. 10, 2018).

[298] *See* Inadmissibility on Public Charge Grounds, 53 FR 51114, 51164 (proposed Oct. 10, 2018).

[299] *See* Inadmissibility on Public Charge Grounds, 53 FR 51114, 51164 (proposed Oct. 10, 2018).

[300] *See* Inadmissibility on Public Charge Grounds, 53 FR 51114, 51164 (proposed Oct. 10, 2018).

[301] *See United States* v. *Mead Corp.,* 533 U.S. 218, 227 (2001) (well-reasoned views of the agency implementing a statute enjoys considerable weight); *see also Chevron, U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837, 866 (1984) (judges have a duty to respect legitimate policy justices and resolving the struggle between competing views of the public interest are not judicial responsibilities—they are vested in the political branches).

[302] *NLRB* v. *SW General, Inc.,* 137 S. Ct. 929, 943 (2017) (''[F]loor statements by individual legislators rank among the least illuminating forms of legislative history.'').

[303] *See Matter of Vindman,* 16 I&N Dec. 131 (Reg'l Comm'r 1977); *Matter of Harutunian,* 14 I&N Dec. 583 (Reg'l Comm'r 1974).

[304] The commenter also suggested the age of the decisions. DHS notes that the age of a precedent decision does not invalidate the precedential effect of the decision. Indeed, the Supreme Court has cited the age of a precedent as a reason to maintain it. *See Montejo* v. *Louisiana,* 556 U.S. 778, 792–93 (2009) (citing ''the antiquity of the precedent'' as a factor against overturning a decision).

[305] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157(proposed Oct. 10, 2018).

[306] *See Matter of Harutunian,* 14 I&N Dec. 583, 586 (Reg'l Comm'r 1974) (''The words 'public charge' had their ordinary meaning, that is to say, a money charge upon or an expense to the public for support and care, the alien being destitute''); *Matter of Vindmam,* 16 I&N Dec. at 132 (Congress intends that an applicant be excluded who is without sufficient funds to support himself, who has no one under any obligation to support him, and whose changes of becoming self-supporting decreases as time passes).

law such as *Howe* v. *United States ex rel. Savitsky,* 247 F. 292, 294 (2d Cir. 1917), and *Ex Parte Hosaye Sakaguchi,* 277 F. 913, 916 (9th Cir. 1922), which rejected a broad definition of the term public charge, tying it instead to a person's likelihood of becoming an occupant of almshouses for want of means of support. This commenter indicated that DHS's historical argument—that the late 19th century history and meaning are irrelevant because the wide array of limited-purpose public benefits now available did not exist at the time—was historically inaccurate. The commenter noted that contemporaneous sources and historical studies reveal that throughout the 19th century's governments, including the Federal Government, provided limited public assistance short of institutionalization. Additionally, the commenter indicated that even if limited-purpose public benefits had not been available, the argument is immaterial because such an expansion would not change the meaning of the term set out in the 1882 Act. In fact, according to the commenter, Congress has declined to change its original meaning of the term.[307]

Response: DHS is aware of the decisions in *Howe* and *Sakaguchi,* but DHS does not believe that these cases are inconsistent with the public charge definition set forth in this rule or with the suggested link between public charge and the receipt of public benefits. In fact, the cases support DHS's belief that courts generally have neither quantified the level of public support nor the type of public support required for purposes of a public charge inadmissibility finding. In *Howe,* the court reviewed whether the immigration inspector rightly attempted to classify the alien as a public charge because the immigration inspector believed the applicant to have engaged in a criminal matter but lacked the requisite evidence to charge the alien.[308] The court rejected such a broad use of the public charge provision, which would have rendered several other inadmissibility grounds unnecessary.[309] Instead, the court emphasized that, in the context of public charge provision and its position within the statute, as it appeared at that time, Congress meant to exclude individuals who are likely to become occupants of government-run almshouses from the United States [310] for want of means to support themselves in the future.[311] The court did note that ''[i]f the words covered jails, hospitals, and insane asylums, several of the other categories of exclusion would seem to be unnecessary.'' [312] But other courts have ruled differently,[313] the surrounding grounds of inadmissibility have been amended many times since, and the fact that two INA provisions that may cover the same conduct does not make either unnecessary.[314] Likewise, DHS does not believe that the current public charge inadmissibility provision is limited to almshouses and its modern equivalents. Later decisions have considered other benefits such as old age assistance.[315]

Skaguchi,[316] a case in which the court based its holding in part on *Howe,*[317] is

[307] In support of the commenter's arguments, the commenter cited *Forest Grove Sch. Dist.* v. *T.A.,* 557 U.S. 230, 239–40 (2009); *Feltner* v. *Columbia Pictures Television, Inc.,* 523 U.S. 340, 358 (1998) (Scalia, J., concurring).

[308] *See Howe* v. *United States ex rel. Savitsky,* 247 F. 292, 294 (2d Cir. 1917). In *Howe,* the alien had been engaged in a contractual dispute in his home country on account of writing a bad check, which the immigration inspector regarded as a dishonest practice. Because the immigration inspector lacked the requisite proof to exclude the applicant on criminal grounds, however, the inspector attempted to deny entry on public charge grounds of inadmissibility under section 2 of the Immigration Act of 1907 (36 Stat 264).

[309] *Howe,* 247 F. at 294 (''Indeed, with such latitudinarian construction of the provision 'likely to become a public charge,' most of the other specific grounds of exclusion could have been dispensed with . . . We are convinced that Congress meant the act to exclude persons who were likely to become occupants of almshouses for want of means with which to support themselves in the future. If the words covered jails, hospitals, and insane asylums, several of the other categories of exclusion would seem to be unnecessary.'')

[310] DHS reviewed a variety of sources to identify a clear definition of the term ''almshouse,'' as it might relate to an interpretation of the term public charge. The Second Circuit, in *Howe,* did not further elaborate on the meaning of the term almshouse or the threshold level of support for purposes of determining whether an alien was likely to become a public charge. Almshouses have also been discussed in contexts other than public charge. For example, for purposes of claiming tax exemption, New York State courts emphasized that an almshouse only qualified for tax exemptions if it offered services free of charge; almshouses which offered services at a reduced charge, for example, did not qualify as almshouses for tax purposes. *See, e.g., In re Vanderbilt's Estate,* 10 N.Y.S. 239, 242 (Sur. 1890) (''The New York Protestant Episcopal City Mission Society claims exemption as an almshouse. It maintains a home and reading-rooms, etc., and provides lodgings and meals free. It also maintains a day nursery, for which it makes a small charge. This takes it out of the domain of pure charity,—a house wholly appropriated to the poor. I have already decided in several cases that a society, to be exempt from this tax as an almshouse, must be absolutely free,—all benefits given gratuitously.'') In *City of Taunton* v. *Talbot,* an almshouse attempted to recover the cost from one of its inmates. 186 Mass 341 (1904). The court denied relief because there were no records to tie the expenses specifically to the inmate, in particular because the agreement between the inmate and the almshouse included support in exchange for the inmate's work. *See id.* at 343. DHS is aware that INS used references to the term ''almshouse'' in its 1999 proposed regulation and in the 1999 Interim Field Guidance to explain, among other things, its primarily dependent model for purposes of public charge. *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51163 (proposed Oct. 10, 2018); *see also* Inadmissibility and Deportability on Public Charge Grounds, 64 FR 28676 (proposed May 26, 1999) and Field Guidance on Deportability and Inadmissibility on Public Charge Grounds, 64 FR 28689 (May 26, 1999). As explained in the NPRM, however, neither INS's reasoning nor any evidence provided, forecloses the agency adopting a different definition consistent with statutory authority. *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51133 (proposed Oct. 10, 2018).

[311] *Howe,* 247 F. at 294 (interpreting the public charge provision under Act of 1907); *see also Ex parte Mitchell,* 256 F. 229, 230 (N.D.N.Y. 1919) (explaining, in addressing the public charge provision of 1917, that ''I am unable to see that this change of location of these words in the act changes the meaning that is to be given them. A 'person likely to become a public charge' is one who for some cause or reason appears to be about to become a charge on the public, one who is to be supported at public expense, by reason of poverty, insanity and poverty, disease and poverty, idiocy and poverty, or, it might be, by reason of having committed a crime which, on conviction, would be followed by imprisonment. It would seem there should be something indicating the person is liable to become, or shows probability of her becoming, a public charge.''

[312] *See Howe,* 247 F. at 294.

[313] *See generally* Leo M. Alpert, *The Alien and the Public Charge Clauses,* 49 Yale L.J. 18, 20–22 (1939) (discussing disagreements with part of the of the *Howe* decision). To be clear, DHS is not taking the position that some of the cases cited in the Alpert article did that someone who is incarcerated is likely to become a public charge based on penal incarnation.

[314] *See Kawashima* v. *Holder,* 565 U.S. 478, (2012) (holding that the aggravated felony provision for fraud or deceit includes tax offenses even though there is a separate aggravated felony provision concerns tax crimes).

[315] *See, e.g., Matter of Harutunian,* 14 I&N Dec. 583 (Reg'l Comm'r 1974).

[316] *See Ex parte Hosaye Skaguchi,* 277 F. 913 (9th Cir. 1922).

[317] The court in *Howe* cited to *Gegiow* v. *Uhl,* 239 U.S. 3 (1915), and *Ex Parte Mitchell,* 256 F. 229 (N.D. NY 1919), both cases that confirmed that a finding of public charge must be based on a defect of a nature that affects an individual's ability to earn a living and cannot be predicated on some external reason such as an overstocked labor market, *see Gegiow,* 239 U.S. at 10, and other speculative and remote conjectures that are unrelated to an alien's defect or other fact that shows or tends to show that the alien is unlikely to earn a living and therefore likely to become a public charge. In *Gegiow,* the Secretary of Labor deemed a group of illiterate aliens who lacked English language proficiency inadmissible as likely to become a public charge, because they had little money on hand, had no sponsor, and intended to travel to a city with a weak labor market. The Court wrote that on the record before it, ''the only ground for the order was the state of the labor market at Portland at that time; the amount of money possessed and ignorance of our language being thrown in only as makeweights.'' *Gegiow,* 239 U.S. at 9. The Court then interpreted the term public charge as similar in kind to the surrounding terms in the governing statute (which included terms such as pauper and beggar). The Court reasoned that because such surrounded terms related to permanent personal characteristics of the alien rather than the alien's destination, the Secretary of Labor could not consider conditions in the aliens' destination city as part of the public charge determination. The Court's characterization of the role of the aliens' assets and resources, as well as language proficiency, is *dicta* and has in any case

not inconsistent with DHS's proposed definition of public charge. As was the case in *Howe,* the court in *Skaguchi* rejected the use of the public charge ground of inadmissibility as a ''catch-all'' form of inadmissibility.[318] The court reiterated that to sustain a public charge inadmissibility finding, there must be evidence of a fact that tends to show that the burden of supporting the alien is likely to be cast upon the public.[319] Therefore, DHS rejects the commenter's suggestion that these cases mandate a result other than the DHS's public charge definition and the level of dependency assigned to it in the NPRM.

DHS agrees that it is immaterial to this rulemaking whether limited-purpose means-tested benefit programs expanded over the course of the last century-plus. DHS simply recited, without endorsing, INS reasoning for the primarily dependent standard in the NPRM, in an effort to explain the primarily dependent standard's limitations and why DHS proposed a different standard in this rule.[320] DHS's reasoning for changing the public charge definition is not based on this statement.

Comment: Some commenters indicated that the proposed rule was at odds with the recommendations of the very agencies that administer the federal programs included in the rule. The commenters also pointed out that, as indicated by DHS in the NPRM, INS had consulted with HHS, the Social Security Administration (SSA), and the Department of Agriculture (USDA) when developing the 1999 Interim Guidance and that these agencies had told INS unequivocally ''that the best evidence of whether an individual is relying primarily on the government for subsistence is either the receipt of public cash benefits for income maintenance purposes or institutionalization for long-term care at government expense'' and that ''neither the receipt of food stamps nor nutrition assistance provided under [SNAP] should be considered in making a public charge determination.'' Commenters indicated that in the NPRM, DHS ''dismissed all of this expertise, stating *ipse dixit* that such input from the federal agencies that actually administer these programs 'd[oes] not foreclose [the Department] adopting a different definition consistent with statutory authority.' '' The commenter believed that this response was legally insufficient because it confused DHS's ability to take action under a statute with its independent obligation to adopt an approach based on sound reasoning. The commenter stated that merely asserting that DHS has the ability to reject other agencies' reasoned analyses (whether or not correct) does nothing to justify its choice to do so. The commenter concluded, therefore that DHS's response—like DHS's overall decision—failed to satisfy the APA's requirements.

Response: As explained in the NPRM,[321] DHS is aware that former INS consulted with various agencies that administer the federal programs. The letters were issued in the context of the approach taken in the 1999 proposed rule and 1999 Interim Field Guidance, and specifically opined on the reasonableness of that INS interpretation, that is, the primarily dependent on the government for subsistence definition. As noted in the NPRM, DHS does not believe that these letters supporting the interpretation set forth in the 1999 Interim Field Guidance foreclose this different interpretation, particularly where DHS's reasoning for the approach in this final rule is grounded in a different basis.

Comment: Some commenters objected to what they describe as the ''per se'' nature of the rule. Specifically, commenters expressed concerns that immigrants receiving any amount of public benefits would be deemed a public charge. An individual commenter said the rule would implicitly classify more than a fifth of Americans as a public charge.

Response: DHS disagrees with the commenters' characterization that the definition of public charge creates an inappropriate per se rule. DHS believes that the nexus between likelihood of becoming public charge at any time in the future, the receipt of public benefits, and self-sufficiency, as described and explained in the NPRM,[322] is consistent with Congress' intent [323] in enacting the public charge inadmissibility ground. DHS also believes it is consistent with the premise underlying much of the public charge case law analyzing the public charge inadmissibility ground [324] that aliens who enter this country should be self-sufficient and not reliant on the government. As explained in the NPRM and detailed above, despite the lack of a definition in the statute and minimal case law defining public charge, there has always been a link between the receipt of public benefits and the public charge determination.[325] Absent a clear statutory definition, courts and administrative authorities have generally tied the concept of public charge to the receipt of public benefits without quantifying the level, type or duration of the public benefits received.[326] To create an administrable way to implement the statute, DHS's NPRM provided a list of specific benefits and a threshold amount that DHS believed reasonably balances an alien's lack of self-sufficiency against temporary welfare assistance that does not amount to a lack of self-sufficiency.[327] Additionally, by proposing to codify the totality of the circumstances approach to the prospective inadmissibility determination, DHS clarified that an alien's past receipt of public benefits

been superseded by multiple revisions to the public charge statute, including a revision in 1996 that specifically called for analysis of the alien's assets, resources, and skills.

[318] *See Ex parte Hosaye Skaguchi,* 277 F. 913 (9th Cir. 1922).

[319] *See Ex parte Hosaye Skaguchi,* 277 F. 913, 916 (9th Cir. 1922).

[320] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51163 (proposed Oct. 10, 2018).

[321] *See Inadmissibility on Public Charge Grounds,* 83 FR 51114, 51133 (proposed Oct. 10, 2018).

[322] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157–58 (proposed Oct. 10, 2018).

[323] As outlined in the NPRM, legislative history suggests the link between public charge and the receipt of public benefits. For example, in the 1950 Senate Judiciary Committee report, preceding the passage of the 1952 Act, concerns were raised about aliens receiving old age assistance. *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157 (proposed Oct. 10, 2018). Debates on public charge prior to Congress' passage of IIRIRA in 1996 also highlighted that an immigrant should be relying on his or her own resources, rather than becoming a burden on the taxpayers. *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157 (proposed Oct. 10, 2018). With the passage of PRWORA, Congress explicitly emphasized that self-sufficiency is a fundamental principle of the United States immigration law and connected receipt of public benefits with a lack of self-sufficiency, further stating that aliens within the Nation's borders should not depend on public resources to meet their needs. *See* 8 U.S.C. 1601(1) and (2). Courts likewise have connected public charge determinations to the receipt or the need for public resources *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157–58 (Oct. 10, 2018).

[324] *See, for example, Matter of Vindman,* 16 I&N Dec. 131 (Reg'l Comm'r, 1977) (concluding that Congress intends that an applicant for a visa be excluded who is without sufficient funds to support himself or herself, or who has no one under any obligation to support him, and whose chances of becoming self-supporting decreases as time passes, and that the respondents' receipt of assistance for approximately three years clearly put them into the confines of the public charge inadmissibility ground); *see also Matter of Harutunian,* 14 I&N Dec. 583 (Reg'l Comm'r 1974) (The words ''public charge'' had their ordinary meaning, that is to say, a money charge upon or an expense to the public for support and care, the alien being destitute); *see* generally cases cited in Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157–58 (proposed Oct. 10, 2018).

[325] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157–51158 (proposed Oct. 10, 2018).

[326] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51157–51158 (proposed Oct. 10, 2018).

[327] *See* 8 CFR 212.21(b).

alone, without consideration of the other factors, would not establish future likelihood of becoming a public charge. DHS further agrees with the commenters that under this new framework, the number of aliens being found inadmissible based on the public charge ground will likely increase.

Comment: Commenters objected to the proposed rule because it equates receipt of benefits with the lack of self-sufficiency. Others stated that the receipt of public benefits is not an indicator of a person's incapacity for self-sufficiency, but helps individuals to become self-sufficient. Many commenters expressed concern with the expansion of the public charge definition to include not just those primarily depending on cash benefits, but also individuals who use basic needs programs to supplement their earnings or need short-term help. Some commenters stated that immigrant women already face a heightened risk of economic insecurity, discrimination, and disproportionate responsibility for caregiving, and that participating in benefit programs is important to their ability to support themselves and their children. A commenter stated that many open jobs require specific training that can be provided through community colleges, and in order to obtain the education to become a contributing member of society, some immigrants draw on public benefits for a short period of time to enable them to complete their studies.

Response: DHS understands that individuals, including immigrant women and their families, as well as students, may supplement their income with public benefits, such as basic needs programs, because they may require short-term help, and that the goal of these benefits assists them to become self-sufficient in the short- and, eventually long-term. DHS also acknowledges that certain individuals who are depending on public benefits may choose to disenroll because of this rulemaking. However, the goals of public benefits programs and the public charge ground of inadmissibility are not the same. The public charge inadmissibility provision is not intended to ensure that aliens *can become* self-sufficient; in fact, Congress specifically articulated policy goals in PRWORA that provided that government welfare programs should not be an incentive for aliens to immigrate to the United States and that aliens inside the United States are expected to *be* self-sufficient. Correspondingly, DHS's assessment of whether an alien is likely at any time to become a public charge is not the same as an assessment whether, at some separate point in the future, an alien who is likely to become a public charge will later become self-sufficient. With this rulemaking, DHS is implementing the public charge ground of inadmissibility and seeking to better ensure that those who are seeking admission to the United States and adjustment of status, as well as those seeking extension of stay or change of status, are self-sufficient, so that they do not need public benefits to become self-sufficient.

Comment: Some commenters provided input on the temporary nature of public benefits as they relate to future self-sufficiency. Commenters expressed a belief the rule's core assumption was that people dependent on the Government for subsistence will remain that way indefinitely.

Response: DHS disagrees that the rule inherently assumes that people who rely in the government for assistance rather than relying on their own capabilities and the resources of their families, sponsors, and private organizations will remain that way indefinitely. As noted above, neither section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), nor this final rule, assess whether an alien subject to the public charge ground of inadmissibility will remain a public charge indefinitely. Rather, the statute and the rule assess whether an alien is likely at any time in the future to become a public charge. An alien may be likely in the future to become a public charge in the future without remaining a public charge indefinitely. For example, a person could receive Medicaid for a number of years and then obtain employment that provides health insurance, avoiding the further need for Medicaid.

Comment: A commenter stated that changing the standard from ''primarily dependent'' upon cash assistance to ''likely at any time in the future to receive one or more public benefits'' will cause an individual to risk his or her immigration status when enrolling in specific programs. The commenter stated that this is problematic in part because aliens enroll in such programs consistent with government policy, and sometimes with the Government's encouragement. Another commenter stated that the INA includes the phrase ''likely to become a public charge'' but the proposed rule ''defines 'public' and 'charge' as separate words, disconnected from each other or from the fact that the phrase also requires a likelihood that the person 'become' a public charge, as opposed to a likelihood that he or she will engage in a specific act.'' The commenter indicated that the proposed approach to ''likely at any time to become a public charge'' departs from the plain meaning of the phrase, ''likely to become a public charge'' in the INA, unnecessarily discarding long-standing and well-developed fairness; relies on an inaccurate measure to predict whether an individual is likely to become a public charge; will eviscerate the totality of circumstances standard; is inefficient; not cost effective; and negatively impacts applicants, the agency, and the economy.[328] The commenter also questioned the focus on public benefits, indicating the case law was based on being ''dependent on support'' rather than focused on the likelihood of receiving a benefit that costs the government some amount of money. The commenter said changing the standard will deter immigrants from pursuing expensive adjustment of status applications if they fear they will be denied, thus forfeiting the corresponding employment authorization that permits access to better-paying jobs unavailable to unauthorized workers. The commenter concluded that such a result thwarts the purported self-sufficiency goals of the proposed rule.

Response: DHS disagrees with the commenters' assessment. As outlined in the NPRM, the approach suggested by INS in the 1999 NPRM and the 1999 Interim Field Guidance does not preclude DHS from suggesting a different approach. As DHS laid out in the NPRM, DHS's interpretation is consistent with the statutory wording which requires a public charge assessment that is prospective in nature, and made at the time of the application for a visa, admission, or adjustment of status.'' [329] DHS understands that certain individuals present in the United States may be impacted by this rule, and therefore hesitant to apply for adjustment of status. However, given the limited number of aliens present in the United States eligible for public benefits under PRWORA, DHS does not believe that the impact is as extensive as alleged by the commenters. Finally, as explained in the NPRM, the receipt of public benefits does not automatically render an alien inadmissible based on public charge; the determination is always based on the totality of the alien's circumstances.

[328] The commenter also indicates that the approach is inefficient, not cost effective, and negatively impact applicants, the agency and the economy.

[329] DHS notes the statutory wording includes the wording ''at any time''—the commenter omitted the language when asserting that the interpretation is not consistent with the plain wording of the statute.

Comment: Several commenters provided feedback on the comparison between public benefits used by non-citizens and native-born residents. A commenter stated that a study concluded that non-citizen households have much higher use of food programs, Medicaid and cash programs compared to households headed by native-born citizens and therefore, a reform of the public charge doctrine is needed. Other commenters stated, providing statistics in support, that immigrants access benefits for which they are eligible at a far lower rate than native-born residents, suggesting that access to public benefits does not make immigrants more of a public charge than native-born residents.

A commenter stated that if the public charge rule were applied to native born citizens, it would exclude one in three U.S. born citizens, whereas the current rule would exclude one in twenty. Similarly, another commenter indicated that the definition would mean that most native-born, working-class U.S. citizens are or have been public charges and that substantial numbers of middle-class Americans are or have been public charges. A commenter stated that according to the MPI's recent analysis, about 69 percent of recent lawful permanent residents have at least one factor that would count against them under the new rule, as opposed to just three percent of noncitizens who make use of cash benefits under the existing standard.

Response: The proposed rule's analysis of public benefits receipt among citizens and noncitizens was meant to inform public understanding of the proposal. DHS need not resolve competing claims regarding the rates of public benefits use by various populations, because the primary basis for the NPRM is a revised interpretation of the term public charge, as informed by the statement of congressional policy in PRWORA. The proposal did not rest on a specific level of public benefits use by particular categories of individuals or households.

DHS notes, however, that the analysis in the NPRM included only a limited number of programs, and did not assume that eligibility for public benefits necessarily meant enrollment. Furthermore, the analysis concerned use by individuals and not households.

Additionally, this rulemaking does not apply to U.S. citizens. Even though some U.S. citizens would fall under the receipt threshold in the public charge definition, this fact is not relevant for the purposes of this rule, as the public charge ground of inadmissibility applies to aliens who are seeking a visa, admission, or adjustment of status, not U.S. citizens. The purpose of this rule is to better ensure that aliens who enter the United States or remain in the United States are self-sufficient.

Statistics on the use of public benefits by non-citizens compared to the use of citizens are not indicative of an individual alien's self-sufficiency. Even though the use of public benefits by noncitizens may be lower than the native-born population for a given benefit, an alien may still qualify and receive public benefits in the future based on his or her particular circumstances and therefore may be likely to become a public charge. Similarly, it is immaterial whether the definition of ''public charge'' in the rule would affect one in twenty U.S. citizens or one in three. The relevant question is whether the rule's definition of public charge is consistent with the statute. DHS believes that it is consistent with the statute.

Comment: Commenters stated that immigrants use public benefits to escape the poverty cycle, using benefits as a ladder to prevent them from becoming public charges. Other commenters stated that the rule is self-defeating, because although DHS prefers self-sufficient families and individuals, the proposed rule dissuades individuals from using public benefits in order to become self-sufficient and thus enhances financial barriers. Many commenters said that those eligible for benefits are entitled to avail themselves of government benefits and should be able to do so without shame or guilt. Commenters stated that when eligible individuals receive such benefits, the outcomes are frequently better for the United States and the economy. Several commenters stated that the United States has always been open to those who needed assistance, and given that that this country was founded on a nation of immigrants, a commenter indicated that it was the Government's responsibility to create policies that reflect the values of equal opportunity and humanitarian support. Another commenter indicated that even under existing policy, the United States has always integrated immigrants sufficiently, such that they become self-sufficient and contributing members of U.S. society.

Response: With this public charge inadmissibility rule, DHS neither seeks to stigmatize receipt of public benefits nor seeks to preclude an individual from seeking public benefits. DHS appreciates the input on the effect of public benefits payments and the role these benefits play in becoming self-sufficient, and on the economy as a whole. DHS does not dispute these positive impacts of public benefits on an individual's long-term self-sufficiency, or the importance of these programs and their goals, including the integration of immigrants. DHS also does not dispute that benefits programs may produce more equal opportunities and provide humanitarian support, and does not intend to in any way diminish these opportunities. DHS, however, is implementing the congressional mandate to assess a prospective immigrant's likelihood of becoming a public charge in the future based on the criteria that Congress put into place. As previously indicated, the INA does not aim to achieve the same goals as public assistance programs; in fact, Congress specifically articulated policy goals in PRWORA that provided that government welfare programs should not be an incentive for immigrants and that immigrants are expected to be self-sufficient. Correspondingly, DHS's assessment of whether an alien is likely to become a public charge is not the same as an assessment of whether an alien is currently a public charge or whether, at some separate point in the future, an alien who is likely to become a public charge will later become self-sufficient.

Comment: Some commenters emphasized not just the self-sufficiency of the immigrants that use public benefits or programs, but their contributions to society as a whole. A few commenters stated that providing support to families is a necessary facet of our economic system and recipients provide more to communities than the aid they receive. A commenter stated that a study in Arizona found that immigrants generate $2.4 billion in tax revenue, which is more than the $1.4 billion in benefits they used. A few commenters stated that broadening the definition of public charge ignores the work, taxes, and other contributions immigrants are making to their communities, and makes a ''false, negative comparison between immigrants' drain on public resources compared to other Americans' use.'' A few commenters said a ''public charge'' is not a person who uses government services that are funded via taxes which immigrants are expected to pay throughout their lifetime. Commenters also indicated that tying public benefits to the public charge definition is not appropriate as the foreign national is working, paying taxes, and contributing to the welfare of the United States and is entitled to public benefits.

Response: DHS appreciates the commenters' input. DHS did not, however, make any changes to the

public charge definition based on these comments. DHS recognizes the contributions foreign nationals have made to American society as a whole and to their communities. However, with this rulemaking, DHS seeks to better enforce the grounds of inadmissibility to ensure that those seeking admission to the United States are self-sufficient, *i.e.,* rely on their own capabilities and the resources of their family, sponsors, and private organizations.

Finally, DHS disagrees with the commenters who stated that tying public benefits to the public charge definition is not appropriate for aliens who are working, paying taxes, and contributing to the welfare of the United States and entitled to public benefits. Simply because an alien is working, paying taxes and contributing to the welfare of the United States does not guarantee an alien's self-sufficiency now or in the future.

Again, an individual may provide significant benefits to their communities, including to the tax base, but nonetheless be a public charge. With this rulemaking, DHS seeks to ensure that those coming to the United States are self-sufficient and not dependent on the government for subsistence now or in the future, even if they are currently contributing to the tax base. Furthermore, the public charge assessment is an assessment based on the individual's facts and circumstances; the greater the taxable income and other resources, the more likely an individual is self-sufficient, and the less likely he or she is to become a public charge. DHS encourages all applicants to bring forward any factors and circumstances they believe are relevant to their adjudication of public charge.

Comment: A commenter suggested that DHS more clearly separate the definition of public charge from the predictive process by moving any predictive language, along with any thresholds based on predictive value, from the definitions in 8 CFR 212 and 214 to a separate section listing factors to be considered as part of the public charge inadmissibility determination. The commenter stated that this would provide a clear separation between the question of what is a public charge, and whether a person is likely to become a public charge.

Response: With respect to the commenter's suggestion to more clearly distinguish between the definition of ''public charge'' and the prospective public charge inadmissibility determination, DHS notes that as proposed, and as codified in this final rule, DHS has a separate definition for public charge and public benefits. In this final rule, DHS has also provided a more detailed definition for ''likely at any time to become a public charge.'' [330] DHS believes that the framework and separate definitions provided with this final rule sufficiently permit its officers to make sound and reasonable public charge inadmissibility determinations, as intended by Congress.

Comment: A commenter stated that DHS's statutory interpretation of ''public charge'' is flawed. The commenter noted that in the proposed rule DHS stated that its proposed definition of public charge was consistent with various dictionary definitions of public charge, including the current edition of the Merriam-Webster Dictionary, which defines public charge simply as ''one that is supported at public expense.'' [331] The commenter stated that DHS's interpretation is flawed, because DHS failed to define the term ''support.'' The commenter stated that ''looking to the Merriam-Webster Dictionary, which is the dictionary favored by the Supreme Court, 'support' is defined as 'pay[ing] the cost of' or 'provid[ing] a basis for the existence or subsistence of.'" [332] The commenter further stated that, in turn, ''one who is 'supported at the public expense' must be having needs met entirely or at least nearly entirely by the government.'' Therefore, the commenter concluded, DHS failed to provide a justification for how DHS's proposal with its low thresholds for benefit use comports with that definition. Another commenter cited to various dictionary definitions of ''charge'' to support the proposition that the term ''public charge'' means a person with a very high level of dependence on the government. For instance, the commenter cited the 1828 edition of Webster's Dictionary, which defined ''charge'' as ''The person or thing committed to another's [sic] custody, care or management; a trust.'' [333]

A commenter also stated that DHS's proposed statutory interpretation is at odds with how DHS justified the proposed thresholds for public benefits use. The commenter explained in defining ''public charge,'' DHS wrote that an individual ''who receives public benefits for a substantial component of their support and care can be reasonably viewed as being a public charge.'' [334] But in justifying the thresholds, DHS wrote that it ''believes that receipt of such benefits, even in a relatively small amount or for a relatively short duration would in many cases be sufficient to render a person a public charge.'' [335] Another commenter stated that some households may be self-sufficient and capable of meeting their basic needs without public benefits, but nonetheless enroll in such benefits to supplement available resources.

Response: DHS disagrees with the commenter that Merriam-Webster's definition of ''support'' compels DHS to abandon the policy proposed in the NPRM.[336] The commenter is correct that some of Merriam-Webster's definitions of ''support'' reference paying the costs of another, or providing a basis for the existence or subsistence of another. Other definitions of ''support'' in the same dictionary do not specify a degree of assistance (for instance, Merriam-Webster's also defines support as ''assist, help'').[337]

But, the public benefits designated under this rule are specifically designed for the Government to pay the costs of the beneficiary with respect to basic necessities, *i.e.,* to provide a basis for the beneficiary's subsistence. This is the case with respect to cash benefits for income maintenance, Medicaid, SNAP, and all other designated benefits. DHS believes that its rule is consistent with all of the aforementioned definitions of ''support'' and especially with the definition of ''public charge'' as ''one that is supported at public expense.'' [338] And for substantially the same reasons, DHS believes that its rule is broadly consistent with the 1828 Webster's Dictionary definition of the term ''charge,'' as well. For instance, the definition cited by the commenter provides an example of appropriate usage: ''Thus the people of a parish are

[330] *See generally* 8 CFR 212.21.

[331] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51158 (proposed Oct. 10, 2018).

[332] Merriam-Webster, definition of ''support,'' available at *https://www.merriam-webster.com/dictionary/supported* (last visited July 26, 2019).

[333] Webster's Dictionary 1828 Online Edition, definition of ''charge,'' available at *http://websterdictionary1828.com/Dictionary/charge* (last visited July 26, 2019).

[334] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51158 (proposed Oct. 10, 2018).

[335] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51164 (proposed Oct. 10, 2018).

[336] In particular, DHS also disagrees with the commenter who indicated that DHS's citing to the 1990 edition of Black's Law Dictionary inappropriate because PRWORA redefined the term public charge. As explained throughout the NPRM and this final rule, PRWORA restricted access for aliens to certain benefits but did not define public benefits.

[337] *See* Merriam-Webster Online Dictionary, Definition of Support, *https://www.merriam-webster.com/dictionary/support* (last visited July 26, 2019).

[338] Merriam-Webster Online Dictionary, Definition of Public Charge, *https://www.merriamwebster.com/dictionary/public%20charge* (last visited July 8, 2019).

called the ministers [sic] charge.'' Just as a parishioner can be a ''charge'' of minister without being entrusted entirely to their care, a person can be a ''charge'' of the public if he or she relies on public benefits to meet basic needs.

Regardless, DHS does not believe that isolated definitions of ''support'' or the word ''charge'' standing alone conclusively determine the possible range of definitions for the term, public charge; neither term standing alone is used in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and neither term, standing alone, is used in the definition of ''public charge'' or ''public benefit'' in this rule. DHS disagrees with the comment that the reference to ''substantial component'' [339] makes the statutory interpretation in the NPRM inconsistent with the justification which references a ''relatively small amount.'' [340] The reference to ''substantial component'' was part of a summary of dictionary definitions and not the basis for the definition of public charge.[341] Nonetheless, as discussed elsewhere in this rule, DHS has revised 8 CFR 212.22 to limit public charge determinations to benefits received for 12 months in a 36-month period and is not considering the value of the amount of benefits received. Finally, DHS rejects the contention that an alien is not a public charge if the alien does not ''need'' the designated benefits that he or she or receives. DHS's view is that an alien, who receives designated benefits under this rule for the specific duration, is a public charge, whether he or she needs those benefits or not.

Comment: A commenter stated that DHS should not have cited to the 1990 Black's Law Dictionary's definition of ''public charge,'' because the edition is out of date and was written pre-PRWORA.

Response: In its NPRM, DHS was attempting to provide a historical review of the term public charge as defined in various reference materials. The 1990 edition would have preceded the IIRIRA amendments by only six years.

Comment: A commenter stated that DHS's recognition that active-duty U.S. servicemembers would qualify as ''public charges'' under the plain terms of the proposed rule is proof positive that the proposal is bad policy. The commenter stated that the exclusion of public benefits received by servicemembers and their families confirms that the DHS has set the threshold for ''self-sufficiency''—or ''public charge''—in an unreasonable way and too high. The commenter stated that in setting the salary levels for members of the U.S. military, Congress has determined that the salary levels are sufficient to render our servicemembers ''self-sufficient,'' and therefore the rule conflicts with this determination. The commenter further stated that employment as an active-duty member of the U.S. military has long been viewed as an honorable, stable job that provides a gateway for all individuals in this country—regardless of race, economic background, social class, or other forms of difference—to succeed in life. The commenter stated that the answer is not to exempt active-duty servicemembers from the ''public charge'' regulation, but to embrace a reasonable definition of ''public charge'' so that active-duty servicemembers are not rendered ''public charges.''

Response: Contrary to the commenter's arguments, to the best of DHS's knowledge there is no indication that Congress considered the public charge ground of inadmissibility when it created the military compensation structure, or that the levels of pay afforded to active duty servicemembers are always adequate to ensure that servicemembers and their families will be self-sufficient for purposes of our immigration laws. In the NPRM, DHS recognized that as a consequence of the unique compensation and tax structure afforded by Congress to aliens enlisting for military service, some active duty alien servicemembers, as well as their spouses and children, as defined in section 101(b) of the Act, 8 U.S.C. 1101(b), may rely on SNAP and other listed public benefits.[342] DHS included a provision for these individuals, as reflected in the proposed rule and as discussed later in this preamble.

a. Threshold Standard

''*Primarily dependent*'' *Based on Cash Public Benefit Receipt or Long-Term Institutionalization at Government Expense*''

Comment: Commenters indicated that DHS, through regulation, cannot institute a definition that Congress had already squarely rejected. The commenters noted that Congress, as part of IIRIRA debates, had rejected a proposal that would have defined a public charge as a person who receives means-tested public benefits. The commenters indicated that Congress' rejection of the proposed definitions of public charge and means-tested public benefit meant that Congress retained the longstanding meaning of public charge as being primarily dependent on the government for subsistence.[343]

A commenter questioned DHS's assertion that the proposed definition of public charge reflects Congress's intent to have aliens be self-sufficient and not reliant on the government for assistance. The commenter indicated that the INA does not mention self-sufficiency and does not list it as a criterion for avoiding a finding of inadmissibility under public charge. Several commenters stated that the rule would drastically increase the scope of who would be considered a public charge to include people who use a much wider range of benefits and not just those who are primarily dependent on the government for subsistence. A few commenters stated that the proposed rule's definition of public charge would equate occasional or temporary use of benefits and services with primary reliance on benefits. A commenter agreed with the current standard, in that it does not penalize individuals from accepting all of the forms of support encompassed within this rule. A commenter, in considering only primary dependence on public benefits as the degree of dependency required to sustain a public charge finding, stated that the standard provides clear and effective guidelines for adjudicators and applicants without endangering the lives of immigrant families and children in this country.

Response: As noted above, although the INA does not mention self-sufficiency in the context of section

[339] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51158 (proposed Oct. 10, 2018).

[340] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51164 (proposed Oct. 10, 2018).

[341] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51158 (proposed Oct. 10, 2018).

[342] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51173 (proposed Oct. 10, 2018).

[343] The commenter indicated that during the debates leading up to IIRIRA, Congress stripped the bill of a provision defining public charge as a noncitizen who uses ''means-tested, public benefits,'' meaning ''any public benefit (including cash, medical, housing, food, and social services) . . . in which eligibility of an individual, household, or family eligibility unit for such benefit or the amount of such benefit, or both are determined on the basis of income, resources, or financial need of the individual household, or unit.'' *See* H.R. Rep. No. 104–208, at 144 (Sept. 24, 1996) (sec. 551 of H.R. 2202, proposing 8 U.S.C. 1183a(e)(defining ''means-tested public benefit''); *see* id. at 138 (sec. 532 of H.R. 2202, proposing 8 U.S.C. 1251(a)(5)(C)(99), (D) (defining term ''public charge'' [to] include[] any alien who receives . . . means-tested public benefits'); H.R. Rep. No. 104–863, at 564, 690–91 (Sept. 28, 1996) (absence of sec. 532 from prior H.R. 2202); *see* 142 Cong. Rec. 25868 (Sept. 28, 1996) (noting that sec 532 was stricken and that proposed subsection (e) to INA section 213A definition ''Federal means-tested public benefit'' was also stricken). Instead, the commenter stated, IIRIRA retained the term's longstanding meaning of primary dependence on the government for subsistence. The commenter further stated that Congress' rejection of the proposed provision was an express political choice to ensure that IIRIRA's passage, and not a clerical change.

212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), DHS believes that there is a strong connection between the self-sufficiency policy statements elsewhere in Title 8 of the United States Code (even if not codified in the INA itself) at 8 U.S.C. 1601 and the public charge inadmissibility language in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), which were enacted within a month of each other.[344] Of particular significance and just prior to the passage of the revised public charge inadmissibility ground in IIRIRA, conference managers noted that the implementing section ''amends INA section 212(a)(4) to expand the public charge ground of inadmissibility. Aliens have been excludable if likely to become public charges since 1882. Self-reliance is one of the most fundamental principles of immigration law.'' [345] Previous House and Senate Judiciary Committee reports included similar statements addressing self-sufficiency and receipt of public benefits in the context of public charge.[346]

Furthermore, DHS disagrees that either congressional actions leading up to IIRIRA or years of precedent mandate the adoption of the primarily dependent standard. As explained in the NPRM, the statute does not expressly prescribe a single method to define the level, type, or duration of public benefit receipt necessary to determine whether an alien is a public charge or is likely at any time to become a public charge.[347] DHS does not interpret the fact that Congress did not define public charge as ''any alien who receives [means-tested public] benefits for an aggregate period of at least 12 months'' prior to enactment of IIRIRA [348] as meaning DHS is precluded from adopting a similar definition now.[349] Rather, DHS views Congress' failure to define ''public charge'' by statute as an affirmation of what the Senate Judiciary Committee acknowledged over 50 years ago, *i.e.,* that the meaning of public charge has been left to the judgment and interpretation of administrative officials and the courts. More specifically, that committee found that the determination whether the alien is a public charge or is likely to become a public charge should rest within the discretion of immigration officers, because the elements constituting public charge are so varied.[350] If Congress had wanted to conclusively define the term public charge as ''primarily dependent,'' it could have done so.[351] DHS also notes that courts that have examined public charge have generally explained public charge in the context of dependence or reliance on the public for support without elaborating on the degree of dependence or reliance required to be a public charge.[352]

As discussed in the NPRM,[353] DHS believes that the primary dependence definition constitutes one permissible, but non-exclusive way of establishing a bright line for considering public benefit receipt relative to a public charge determination. Because Congress already identified certain classes of aliens, including those who are particularly vulnerable, and has exempted or authorized DHS to exempt them from the public charge ground of inadmissibility, DHS believes that with respect to other aliens not similarly protected, the current approach of excluding receipt of non-cash benefits and only finding to be inadmissible individuals who are likely to become *primarily* dependent on the government, as a policy matter, does not go far enough in enforcing this ground of inadmissibility.

Given that the statute and case law do not prescribe the type or extent of public benefit receipt that makes an alien a public charge, DHS believes that benefits designated in this rule are directly relevant to public charge inadmissibility determinations. These enumerated public benefits are directed toward meeting the basic necessities of life through the provision of food and nutrition, housing, and healthcare.[354] This basic fact is underscored by the many comments identifying significant consequences for individuals who decide to disenroll from these benefits. Ultimately, the public charge ground of inadmissibility is targeted to individuals who, in the absence of government assistance, would lack the basic necessities of life. DHS acknowledges that this rule constitutes a change that will have a practical impact on aliens covered by this rule; however, it views the current policy as unduly restrictive in terms of which benefits are considered for public charge inadmissibility. Therefore, expanding the list of public benefits to include a broader list of public benefits that satisfy basic living needs as a policy matter better enforces this ground of inadmissibility.

Equally important, given that the statute and case law do not prescribe the *degree* or *duration* of public benefit receipt that make an alien a public charge, DHS has determined that it is permissible to adopt a threshold other than the primarily dependent standard. In its annual reports to Congress on welfare indicators and risk factors, HHS explains that defining welfare dependence and developing consensus around a single measure of welfare dependence are difficult and adopting any definition of welfare dependence has its limitations and represents a choice of demarcation beyond which someone is or will be considered dependent.[355] In HHS's efforts to examine the range of dependence from complete long-term dependence to total self-sufficiency, HHS acknowledges that

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[344] *See* Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (enacting 8 U.S.C. 1601) and Public Law 104–208, div. C, sec. 531, 110 Stat. 3009–546, 3009–674 (Sept. 30, 1996) (amending INA section 212(a)(4), 8 U.S.C. 1182(a)(4)).

[345] *See* United States. Cong. House. Committee on the Conference. *Illegal Immigration Reform and Immigrant Responsibility Act of 1996.* 104th Cong. 2nd Sess. H. Rpt. 828, at 240–241 (1996). *https://www.congress.gov/104/crpt/hrpt828/CRPT-104hrpt828.pdf* (last visited 5/9/2019).

[346] *See* United States. Cong. House. Committee on the Judiciary. *Immigration in the National Interest Act of 1995.* 104th Cong. 2nd Sess. H. Rpt. 469, pt 1, at 109 (1996). *https://www.congress.gov/104/crpt/hrpt469/CRPT-104hrpt469-pt1.pdf* (last visited 5/9/2019). *See* also United States. Cong. Senate. Committee on the Judiciary. *Immigration Control and Financial Responsibility Act of 1996.* 104th Cong. 2nd Sess. S. Rpt. 249, at 5–7 (1996). *https://www.congress.gov/104/crpt/srpt249/CRPT-104srpt249.pdf* (last visited 5/9/2019.).

[347] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51163–51164 (proposed Oct. 10, 2018).

[348] United States. Cong. House. Committee on the Conference. *Illegal Immigration Reform and Immigrant Responsibility Act of 1996.* 104th Cong. 2nd Sess. H. Rpt. 828, at 138 (1996). *https://www.congress.gov/104/crpt/hrpt828/CRPT-104hrpt828.pdf* (last visited 5/9/2019).

[349] *See Competitive Enterprise Inst.* v. *U.S. Dep't of Transp.,* 863 F.3d 917 (D.C. Cir. 2017) (''But 'Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change.' '' (citing *Consumer Elecs. Ass'n* v. *FCC,* 347 F.3d 291, 299 n.4 (DC Cir. 2003) (quoting *Pension Benefit Guar. Corp.* v. *LTV Corp.,* 4966 U.S. 633, 650 (1990))).

[350] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51123 n.21 (proposed Oct. 10, 2018). *See also* The 1950 Omnibus Report of the Senate Judiciary Committee, S. Rep. No. 81–1515, at 349 (1950).

[351] *See, e.g., Cyan, Inc.* v. *Beaver Cty. Emp. Ret. Fund,* 138 S. Ct. 1061, 1070 (2018) (explaining that, if Congress had wanted to deprive state courts of jurisdiction over certain class actions, it could have easily done so by inserting a provision.).

[352] *See* Inadmissibility on Public Charge Grounds, 83 FR 51158 (proposed Oct. 10, 2018).

[353] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51163–51164 (proposed Oct. 10, 2018).

[354] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51159 (proposed Oct. 10, 2018).

[355] *See* U.S. Dep't of Health & Human Servs., Indicators of Welfare Dependence: Annual Report to Congress, at Foreword and Chapter II (1997), *available at https://aspe.hhs.gov/report/indicators-welfare-dependence-annual-report-congress-1997* (last visited July 26. 2019). *See also* U.S. Dep't of Health & Human Servs., Welfare Indicators and Risk Factors, at I–2 (2015), *available at https://aspe.hhs.gov/report/welfare-indicators-and-risk-factors-fourteenth-report-congress* (last visited July 26. 2019).

mere public benefit receipt is not a good measure of dependence [356] but that: ''Welfare dependence, like poverty, is a continuum, with variations in degree and in duration.'' [357] As HHS explains, an individual may be more or less dependent based the share of total resources derived from public benefits or the amount of time over which the individual depends on the public benefit. As HHS further elaborates, ''A summary measure of dependence . . . as an indicator for policy purposes must have some fixed parameters that allow one to determine [who] should be counted as dependent, just as the poverty line defines who is poor under the official standard.'' [358] In this context, DHS has determined that it is permissible to adopt a uniform duration threshold so long as the threshold has fixed parameters to allow DHS to determine who is considered a public charge. Accordingly, as explained further below, DHS has defined ''public charge'' in this final rule to mean a person who receives the designated benefits for more than 12 months in the aggregate in any 36-month period. This fixed standard will assist DHS to determine which aliens are inadmissible as likely to become a public charge at any time in the future based on the totality of the alien's circumstances.

b. Standards for Monetizable and Non-Monetizable Benefits

Numerical Percentage Threshold

Comment: One commenter supported the explanation in the NPRM that the 15 percent threshold is an acceptable proxy for benefits use, and indicated that the 15 percent threshold is ''widely used and thus arguably more transparent than other alternatives.''

In contrast, many commenters voiced general opposition to the 15 percent threshold, believing that the standards will likely reverse public health strides communities have made relating to vaccinations, communicable diseases and nutrition; that benefits amount received at that threshold level or any level, did not represent an individual's inability to achieve self-sufficiency; or that the 15 percent threshold was unfair and unnecessary in scope because the minimal financial support provided by federally funded benefits did not promote dependency, but were a safety net for vulnerable families and therefore should not be linked to threats of deportation.

Commenters stated that DHS had offered no basis for its use of 15 percent as the relevant benchmark for who is a public charge. Commenters also indicated that DHS's own conclusory assumption that receipt of this level of funding represents a lack of self-sufficiency was rebutted by the ample research showing that immigrants pay more into the United States healthcare system than they take out and that most immigrants pay taxes. This commenter also indicated that DHS provided little to no guidance as to how DHS officials would go about predicting a person's future likelihood of receiving the requisite amount of benefits and that the use of a specific dollar benchmark belies the Department's assurances that it will not consider prior receipt of benefits to be the dispositive factor in public charge determinations. Another commenter indicated that DHS does not provide an explanation as to why the quantifiable amount of dependency was set at 15 percent rather than 50 percent, which would reflect primary dependency, or even 30 or 40 percent. Citing to *United States* v. *Dierckman,* 201 F.3d 915, 926 (7th Cir. 2000) and *Allied-Signal, Inc.* v. *Nuclear Reg. Comm'n,* 988 F.2d 146, 152 (D.C. Cir. 1993), the commenters indicated that DHS failed to provide the essential facts upon which the administrative decision is based. The commenter also stated that DHS's attempt to justify its public charge definition with existing case law that, according to DHS, failed to stipulate quantifying levels of public support required, may have explained DHS's proposal to quantify the amount, but failed to explain why that quantifiable amount should be 15 percent of FPG, and not a higher percentage like 30 or 40 percent, or another amount that is less than 51 percent.

Other commenters stated DHS did not provide adequate data to support using the 15 percent threshold in public charge determinations, that the threshold was contrary to the spirit of public charge and did not prove an immigrant is ''primarily dependent'' on government assistance; and that the standard ignored the economic realities of low-wage work.

Multiple commenters stated that the 15 percent threshold is too low or restrictive, and arbitrary. A commenter also equated the threshold with having no threshold at all and stated that noncitizens will be too afraid to apply for benefits. Similarly, commenters stated that the 15 percent threshold is particularly low for immigrants living in areas with a high cost of living, for those receiving cash assistance, or for those receiving housing assistance, especially in cities or states where the cost of housing exceeds those detailed in the rule. Some commenters asserted that the standard should be 50 percent of the FPG, while other stated that DHS should conduct a sensitivity analysis comparing the economic impacts of using a 15 percent of the FPG cutoff versus a 50 percent of the FPG cutoff for benefits before determining the threshold. A commenter stated that the FPG have long been criticized for being inadequate and low—failing to take into account, for example, of geographical variances in cost of living, as well as expenses that are necessary to hold a job and to earn income (*e.g.,* child care and transportation costs). The commenter wrote that given these well-documented and critical flaws with the FPG, DHS's proposed thresholds are particularly egregious.

Many commenters provided examples of individuals who would be found to be public charges under the proposed benefit thresholds, despite being largely self-sufficient. Several commenters also stated that a noncitizen receiving slightly less than $5 per day, or roughly $1,800 per year, in benefits would be enough to trigger a public charge finding. Other commenters stated that a noncitizen family of four making 250 percent of the federal poverty line could be deemed public charges if they received $2.50 per person per day, although such a family would be about 95 percent self-sufficient. A commenter stated that therefore, DHS's standard to measure self-sufficiency had no rational connection with actual self-sufficiency. Many commenters cited studies finding that those who are widely self-sufficient, upwards of 90 percent, but who receive or previously received ten percent of their income in benefits could be found inadmissible under the proposed threshold, especially in light of the fact that past receipt counts as a heavily-weighted factor. Another commenter cited a study indicating that the rule could effectively ban a family of four making 175 percent of FPG, but which received $2.50 per day per person in government aid, even though this family is only receiving 8.6 percent of their income from the government and is 91.4 percent self-sufficient. A

[356] *See* U.S. Dep't of Health & Human Servs., Indicators of Welfare Dependence: Annual Report to Congress, at Chapter II (1997), *available at https://aspe.hhs.gov/report/indicators-welfare-dependence-annual-report-congress-1997* (last visited July 26. 2019).

[357] *See* U.S. Dep't of Health & Human Servs., Welfare Indicators and Risk Factors, at I–2 (2015), *available at https://aspe.hhs.gov/report/welfare-indicators-and-risk-factors-fourteenth-report-congress* (last visited July 26. 2019).

[358] *See* U.S. Dep't of Health & Human Servs., Welfare Indicators and Risk Factors, at I–2 (2015), *available at https://aspe.hhs.gov/report/welfare-indicators-and-risk-factors-fourteenth-report-congress* (last visited July 26. 2019).

commenter also stated that the proposed threshold could have the perverse effect of discouraging immigrants from accessing benefits they need to eventually become self-sufficient. One commenter stated that it would be unreasonable to use the receipt of public benefits in excess of 15 percent against an individual if the individual received the aid after an accident or emergency, as such use would not be evidence indicating that it will happen again. A commenter stated that the proposed threshold was so low that it would be more of an indicator that the alien is subject to the inherent uncertainties and exigencies of life, *e.g.,* if a sponsoring company goes out of business or with the occurrence of a heart attack or a child developing a disability, that it would be an indicator of the alien's ongoing dependence on public benefits. Another commenter stated that a higher threshold would better keep with the prudence dictated by the precautionary principle. The commenter wrote that significantly tightening the public benefits threshold from the old primary dependence paradigm will entail unanticipated consequences and ought to be conducted slowly.

Many commenters stated that the 15 percent threshold is overly complicated and would lead to widespread confusion. A commenter said that because of the low threshold, it would be difficult or impossible for families to understand how to utilize public safety nets without becoming a public charge, or to know at the time of an application if a specific benefit program would meet the 15 percent threshold. A commenter stated that the proposed cutoff of 15 percent would not serve to improve clarity when making public charge determinations, but would instead reduce the number of immigrants whose applications will be approved.

Response: After considering all of the public comments on the proposed thresholds for the receipt of public benefits, DHS decided against finalizing separate thresholds for monetizable and non-monetizable benefits, including the combination threshold. Instead, DHS has determined that a better approach from a policy and operational perspective, and one indicative of a lack of self-sufficiency is a single duration-based threshold, which this rule incorporates directly into the definition of public charge,[359] and the determination of likely to become a public charge.[360]

Therefore, under this final rule, DHS will consider an alien likely to become a public charge at any time in the future if the alien is more likely than not to receive public benefits for longer than 12 months in the aggregate in any 36-month period. As with the proposed rule, current receipt or past receipt of more than 12 months of public benefits, in the aggregate, in any 36-month period will not necessarily be dispositive in the inadmissibility determination; *i.e.,* in determining whether the alien is likely to become a public charge at any time in the future, but will be considered a heavily weighted negative factor in the totality of the alien's circumstances.

By moving the threshold standard into the ''public charge'' definition, DHS intends to alleviate confusion about the threshold for being a public charge. As part of the inadmissibility determination, an officer will review the likelihood of whether an alien will receive public benefits over the durational threshold. The ''public benefit'' definition will only list the specific programs considered and the list of exclusions. Separating concepts of ''public charge'' and ''public benefits'' also clarifies that DHS will consider in the totality whether an alien has applied for, received, or been certified or approved to receive any public benefits, as defined in 8 CFR 212.21(b), in assessing whether he or she is likely to become a public charge as part of the totality of the circumstances.

DHS believes that this approach is particularly responsive to public comments that communicated concerns about the complexity of the bifurcated standard and lack of certainty. As revised, this determination includes the consideration of public benefit application, certification, or receipt over any period of time. However, as indicated above, the alien's application for, certification, or receipt of public benefits will only be weighted heavily in certain circumstances, namely where such application, certification, or receipt of public benefits exceeded 12 months in the aggregate within any 36-month period, beginning no earlier than 36 months prior to the alien's application for admission or adjustment of status on or after the effective date. Similarly, DHS has revised the public benefit condition that applies in the context of an extension of stay or change of status application or petition, to include this new standard as well.

Valuation

Comment: DHS also received comments on the valuation of monetizable benefits. A commenter acknowledged that the proposed rule including provisions for pro rata attribution of monetizable benefits (such that benefits granted to a multi-person household would not all be attributed to a single person), but stated that the proposed rule was confusing, and that families are highly likely to avoid seeking social services entirely, rather than rely on the valuation formulas.

Some commenters suggested that it would be unreasonable to refer to FPG for a household of one, when evaluating an alien who is part of a large household. One commenter wrote that the correlation between household receipts of public benefits in absolute dollar terms and the likelihood that one member of that household will become a public charge can be assumed to be stronger, the smaller the size of the household. For a given level of receipt, a larger household is more likely to be self-sufficient. The commenter suggested that DHS set the threshold for monetary receipt based on actual household size. The commenter did not address the fact that the proposed valuation methodology called for prorating the benefit valuation based on household size.

Response: DHS appreciates these comments. Because DHS is eliminating the percentage-based threshold for monetizable benefits, as well as the combination threshold, DHS is not making any adjustments to the application of the FPG to the valuation of monetizable benefits because the entire valuation concept is being eliminated from the rule. Similarly, because DHS will not be monetizing public benefits, the household size applicable to the FPG (*i.e.,* the household size of one) is no longer relevant. That said, DHS does not believe that public benefits received by a member of the alien's household would serve as a reliable measure of the likelihood of an alien becoming a public charge at any time in the future because the receipt of benefits by a household member does not indicate that the applicant is likely to receive public benefits as well. Therefore, if someone in the household other than the applicant is receiving the public benefit, DHS will not consider receipt of the public benefit. Similarly if the recipient is a member of the alien's household, any income derived from such public benefit will be excluded from the calculation of household income. However, because DHS is eliminating the percentage-based threshold for monetizable benefits and instead establishing a single, duration-based threshold, the length of time an alien receives any public benefit, as defined in 8 CFR 212.21(b), will be considered in the totality of the circumstances,

[359] *See* 8 CFR 212.21(a).

[360] *See* 8 CFR 212.22(a).

regardless of whether the alien is the only person in the household receiving the benefit, or is one of the people receiving the same benefit. This differs from the approach in the proposed rule where valuation of certain benefits that are based on the household size (*e.g.,* SNAP) would have been proportionally attributed to the alien.[361]

Comment: DHS also received comments on the non-monetizable benefits standards. One commenter stated that the 12- and 9-month minimum use thresholds are acceptable proxies for being a public charge, but the NPRM provides almost no explanation of how or why DHS determined that the 12- and 9-month threshold for non-monetizable benefits was indicative that an alien is a public charge. The commenter said a more detailed analysis of the non-monetizable benefits threshold in a final rule would go a long way to legitimizing this rulemaking. Many commenters either voiced general opposition to the 12-month standard for non-monetizable benefits or indicated that the standard was unreasonable in the context of specific non-monetizable benefits, such as Medicaid (which according to the commenters is designed for continuous enrollment) and public housing (which frequently requires a year-long lease agreement. A commenter stated that the threshold would not be well understood by the public, or provide sufficient assurance that a brief period of enrollment would be worthwhile. For instance, with respect to Medicaid, if the alien learned about the thresholds at all, she or he might still be concerned about signing up for a brief period of coverage, fearing that they might experience more acute healthcare needs later and should refrain from using Medicaid until or unless that occurred. The alien might also know that Medicaid eligibility periods typically last a year and may be unclear about how that period can be shortened. Another commenter stated that the 12-month standard is arbitrary and would produce ''absurd results'' when applied in a real-world context. For example, someone with cancer might use Medicaid to help cover their expenses, and the 12-month standard could cause them to discontinue care too early, leading to devastating consequences. Commenters stated that using duration to determine dependency is particularly problematic in the context of Medicaid, where the threshold does not allow DHS to determine the extent to which the benefit was used. A commenter suggested this threshold would be prohibitive for all households participating in federal housing programs, regardless of immigration status. The commenter also stated that durational receipt measures are meaningless in the context of health coverage since duration does not represent the extent of benefits actually used. Commenters stated that DHS's public charge assumption rests on arbitrary time periods for receiving benefits. Without citing to the source of information, one commenter stated that the average length a person is on SNAP is 8–10 months, Medicaid assistance for children is provided on average for 28 months, and the average length of receipt for public housing for families is no more than 4 years. Similarly without attributing the source of information, a commenter said a 20-year analysis makes clear that seemingly dependent immigrants will become self-sufficient and productive in the long-term. One commenter stated strong opposition to the double counting of months where more than one benefit is received.

Response: DHS has decided to adopt a uniform duration standard for the following reasons. First, the new standard is simpler and more administrable than the proposed approach for monetizable and non-monetizable benefits. It eliminates the need for complicated calculations and projections related to the 15 percent of FPG threshold. By eliminating the 15 percent of FPG threshold for monetizable benefits, DHS is also able to eliminate the complicated assessment for the combination of monetizable and non-monetizable benefits and the provision for the valuation of monetizable benefits, including the need to prorate such benefits.

Second, the standard is consistent with DHS's interpretation of the term ''public charge.'' DHS believes that public benefit receipt for more than 12 cumulative months over a 36-month period is indicative of a lack of self-sufficiency. The threshold is intended to address DHS's concerns about an alien's lack of self-sufficiency and inability to rely on his or her own capabilities as well as the resources of family, sponsors, and private organizations to meet basic living needs. DHS believes that an alien who receives the designated public benefits for more than 12 months in the aggregate during a 36-month period is not self-sufficient. Receipt of public benefits for such a duration exceeds what DHS believes is a level of support that temporarily or nominally supplements an alien's independent ability to meet his or basic living needs. Although an alien who receives the designated public benefits for more than 12 months in the aggregate may soon disenroll, the fact that she or he received such support for such a substantial period of time establishes that they are a public charge until such disenrollment occurs. DHS would consider the alien's request to disenroll in the totality of the circumstances review.

Ample basis exists for using a duration-based standard even if, as commenters noted, neither the 1999 Interim Field Guidance nor any other source provides an authoritative basis for a specific duration-based standard. As indicated in the NPRM, under the 1999 Interim Field Guidance, the duration of receipt is a relevant factor with respect to covered benefits and is specifically accounted for in the guidance's inclusion of long-term institutionalization at government's expense.[362] But the 1999 Interim Field Guidance did not create a standard by which an alien's long-term reliance on public benefits would indicate a lack of self-sufficiency. In addition, HHS has repeatedly cited and measured the duration of time individuals receive means-tested assistance as an indicator

[361] In the NPRM, DHS had proposed calculating the value of the benefit attributable to the alien in proportion to the total number of people covered by the benefit in determining the cumulative value of one or more monetizable benefits. *See* proposed 8 CFR 212.24, Valuation of Monetizable Benefits.

[362] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51165 (proposed Oct. 10, 2018). In assessing the probative value of past receipt of public benefits, ''the length of time . . . is a significant factor.'' 64 FR 28689, 28690 (May 26, 1999) (internal quotation marks and citation omitted). The NPRM also noted that in the context of both state welfare reform efforts and the 1990s Federal welfare reform, Federal Government and state governments imposed various limits on the duration of benefit receipt as an effort to foster self-sufficiency among recipients and prevent long-term or indefinite dependence. States have developed widely varying approaches to time limits. Currently, 40 states have time limits that can result in the termination of families' welfare benefits; 17 of those states have limits of fewer than 60 months. *See, e.g.,* MDRC, formerly Manpower Demonstration Research Corporation, Welfare Time Limits State Policies, Implementation, and Effects on Families. *https://www.mdrc.org/sites/default/files/full_607.pdf* (last visited July 26, 2017). Similarly, on the Federal level, PRWORA established a 60-month time limit on the receipt of TANF. *See* Temporary Assistance for Needy Families Program (TANF), Final Rule; 64 FR 17720, 17723 (Apr. 12, 1999) (''The [Welfare to Work (WtW)] provisions in this rule include the amendments to the TANF provisions at sections 5001(d) and 5001(g)(1) of Public Law 105–33. Section 5001(d) allows a State to provide WtW assistance to a family that has received 60 months of federally funded TANF assistance . . .''). These time limits establish the outer limits of how long benefits are even *available* to a beneficiary as a matter of eligibility for the public benefit, and therefore how long an individual can receive those benefits. But DHS cannot use these time limits to establish a specific standard to determine how long an individual can receive such benefits while remaining self-sufficient for purposes of the public charge inadmissibility determination.

of welfare dependence in its annual reports on welfare dependence, indicators, and risk factors.[363] HHS states, ''The amount of time over which [an individual] depends on welfare might also be considered in assessing [the individual's] degree of dependence.'' [364]

This rule aims to create such a standard, in order to provide aliens and adjudicators with a bright-line rule upon which they can rely. The proposed rule cited longitudinal studies of welfare receipt, such as the Census Bureau's Dynamics of Economic Well-Being study,[365] and the welfare leaver study.[366] Both studies offer insight into the length of time that recipients of public benefits tend to remain on those benefits, and lend support to the notion that this rule's standard provides meaningful flexibility to aliens who may require one or more of the public benefits for relatively short periods of time, without allowing an alien who is not self-sufficient to avoid facing public charge consequences.[367]

For example, according to the Census Bureau, the largest share of participants (43.0 percent) who benefited from one or more means-tested assistance programs in the 48 months from January 2009 to December 2012, stayed in the program(s) between 37 and 48 months. By contrast, 31.2 percent of participants in such benefits stayed in the program(s) for between one and 12 months, and the remaining 25.8% of participants stayed in the program for between 13 and 36-months.[368] The study thus showed that a significant portion of the benefits-receiving population ended their participation within a year. In fact, the study compared participants' months of program participation across various income and age ranges, racial groups, family types, levels of educational attainment, and types of employment status, and found that nearly across the board, there was a relatively large group of people who participated for between one and 12 months, followed by relatively smaller groups who participated for between 13 and 24 months and between 25 and 36 months, respectively, followed by a relatively large group of people who participated for between 37 and 48 months. Similarly, an earlier study showed that across a 24-month period of study, those who were enrolled in one or more major assistance programs (approximately 25.2 percent of the overall population studied) were most likely to be enrolled for the entire 24-month period (10.2 percent).[369] But a substantial portion of the population enrolled in such programs only participated between one and 11 months (8.5 percent) or 12 to 23 months (6.5 percent).[370] All of this suggests that a 12-month standard is not absurd, as indicated by commenters, but in fact accommodates a significant proportion of short-term benefits use, while also providing a simple and accessible touchstone (more than a year) and an easily administrable cutoff that is a midpoint between the cutoffs established in the studies (36 months).

The ''welfare leaver'' study referenced above also provides support for a 12-month standard. Although most people who leave welfare programs work after they leave those programs, people may come back to receive additional public benefits.[371] In the welfare leaver study, researchers found that on average, ''cyclers'' received 27 months of cash assistance within the study's four-year observation period, compared with an average of 12 months for short-term recipients and 40 months for long-term recipients.[372]

DHS acknowledges that the duration standard is imperfect, because it is an exercise in line-drawing, it does not monetize public benefit receipt, and it is applied prospectively based on the totality of the alien's circumstances instead of an algorithm or formula. In some cases, DHS may find an alien admissible, even though the alien may receive thousands of dollars, if not tens of thousands of dollars, in public benefits without exceeding the duration threshold at any time in the future. DHS recognizes this scenario is plausible based on estimates of Medicaid costs and receipt of Medicaid only. For example, the Office of the Actuary in the Centers for Medicare and Medicaid Services estimated that annual Medicaid spending per enrollee ranged from approximately $3,000-$5,000 for children and adults to approximately $15,000-$20,000 for the aged and persons with disabilities in Fiscal Year 2014.[373] DHS's analysis of SIPP data shows that among individuals receiving SSI, TANF, GA, SNAP, Section 8 Housing Vouchers, Section 8 Rent Subsidy, or Medicaid in 2013, over 32 percent were receiving Medicaid only on average each month.[374]

In other cases, DHS may find an alien inadmissible under the standard, even though the alien who exceeds the duration threshold may receive only hundreds of dollars, or less, in public

[363] *See, e.g.,* U.S. Dep't of Health & Human Servs., Welfare Indicators and Risk Factors (2014–2015) and U.S. Dep't of Health & Human Servs., Indicators of Welfare Dependence (1997–1998, 2000–2013), available at *https://aspe.hhs.gov/indicators-welfare-dependence-annual-report-congress* (last visited July 26. 2019).

[364] *See* U.S. Dep't of Health & Human Servs., Welfare Indicators and Risk Factors, at I–2 (2015), available at *https://aspe.hhs.gov/system/files/pdf/76851/rpt_indicators.pdf* (last visited July 26. 2019).

[365] *See* Shelley K. Irving & Tracy A. Loveless, U.S. Census Bureau, Dynamics of Economic Well-Being: Participation in Government Programs, 2009–2012: Who Gets Assistance? 10 (May 2015), available at *https://www.census.gov/content/dam/Census/library/publications/2015/demo/p70–141.pdf* (last visited July 26, 2019).

[366] *See* Lashawn Richburg-Hayes & Stephen Freedman, A Profile of Families Cycling On and Off Welfare 4 (Apr. 2004), available at *https://aspe.hhs.gov/system/files/pdf/73451/report.pdf* (last visited July 26, 2019).

[367] *See* Shelley K. Irving & Tracy A. Loveless, U.S. Census Bureau, Dynamics of Economic Well-Being: Participation in Government Programs, 2009–2012: Who Gets Assistance? 10 (May 2015), available at *https://www.census.gov/content/dam/Census/library/publications/2015/demo/p70-141.pdf* (last visited July 26, 2019). *See also* Lashawn Richburg-Hayes & Stephen Freedman, A Profile of Families Cycling On and Off Welfare 4 (Apr. 2004), available at *https://aspe.hhs.gov/system/files/pdf/73451/report.pdf* (last visited July 26, 2019).

[368] *See* Shelley K. Irving & Tracy A. Loveless, U.S. Census Bureau, Household Economic Studies, Dynamics of Economic Well-Being: Participation in Government Programs, 2009–2012: Who Gets Assistance? 4 (May 2015), available at *https://www.census.gov/content/dam/Census/library/publications/2015/demo/p70-141.pdf* (last visited July 26, 2019). This report includes TANF, General Assistance (GA), SSI, SNAP, Medicaid, and housing assistance as major means-tested benefits.

[369] The programs included in the study were TANF, GA, SNAP, SSI, and Housing Assistance, all of which are covered to at least some degree by this rule.

[370] *See* Jeongsoo Kim, Shelley K. Irving, & Tracy A. Loveless, U.S. Census Bureau, Dynamics of Economic Well-Being: Participation in Government Programs, 2004 to 2007 and 2009—Who Gets Assistance? 4 (July 2012), available at *https://www2.census.gov/library/publications/2012/demo/p70–130.pdf* (last visited July 26, 2019).

[371] *See* Lashawn Richburg-Hayes & Stephen Freedman, A Profile of Families Cycling On and Off Welfare ES–1 (Apr. 2004), available at *https://aspe.hhs.gov/system/files/pdf/73451/report.pdf* (last visited July 26, 2019).

[372] For most analyses in the report, the report divides the samples into three key outcome groups, based on each sample member's pattern of welfare receipt: Cyclers, short-term recipients, and long-term recipients. The report states that this grouping reflects definitions used in the literature, combined with an examination of the full sample. The report defines a cycler as someone who had 3 or more spells of welfare receipt during the 4-year observation period. The report defines a short-term recipient as someone who had 1 or 2 spells and a total of up to 24 months of welfare receipt during the observation period. The report defines long-term recipients as sample members with 1 or 2 spells and a total of 25 to 48 months of welfare receipt during the observation period. *See* Lashawn Richburg-Hayes & Stephen Freedman, A Profile of Families Cycling On and Off Welfare 22 (Apr. 2004), available at *https://aspe.hhs.gov/system/files/pdf/73451/report.pdf* (last visited July 26, 2019).

[373] *See* United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the Office of the Actuary, 2017 Actuarial Report of Financial Outlook for Medicaid, Table 21, page 61, at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf* (last visited July 26, 2019).

[374] DHS analysis of Wave 1 of the 2014 Panel of the Survey of Income and Program Participation.

benefits annually. A DHS analysis of SIPP data related to public benefit receipt and amounts indicates that among the 25 percent of SNAP recipients in 2013 who only received SNAP (rather than SNAP and some other benefit), eight percent lived in households receiving between $11 and $50 per month, compared to 80 percent of recipients who lived in households receiving over $150 per month. Among the 3 percent of TANF recipients who only received TANF in 2013, nearly eight percent of recipients lived in households receiving between $11 and $50 per month compared to 60 percent of recipients who lived in households receiving over $150 per month. And among the 26 percent of TANF, SNAP, GA, and SSI recipients who only received one of those public benefits, six percent of recipients lived in households receiving between $11 and $50 per month compared to 80 percent of recipients who lived in households receiving over $150 per month. Among TANF, SNAP, GA, and SSI recipients receiving any of those public benefits, four percent lived in households receiving between $11 and $50 per month cumulatively across all such benefits received, compared to 87 percent of recipients who lived in households receiving over $150 per month.[375]

These potential incongruities are to some extent a consequence of having a bright-line rule that (1) provides meaningful guidance to aliens and adjudicators, (2) accommodates meaningful short-term and intermittent access to public benefits, and (3) does not excuse continuous or consistent public benefit receipt that denotes a lack of self-sufficiency during a 36-month period.[376] At bottom, DHS believes that this standard appropriately balances the relevant considerations, and that even an alien who receives a small dollar value in benefits over an extended period of time can reasonably be deemed a public charge, because of the nature of the benefits designated by this rule.

DHS also notes the operational difficulties associated with a monetary threshold particularly given that several of the benefits under consideration are benefits received by a family unit and the public charge determination is, by statute, an individual determination. For example, in the case of SNAP or a housing voucher it would be difficult to meaningfully assign proportions of the group benefit to individuals in the family, who may benefit in different amounts or account for less or more than a pro rata share of the benefit, from the benefits-granting's agency's perspective. At its core, the prospective determination seeks to determine, based on the totality of the circumstances, the likelihood of an individual to use the public benefits enumerated in this rule to support themselves at any point in the future. This is a determination more aptly made by examining a pattern of behavior than by a monetary threshold which could represent a lump sum payment due to a one-time need. DHS believes that short-term benefits use may not be as reliable an indicator of an alien's lack of self-sufficiency, and believes that longer-term benefits use serves as a better indicator.

Of course, if an alien who receives a small dollar value in public benefits over an extended period of time disenrolls from a benefit and later applies for admission or adjustment of status, she or he will not necessarily be inadmissible or ineligible for adjustment of status by virtue of such past receipt. This is because, as noted throughout this preamble, the public charge inadmissibility determination is prospective in nature, and depends on DHS's evaluation of the totality of the circumstances. Moreover, the amount of past benefit receipt may be considered in the totality of the circumstances. For instance, all else being equal, an alien who previously received $15 in monthly SNAP benefits for a lengthy period of time, but has since disenrolled, is less likely to require such benefits in the future, as compared to an alien who only recently disenrolled from a $100 SNAP benefit monthly, or who recently left public housing after a lengthy stay.

Finally, DHS believes that it is appropriate to aggregate the 12 months, inasmuch as the aggregation ensures that aliens who receive more than one public benefit (which may be more indicative of a lack of self-sufficiency, with respect to the fulfillment of multiple types of basic needs) reach the 12-month limit faster. Namely, DHS believes that receipt of multiple public benefits in a single month is more indicative of a lack of self-sufficiency than receipt of a single public benefit in a single month because receipt of multiple public benefits indicates the alien is unable to meet two or more basic necessities of life. This is not an uncommon occurrence. For example, DHS's analysis of SIPP data reveals that among individuals who received the enumerated public benefits in 2013, at least nearly 35 percent of individuals received two or more public benefits on average per month. Table 7 provides additional context with respect to the concurrent receipt of multiple benefits.

TABLE 7—PUBLIC BENEFIT RECEIPT COMBINATIONS AMONG INDIVIDUALS RECEIVING ONE OR MORE ENUMERATED PUBLIC BENEFITS (AVERAGE PER MONTH), 2013

Program	Percent of individuals with combination	DHS view
Individuals Receiving Public Benefits	100.0	
Medicaid only	32.5	Meeting healthcare needs.
Medicaid and Supplemental Nutrition Assistance Program (SNAP).	22.8	Meeting healthcare and food/nutrition needs.
SNAP Only	13.1	Meeting food/nutrition needs.
Section 8 Rental Assistance Only	3.6	Meeting housing needs.
Medicaid, SNAP, and Supplemental Security Income (SSI)	3.2	Meeting healthcare, food/nutrition, and cash assistance needs.
Medicaid, SNAP, and Section 8 Rental Assistance	3.0	Meeting healthcare, food/nutrition, and housing needs.
Medicaid and SSI	2.9	Meeting healthcare and cash assistance needs.

[375] DHS analysis of Wave 1 of the 2014 Panel of the Survey of Income and Program Participation.

[376] *Cf., e.g., Harris* v. *FCC,* 776 F.3d 21, 28–29 (D.C. Cir. 2015) (''An agency does not abuse its discretion by applying a bright-line rule consistently in order both to preserve incentives for compliance and to realize the benefits of easy administration that the rule was designed to achieve.''); *Turro* v. *FCC,* 859 F.2d 1498, 1500 (D.C. Cir. 1988) (''Strict adherence to a general rule may be justified by the gain in certainty and administrative ease, even if it appears to result in some hardship in individual cases.'').

TABLE 7—PUBLIC BENEFIT RECEIPT COMBINATIONS AMONG INDIVIDUALS RECEIVING ONE OR MORE ENUMERATED PUBLIC BENEFITS (AVERAGE PER MONTH), 2013—Continued

Program	Percent of individuals with combination	DHS view
Medicaid, SNAP, Section 8 Housing Vouchers, and Section 8 Rental Assistance.	2.8	Meeting healthcare, food/nutrition, and housing needs.
SSI Only	2.1	Meeting cash assistance needs.
All other combinations	13.3	

Note: Because of rounding, percentages may not sum to 100.0.
Source: This table was derived from DHS analysis of Wave 1 of the 2014 Panel of the Survey of Income and Program Participation.

DHS does not believe that the threshold should operate in a way that effectively ignores receipt of multiple benefits in a single month and results in differential treatment for an alien who receives one designated benefit in one month and another in the next month, as compared to an alien who receives each of those designated benefits in the same month. DHS appreciates the references one commenter makes to average durations of receipt for certain benefits but notes that the commenter's statements could not be evaluated without a reference to a study or sources data.

DHS strongly disagrees with commenters' assertion that the duration standard is problematic in the context of Medicaid because the standard does not take into account the extent to which Medicaid is used. As DHS explained in the NPRM, Medicaid serves as a last-resort form of health insurance for people of limited means. Medicaid expenditures are significant across multiple enrollee groups, and are particularly pronounced among persons with disabilities and the aged. The Office of the Actuary in the Centers for Medicare and Medicaid Services, HHS, most recently reported that Medicaid spending per enrollee in FY 2016 was $3,555 for children, $5,159 for adults, $19,754 for persons with disabilities, and $14,700 for the aged.[377] Even if a Medicaid enrollee claims that he or she did not or will not use Medicaid benefits (*i.e.,* by going to the doctor or hospital) within a given time period, the value of Medicaid is not merely the value of claims paid out. Like any insurance plan, Medicaid protects against future potential expenses and ensures that enrollees can receive the services they need. Medicaid coverage constitutes a significant benefit received by enrollees regardless of direct expenditures, even if states require enrollees to pay subsidized premiums and pay for cost-sharing services.[378] According to the Centers for Medicare and Medicaid Services, Office of the Actuary, ''beneficiary cost sharing, such as deductibles or copayments, and beneficiary premiums are very limited in Medicaid and do not represent a significant share of the total cost of healthcare goods and services for Medicaid enrollees.'' [379] Ninety-five percent of total outlays in 2016 were for medical assistance payments, such as acute care benefits, long-term care benefits, capitation payments and premiums, and disproportionate share hospital (DSH) payments. Capitation payments and other premiums, which include premiums paid to Medicaid managed care plans, pre-paid health plans, other health plan premiums, and premiums for Medicare Part A and Part B, represented 49 percent of Medicaid benefit expenditures in 2016.[380] Accordingly, the duration of an alien's receipt of non-monetizable benefits like Medicaid is a reasonable proxy for assessing an alien's reliance on public benefits. DHS also believes that benefits received, including Medicaid, over that timeframe likely exceeds a nominal level of support that merely supplements an alien's independent ability to meet his or her basic living needs.[381]

DHS also disagrees that the standard is arbitrary. As discussed in the NPRM and this final rule, researchers have shown that welfare recipients experienced future employment instability, and continued to move in and out of welfare benefit programs such as Medicaid and SNAP.[382] Based on this research, DHS considers any past receipt of public benefits a negative factor in the public charge determination, although the weight accorded to such receipt would vary according to the circumstances. Similarly, application for or certification to receive a public benefit, or current receipt of public benefits for longer periods of time or moving in and out of benefit programs for an aggregate period of more than 12 of the most recent 36 months preceding the filing of the application for admission or application for adjustment of status is considered a heavily-weighted negative factor.

The duration standard should provide a more predictable threshold that will better permit applicants to adjust their behavior as they deem necessary and appropriate. An applicant should be readily aware whether he or she has received public benefits for more than 12 cumulative months within a 36-month period. Note that this rule clarifies that DHS will take into consideration evidence that an alien made requested to be disenrolled from public benefits and has made clarifying edits in 8 CFR 212.22(b)(4)(ii)(E) to make such consideration explicit.

Finally, DHS notes that the change to a duration-only standard is responsive to comments indicating that the 15 percent of FPG threshold would be too low or unreasonable for those living in cities and areas with high costs of living. For example, under the NPRM,

[377] *See* United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the Office of the Actuary, 2017 Actuarial Report of Financial Outlook for Medicaid, Table 21, page 61, at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf* (last visited April 25, 2019).

[378] *Premium* means any enrollment fee, premium, or other similar charge. *Cost sharing* means any copayment, coinsurance, deductible, or other similar charge. *See* 42 CFR 447.51 for definitions.

[379] *See* U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, the Office of the Actuary, 2017 Actuarial Report of Financial Outlook for Medicaid, page 3, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf* (last visited June 6, 2019).

[380] *See* United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the Office of the Actuary, 2017 Actuarial Report of Financial Outlook for Medicaid, pages 5–6, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf* (last visited June 6, 2019).

[381] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51165 (proposed Oct. 10, 2018).

[382] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51165 (proposed Oct. 10, 2018).

DHS would have considered an alien receiving a Section 8 Housing Voucher in an area where the eligibility requirement amounted to income more than 250 percent of the FPG in the same manner as another alien living area where the income eligibility was 50 percent of the FPG. Under the new standard, the effect of cost living is minimized.

DHS understands that certain applicants may be hesitant to receive certain benefits in light of the public charge assessment. DHS reiterates that this rule does not prevent individuals who are eligible for public benefits from receiving these benefits. And as explained below, in its public charge inadmissibility determination DHS will not consider receipt of Emergency Medicaid, the Medicare Part D LIS, Medicaid received by alien under age 21 or pregnant women, and a wide range of other benefits, such as emergency or disaster relief. This rule also explains the criteria under which DHS will determine whether an alien subject to section 212(a)(4), 8 U.S.C. 1182(a)(4), has established that he or she is not inadmissible on that ground. As explained, DHS will assess all factors and circumstances applicable to the public charge determination, including the past receipt of public benefits listed in 8 CFR 212.21(b). No one factor alone will render an applicant inadmissible on account of public charge; DHS will assess whether the alien is likely to become a public charge, *i.e.,* to receive the designated benefits above the threshold, in the totality of the circumstances.

DHS also acknowledges that the regulation may result in fewer numbers of nonimmigrants and immigrants being admitted to the United States or granted adjustment of status to that of a lawful permanent resident. DHS notes that the ground of inadmissibility under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) applies to aliens seeking admission to the United States, or adjustment of status to that of a lawful permanent resident. The public charge ground of inadmissibility does not apply to nonimmigrants present in the United States seeking an extension of stay [383] or change of nonimmigrant status.[384] As indicated in the NPRM, however, when adjudicating an alien's application for extension of stay or change of status, DHS will assess whether the alien has demonstrated that he or she has not received, since obtaining the nonimmigrant status and through the time of filing and adjudication, any public benefit, as defined in 8 CFR 212.21(b), for 12 months, in the aggregate, within a 36-month period.[385]

Finally, DHS understands that certain individuals may become self-sufficient in the long-term after a certain duration of benefits use and that individuals may use benefits for shorter or longer periods of time. But similar to the explanation above, the fact that a person may ultimately become self-sufficient is not the material question. The material questions is whether the person is likely to become a public charge at some point in the future. Therefore, DHS will not limit its definition of ''public charge'' based on the potential that an alien who is currently public charge may not remain so indefinitely. The appropriate way to address that nuance is through the totality of the circumstances prospective determination, rather than the definition of public charge. Accordingly, DHS properly considers the receipt of public benefits for more than 12 months in the aggregate within a 36-month period a heavily weighted negative factor in public charge inadmissibility determinations.

Alternatives to the Duration Standard

Comment: Some commenters recommended a ''grace period'' for foreign nationals coming to the United States to use public benefits and reach self-sufficiency, including an 18-month period to become a fully acclimated and productive person or to recover from emergencies or severe medical issues.

Response: As previously discussed, the purpose of this rule is to implement the public charge ground of inadmissibility consistent with the principles of self-sufficiency set forth by Congress, and to minimize the incentive of aliens to attempt to immigrate to, or to adjust status in, the United States due to the availability of public benefits.[386] In particular, Congress indicated that the immigration policy continues to be that ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' [387] When Congress enacted section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), it did not provide a grace period or a time period in which aliens could use public benefits after entering the United States. Therefore, DHS does not believe it is appropriate to add a grace period for the receipt of public benefits. For purposes of this rule, there will be a period between the publication of this rule, and the rule's effective date, which would serve as a ''grace period'' of sorts. DHS has also specified how it will consider receipt of public benefits prior to the rule's effective date. Ultimately, however, all aliens who apply for admission or adjustment of status on or after the rule's effective date will be subject to a prospective public charge inadmissibility determination.

DHS notes that as part of the totality of the circumstances determination, DHS will consider evidence that is relevant to its determination whether an alien is likely to become a public charge at any time in the future. For example, if an alien received public benefits in excess of the threshold duration but has evidence that his or her circumstances have changes or that the alien has requested to be disenrolled from such benefits, DHS will take such evidence into consideration in the totality of the circumstances.

Comment: A commenter stated that the 12-month period ought to be lengthened to approximately 36 months, because according to a report, 45 percent of people who received government assistance for less than 36 months stop receiving assistance sometime after the first 12 months. According to the commenter, the 45 percent are people who are on their way out of poverty due to public benefit programs. By contrast, approximately 43 percent of welfare recipients stay dependent for at least 3 years. According to the commenter, these are the people who truly lack self-sufficiency, as they have failed to exit the welfare system.

Response: DHS disagrees with this recommendation. As discussed in the NPRM and above, while some recipients may disenroll from public benefits after 12 months, this only addresses short-term welfare recipients.[388] For example, as indicated in the NPRM, ''the proportion of [Medicaid and food stamp participation] leavers who receive these benefits at some point in the year after exit is much higher than the proportion who receives them in any given quarter, suggesting a fair amount of cycling into and out of these programs.'' [389] HHS also funds various research projects on welfare. Across fifteen state and county

[383] *See* 8 CFR 214.1.

[384] *See* INA section 248, 8 U.S.C. 1258; *see* 8 CFR 248.

[385] *See* 8 CFR 214.1(a)(3)(iv) and 8 CFR 248.1.

[386] *See* 8 U.S.C. 1601.

[387] *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

[388] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51199 (proposed Oct. 10, 2018).

[389] *See* Lashawn Richburg-Hayes & Stephen Freedman, *A Profile of Families Cycling On and Off Welfare* 4 (Apr. 2004), *available at https://aspe.hhs.gov/system/files/pdf/73451/report.pdf* (last visited July 26, 2019).

welfare studies funded by HHS, it was found that the number of leavers who received food stamps within one year of exit was between 41 and 88 percent. Furthermore, TANF leavers returned to the program at a rate ranging between 17 and 38 percent within one year of exit. Twelve of these studies included household surveys, with some conducting interviews less than a year post-exit, and some as much as 34 months after exit. A review of these surveys found that among those who left Medicaid, the rate of re-enrollment at the time of interview was between 33 and 81 percent among adults, and between 51 and 85 percent among children. Employment rates at the time of interview ranged between 57 and 71 percent.'' [390] For these reasons, DHS does not believe that it should lengthen the 12-month period to 36 months.

Comment: Commenters also stated that receipt of benefits after an event such as a natural disaster ought not render an alien a public charge, but that sometimes the effects of a natural disaster can last longer than 12 months. The commenter disagreed with DHS's statement in the proposed rule that ''an individual who receives monetizable public benefits for more than 12 cumulative months during a 36-month period is neither self-sufficient nor on the road to achieving self-sufficiency.'' [391] The commenter stated that it can take much longer than 12 months to recover from a natural disaster, and noted that following a tornado in the commenter's community in 2013, some families were still recovering in 2018, and required the designated benefits.

Response: As indicated in the NPRM, DHS will not consider public benefits beyond those covered under 8 CFR 212.21(b), but even within that category, DHS will not consider all cash assistance as cash assistance for income maintenance under the rule. For instance, DHS would not consider Stafford Act disaster assistance, including financial assistance provided to individuals and households under Individual Assistance under the Federal Emergency Management Agency's Individuals and Households Program (42 U.S.C. 5174) as cash assistance for income maintenance. The same would hold true for comparable disaster assistance provided by State, local, or tribal governments. Other categories of cash assistance that are not intended to maintain a person at a minimum level of income would similarly not fall within the definition. In addition, DHS will not consider medical assistance for emergency medical condition (42 U.S. C. 1396(v)(3)) or short-term, non-cash, in-kind emergency disaster relief.[392] Finally as discussed above, DHS will also take into consideration evidence that an alien has disenrolled or requested to disenroll from public benefits in the totality of the circumstances when determining whether an alien is likely at any time in the future to become a public charge.

Combination Standard

Comment: DHS received comments on the proposed rule's provision for combining monetizable and non-monetizable benefits. Commenters generally opposed the proposed standard for combination of monetizable benefits under 15 percent of FPG and one or more non-monetizable benefits. Under this proposal, if an alien received a combination of monetizable benefits equal to or below the 15 percent threshold together with one or more benefits that cannot be monetized, the threshold for duration of receipt of the non-monetizable benefits would be 9 months in the aggregate (rather than 12 months) within a 36-month period (*e.g.,* receipt of two different non-monetizable benefits in one month counts as two months, as would receipt of one non-monetizable benefit for one month in January 2018, and another such benefit for one month in June 2018).[393]

Some commenters stated that the proposed combination standard lacked clarity in its explanation and some explained that they opposed this combination standard as it would have a similar effect to having no threshold at all, resulting in immigrants being too afraid to apply for and receive benefits. Commenters stated that DHS did not provide a rationale for the combination of monetizable benefits under 15 percent of the FPG and one or more non-monetizable benefits. One commenter suggested deleting this provision, because it would render a person a public charge based on any amount of SNAP or housing benefits, combined with 9 months of Medicaid coverage. The commenter indicated that this outcome was too severe.

Response: DHS disagrees with commenters that the combination standard lacked clarity or justification. However, as indicated above, DHS has eliminated the threshold standard and is applying a single duration-based threshold standard to all covered public benefits. DHS believes that this approach is responsive to public comments that raised concerns about the complexity of the proposed standards as well as the need for certainty and predictability in public charge determinations.

2. Public Benefits

Comment: A majority of commenters recommended that public benefits encompassed by the definition of that term in the proposed rule (both monetizable and non-monetizable), such as SSI, SNAP, Medicaid, TANF, and housing not be included in the public charge determination and described the negative outcomes that would arise if immigrants' access to the benefits were reduced due to this rule. A commenter stated that public charge determinations never considered non-cash benefits in the past, and including them now is inhumane, and will cost the local, State, and Federal governments in the long-run. One commenter requested that the listed programs be removed, and that no additional programs be added to the determination. One commenter said that expanding the public benefits definition would result in sweeping negative consequences and cause detrimental effects to public access to benefits by discouraging vulnerable populations from seeking the services they need. A commenter asserted that this rule affects more than just immigration status determinations, as it would impede access to supplemental services that raise the standard of living for the individual and their family.

Another commenter indicated that lawfully present noncitizens who have jobs within needed sectors simply might not earn enough to provide quality healthcare, nutritious food, and safe, stable housing to their families. The commenter further indicated that programs like SNAP, CHIP, and Medicaid are designed to help individuals meet their families' basic needs to keep them healthy and safe, and to penalize hardworking families for using the program designed for them is morally bankrupt. A couple of commenters said the policy penalizes the use of public benefits, and indicated that safety-net programs are correlated with the positive health and education outcomes that help low-income families escape poverty. Commenters stated that access to non-cash programs and other public benefits offers dignity and comfort as individuals work to build a new and better life, acquiring the skills

[390] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51199 (proposed Oct. 10, 2018) (quoting Lashawn Richburg-Hayes & Stephen Freedman, *A Profile of Families Cycling On and Off Welfare* 4 (Apr. 2004) (citation omitted)).

[391] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51165 (proposed Oct. 10, 2018).

[392] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51128, 51159 (proposed Oct. 10, 2018).

[393] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51166 (proposed Oct. 10, 2018).

and training to qualify for better-paying jobs. Several commenters that opposed the proposed rule stated that the inclusion of the public benefits included in the NPRM, including SNAP, in the public charge determination would reverse longstanding national policy.

Many commenters provided information and data on the general benefits of these public benefits programs; the number of people, children, and businesses affected; and the assistance that these public benefits provide to needy individuals and families. Comments referenced, for instance, the importance of TANF assistance for child care, Medicaid's role in helping families and communities manage healthcare costs, and SNAP's role in fighting food insecurity for children and families. Commenters stated that the proposed rule would exacerbate problems that the designated benefit programs are designed to address. Other commenters provided data suggesting that the designated public benefits help reduce homelessness and improve health outcomes. Commenters stated that these benefits are crucial for the health and development of children and individuals. Commenters also cited research that emphasized the important role public benefits and access to those benefits, including SNAP, plays for pregnant women and the elderly, including that the benefits make elderly individuals less likely to be admitted to nursing homes and hospitals; patients with medical problems, because public benefits reduce financial stress; and college and university students who are struggling with food insecurity.

Many commenters described adverse impacts of homelessness, including childhood depression and the positive impacts of affordable housing, including increased health benefits and chronic disease management and lowering the cost of healthcare. Another commenter cited studies where more students may experience homelessness under this rule, and described the negative impacts on rural subsidized housing and the agriculture economic market.

A commenter stated that receipt of public benefits, including SNAP, support work and improve a family's immediate and long-term prospects, decreasing the odds that the individuals will become primarily dependent on government benefits to support themselves. Similarly, another commenter stated that nutritional, healthcare, and housing assistance are all critical programs that support work, which the commenter identified as the ultimate path to self-sufficiency. A commenter stated that SNAP supports employment by increasing access to nutritious foods that enable workers to stay healthy and productive, and by enabling families to spend more of their income on work-related expenses like transportation, childcare, and laundry. Many commenters stated the benefits of Medicaid for different people and groups, including better health outcomes for pregnant women and children throughout adulthood. Some commenters described how access to affordable health insurance like Medicaid enables workers to find and retain jobs, and how a lack of affordable insurance contributes to worse health outcomes, unmet physical, behavioral and mental health needs, and eventual joblessness. Commenters stated that access to affordable insurance leads to better performance on the job, an easier time staying employed or seeking employment, and less unpaid bills and other debt; and important economic benefits, such as increased tax contributions, decreased reliance on other public assistance programs, and more disposable income to spend in the local economy. Commenters stated that states that expanded Medicaid experienced savings in costs associated with uncompensated care and state-funded health programs, as well as growth in jobs and general fund revenue. A commenter stated that reimbursement for services rendered to Medicaid patients was especially important for hospitals, and cited research documenting positive effects on hospitals' financial performance in States which decided to expand Medicaid.

Other commenters discussed a study in which the use of certain housing vouchers and access to public housing reduced the chance of families living in crowded conditions, shelters, or on the street, help ease the burden of rent in high-cost cities, prevent or alleviate homelessness, allow the flexibility for families to pay for other necessities, and promote self-sufficiency. Commenters also said this rule will deter landlords from participating in the housing voucher program, affecting the private housing market. Some commenters discussed the difficulty of immigrants obtaining affordable housing.

Other commenters cited research on children's health outcomes, asserting that access to public housing creates long-term improvements in educational attainment, income, self-sufficiency, and children's health outcomes; child development; greater attendance and prospects at school. Commenters also noted that access to affordable housing has positive effects on family stability and the economy overall, and that access to such housing frees up income for other living necessities. Others cited to research showing that public benefits, such as subsidized housing, positively impacts the health of children, people with disabilities, families, domestic violence victims, pregnant women and people of color; reduces poverty and homelessness, and promotes economic stability; helps low-earning immigrants increase their economic opportunities; facilitates upwards economic mobility; builds safe and affordable housing communities and decreases foreclosures; and benefits of immigrants to the housing market during economic downturns. Other commenters cited research showing that housing instability is associated with a broad range of health impacts, including worsening HIV side effects, heart disease, asthma, and cancer.

Several commenters stated that immigrants in high rent areas need public housing, specifically where income has not kept pace with rent prices. Some of these commenters cited research and figures on the rent prices in areas across the United States. Other commenters stated that only one in four families who need affordable housing receive it, arguing that even fewer families who need affordable housing receive it factoring in immigration status and family size. Multiple commenters stated that housing instability and unaffordability are strongly correlated with involuntary job loss and other economic barriers that undermine self-sufficiency, citing statistics. Several commenters stated that the rule undermines the mission of public housing. A commenter cited research indicating that including affordable housing in the rule may increase the poverty rate and disability rates.

In contrast, a few commenters supported the inclusion of the public benefits as part of the public charge determination. Some stated that only citizens should be eligible for the benefits. A commenter stated that the public charge rule should cover benefits that are provided for long periods of time, such as TANF.

Response: DHS appreciates the comments and recognizes that the public benefits listed in the rule provide assistance to needy individuals, and that rigorous application of the public charge ground of inadmissibility will inevitably have negative consequence for some individuals. DHS is aware that individuals may reconsider their receipt of public benefits in light of future immigration consequences. However, the rule does not prevent individuals from receiving any public benefits for

which they are eligible. Additionally, as noted in the NPRM, the rule, particularly the inclusion of the designated benefits into the public benefits definition, is consistent with congressional statements in 8 U.S.C. 1601 concerning self-sufficiency of foreign nationals. In particular, Congress indicated that the immigration policy continues to be that ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' [394] DHS will therefore continue to consider the public benefits proposed in the NPRM in public charge inadmissibility determinations with certain exceptions described below.

As discussed in the NPRM, the benefits that will be considered in this rule account for some of the largest federal expenditures on low-income individuals and bear directly on self-sufficiency.[395] The benefits listed are directed toward food and nutrition, housing, and healthcare, and are directly relevant to the public charge inadmissibility determination, because a person who needs the public's assistance to provide for these basic necessities of life and receives such benefits for longer periods of time is more likely to receive such benefits in the future.[396] DHS also notes, as updated in the regulatory text, that receipt of a public benefit occurs when a public benefit-granting agency provides such benefit, whether in the form of cash, voucher, services, or insurance coverage. Certification for future receipt of a public benefit does not constitute receipt, although it may suggest a likelihood of future receipt. With respect to Medicaid in particular, DHS would consider receipt to have occurred when coverage commences, regardless of whether the alien accesses services using such coverage.

Comment: A commenter said data refutes the notion that immigrant families rely disproportionately on all forms of public assistance, citing to a study from the National Academies of Sciences, Engineering, and Medicine indicating that just 4.2 percent of immigrant households with children utilize housing assistance as compared to 5.3 percent of U.S.-born households. A commenter stated that only 6.5 percent of people using public benefits are noncitizens and this rule will reach beyond that population. One commenter stated that immigrants use public benefits at a lower rate than U.S. born citizens, while other commenters stated that DHS did not consider whether the temporary benefits immigrants might receive would result in a net positive impact to the budget or society.

Response: DHS appreciates the comments and references to data. DHS does not assume, and has not based the rule on the assumption, that immigrant families rely disproportionately on public benefits. The statistical analysis provided in the preamble of the NPRM did not reach that conclusion. The NPRM provided data regarding both citizens and noncitizens in the discussion of the factors that may lead a person to receive public benefits. However, only aliens seeking admission to the United States or adjustment of status are subject to the public charge ground of inadmissibility. Therefore, whether citizens' receipt of public benefits is higher than that of aliens is immaterial. DHS notes that with respect to the comment that the temporary receipt of public benefits would result in a positive impact on the economy, such considerations are not the aim of this rule. This rule is intended to better ensure that aliens seeking to come to and remain in the United States are self-sufficient, and rely on their resources and those of their families, sponsors, and private organizations.

Comment: One commenter stated that including Medicaid, SNAP and housing assistance programs as public benefits ''would undermine decades of the federal government's work to address poverty and build a clearer path to the middle class for millions of families,'' because individuals may decide to forego WIC, which is connected to SNAP or other similar benefits. A commenter stated that the inclusion of Medicaid/CHIP, SNAP and housing assistance in public charge review would undermine decades of the federal government's work to address poverty and build a clearer path to the middle class for millions of families.

Response: DHS understands that many public benefits may be interconnected, such that when a person enrolls in one benefit, the benefit-granting agency will automatically qualify that person in another benefit. In those circumstances, an alien's decision to forego enrollment in a designated public benefit could result in the alien not being automatically qualified in a non-designated benefit. Similar outcomes could occur if a state conditions eligibility for the second benefit on enrollment in the first. That said, DHS disagrees that the rule would materially undermine decades of work to address poverty. The population affected by this rule is limited to those applicants seeking admission to the United States and adjustment of status, who are subject to public charge. The data and information provided by the commenter involves a much broader population that may not be affected by the rule.

Comment: A commenter stated that Congress had already made clear its intent on immigrants' eligibility for SNAP and Medicaid. The commenter went on to state that IIRIRA established criteria to be weighted by immigration authorities using a ''totality of circumstances'' test, and stated that the criteria specifically did not include receipt of public benefits. The commenter also stated that PRWORA established a set of eligibility rules for certain lawful immigrants to receive Medicaid, SNAP, and other means-tested programs, and Congress later modified these rules to allow Medicaid coverage for pregnant women without the typical five-year waiting period.

Response: Through PRWORA, Congress declared that aliens generally should not depend on public resources and that these resources should not constitute an incentive for immigration to the United States.[397] With IIRIRA, Congress codified minimum factors that must be considered when making public charge determinations: [398] Age; health; family status; assets, resources, and financial status; education and skills.[399]

As explained in the NPRM,[400] policy goals articulated in PRWORA and IIRIRA inform DHS's implementation of the public charge ground of inadmissibility. DHS does not believe there is tension between the availability of public benefits to some aliens as set forth in PRWORA and Congress' intent to deny admission, and adjustment of status to aliens who are likely to become a public charge. Indeed, DHS believes that Congress, in enacting PRWORA and IIRIRA very close in time, must have recognized that it made certain public benefits available to some aliens who are also subject to the public charge ground of inadmissibility, even though receipt of such benefits could render the

[394] *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

[395] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51166 (proposed Oct. 10, 2018).

[396] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51159 (proposed Oct. 10, 2018).

[397] *See* Public Law 104–193, sec. 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601).

[398] Public Law 104–208, div. C, sec. 531, 110 Stat. 3009–546, 3009–674 (Sept. 30, 1996) (amending INA section 212(a)(4), 8 U.S.C. 1182(a)(4)).

[399] *See* INA section 212(a)(4)(B), 8 U.S.C. 1182(a)(4)(B).

[400] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51132 (proposed Oct. 10, 2018).

alien inadmissible as likely to become a public charge. Under the scheme envisioned by Congress, aliens generally would not be issued visas, admitted to the United States, or permitted to adjust status if they are likely to become public charges. This prohibition may deter aliens from making their way to the United States or remaining in the United States permanently for the purpose of availing themselves of public benefits.[401] DHS believes that Congress must have understood, however, that certain aliens who were unlikely to become public charges when seeking admission or adjustment of status might thereafter reasonably find themselves in need of public benefits. Consequently, in PRWORA, Congress made limited allowances for that possibility. Nevertheless, if an alien subsequent to receiving public benefits wishes to adjust status in order to remain in the United States permanently or leaves the United States and later wishes to return, the public charge inadmissibility consideration (including consideration of receipt of public benefits) would again come into play. In other words, although an alien may obtain public benefits for which he or she is eligible, the receipt of those benefits may be considered, consistent with IIRIRA and PRWORA, for future public charge inadmissibility determination purposes. DHS recognizes that Congress through CHIPRA expanded the Medicaid coverage for children and pregnant women who are lawfully residing in the United States, including those within their first five years of having certain legal status. In this final rule, DHS has exempted from consideration receipt of Medicaid by children under 21 and pregnant women during pregnancy and 60 days following pregnancy by amending the definition of public benefit in 8 CFR 212.21(b).

Comment: Some commenters stated that immigrants' eligibility for some of the public benefits is already restricted, including SSI, TANF, and housing programs. Another commenter said the inclusion of Medicaid in the proposed rule was unnecessary, since existing law already requires that lawful permanent residents wait five years before becoming eligible for Medicaid or Medicare.

Response: DHS recognizes that most aliens are ineligible for the public benefits listed in the rule. However, the public charge inadmissibility determination reviews the likelihood of a person receiving a public benefit at any time in the future, including points in time when an alien may become eligible for the public benefits. In addition, some aliens are eligible for public benefits, as noted in Table 3 of the NPRM.[402]

Comment: A commenter indicated that immigrants contribute far more to America (*i.e.,* taxes, premiums, economic and military contributions) than they use in assistance. Other commenters indicated that immigrants contribute by paying taxes and the rule penalizes immigrants who file taxes and utilize programs to which they are legally entitled. Several commenters stated that immigrants make significant contributions to the economy, and the proposed rule would prevent immigrants from partaking in programs that their tax dollars support. Other commenters said that individuals covered by Medicaid or CHIP paid more in taxes and collected less in Earned Income Tax Credit (EITC) payments. According to a commenter, one study reviewing Medicaid expansion during the 1980s and 1990s estimated that, based on children's future earnings and tax contributions alone, the government would recoup 56 cents of each dollar spent on childhood Medicaid by the time the children turned 60.

Response: Paying taxes owed and filing tax returns is legally required for all individuals making a sufficient income in the United States.[403] The rule does not penalize those people who fulfill their legal responsibilities to do so. In addition, people are entitled to use benefits for which they qualify, and this rule does not prohibit anyone from using a benefit for which they qualify. However, DHS believes the use of certain benefits is appropriate to consider in determining public charge inadmissibility. Congress mandated the public charge assessment.[404] But Congress did not stipulate in legislation that public benefits received by eligible individuals should not be considered for public charge purposes; instead, Congress clearly stated the policy that those coming to the United States must be self-sufficient and not rely on public resources. Therefore, to implement Congress' requirement to consider public charge inadmissibility, DHS must consider the receipt of benefits by eligible individuals, as indeed the 1999 Interim Field Guidance did. DHS believes that the public charge rule strikes an appropriate balance with the benefits that are considered.

a. Specific Groups and Public Benefits

Individuals With Disabilities

Comment: Commenters stated that the inclusion of non-monetizable benefits in the proposed rule would disproportionately harm people with disabilities.[405] One commenter stated that ''[p]eople with disabilities would be uniquely affected by the inclusion of Medicaid-funded services in the public charge calculus, including Medicaid-funded community-based services that are efficiently delivered in homes and communities (the current public charge rule only requires consideration of Medicaid-funded institutional long-term care).'' Commenters said that because non-emergency benefits were included, the proposal would make it nearly impossible for immigrants with disabilities to become citizens unless they are independently wealthy. Many commenters indicated that the federal resources individuals with disabilities and their families depend on, such as Medicaid, SNAP, and housing vouchers, would be included in the determination of public charge under the rule. A commenter also noted that ''[p]eople with disabilities would be disproportionally impacted by the inclusion of housing and food assistance in the public charge test.'' One commenter stated that ''[b]y deeming immigrants who use such programs a 'public charge,' the regulations will disparately harm individuals with disabilities and impede their ability to maintain the very self-sufficiency the Department purports to promote and which the Rehabilitation Act sought to ensure.''

Several commenters stated that individuals with disabilities rely on non-cash benefits disproportionately, often due to their disability, in order to continue working, stay healthy, and remain independent and productive members of the community. Some commenters stated that Medicaid is often the only program available to and appropriate for people with disabilities as many of the services covered by Medicaid, including housing services and community-based services, are often not covered by private insurance. Many commenters cited the statistic that about one-third of adults under age 65 enrolled in Medicaid have a disability, compared with about 12 percent of adults in the general population. Other commenters cited the statistic that more than one-quarter of individuals who use SNAP are also disabled. Several commenters stated that individuals with disabilities disproportionately experience poverty.

[401] H.R. Rep. No. 104–469(I), at 144–45 (1996).

[402] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51128–30 (proposed Oct. 10, 2018).

[403] *See* 26 U.S.C. 1 and 6012(a)(1).

[404] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

A commenter stated that the rule would require immigrants with disabilities to meet economic standards that do not take into account the barriers to employment and wealth accumulation issues that individuals with disabilities face. Another commenter added that food insecurity rates in households that include at least one disabled working-age adult are substantially higher, even where the disabled person is working, and that such food insecurity leads to chronic illnesses. Many commenters stated that the rule would cause many individuals with disabilities or families with individuals with disabilities to disenroll from public benefit programs. A commenter cited research indicating that the rate of disability drastically increases as poverty increases, and that by creating fear around participating in public anti-poverty programs, the proposed public charge rule will lead to an increase in disability and negative health impacts for an already vulnerable community of people.

Response: DHS understands that individuals with disabilities receive public benefits that are listed in the rule. However, Congress did not specifically provide for a public charge exemption for individuals with disabilities and in fact included health as a mandatory factor in the public charge inadmissibility consideration.[406] Therefore, DHS will retain the designation of Medicaid and SNAP as public benefits, notwithstanding the potentially outsized impact of such designation on individuals with disabilities. With respect to DHS's consideration of the alien's disability as such, DHS would consider disability as part of the health factor, to the extent such disability makes the alien more likely than not to become a public charge. This consideration is not new and has been part of public charge determinations historically.[407] Those determinations include consideration of whether, in the context of the alien's individual circumstances, the alien has been diagnosed with a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide and care for himself or herself, such as by working or attending school. As noted in the proposed rule, as an evidentiary matter, USCIS would rely on medical determinations made by a medical professional. This would entail consideration of the potential effects of the disability on the alien's ability to work, attend school, or otherwise support himself or herself.

However, it is not the intent, nor is it the effect of this rule to find a person a public charge solely based on his or her disability. The public charge inadmissibility determination evaluates the alien's particular circumstances. Under the totality of the circumstances framework, the disability itself would not be the sole basis for an inadmissibility finding. DHS would look at each of the mandatory factors, and the affidavit of support, if required, as well as all other factors in the totality of the circumstances. For example, if an individual has a disability but there is no indication that such disability makes the alien more likely to become a public charge, the alien's disability will not be considered an adverse factor in the inadmissibility determination. This could occur if the individual is not currently enrolled in the designated benefits, has not previously been enrolled in any designated public benefit, and is employed or otherwise has sufficient income, assets and resources to provide for himself or herself, or has family willing and able to provide for reasonable medical costs, or the person has private health insurance or would soon be able to obtain private health insurance upon adjustment of status.

Vulnerable Populations

Comment: Some commenters identified specific groups of individuals who would be impacted by the inclusion of public benefits in the public charge determination. Several commenters stated that cash assistance provides crucial support for survivors of domestic violence and sexual assault, and would undermine Federal and State policies to support victims of domestic violence and assault by discouraging them to access critical services. A commenter stated that for many survivors, cash assistance, such as TANF or state-funded cash benefits, provides the crucial support they need to begin the journey of stabilizing their lives and achieving self-sufficiency. The commenter provided a data from a survey in 2017, where 85 percent of respondents said that TANF was a critical resource for domestic violence and sexual assault survivors, and that two-thirds of respondents said that most domestic violence survivors rely on TANF to help address their basic needs and to establish safety and stability, and 45 percent of respondents said the same is true of most sexual assault survivors. The commenter indicated that financial instability poses limited options for escaping or recovering from abuse and that access to cash assistance is an important factor in survivors' decision-making about whether and how they can afford to leave a dangerous situation, and in planning how to keep themselves and their children healthy, fed, and housed. The commenter indicated that the rule risk significant physical, emotional, and mental harm to these populations. Commenters described a survey that found that nearly 80 percent of service providers included in the survey reported that most domestic violence survivors rely on SNAP to establish their safety and stability. Another commenter stated that being able to meet basic food and nutritional needs provides a means for survivors of domestic violence and sexual assault to take care of themselves and their children while working to address their trauma and take steps toward independence.

Other commenters stated that nearly half a million Asian American and Pacific Islander (AAPI) noncitizens rely on the SNAP program to feed their families, and the rule will lead to less food assistance within family units. A commenter stated that almost 48 percent of noncitizen recipients of SNAP benefits were women in 2017, compared to 40 percent who were men, and 12 percent who were children. Another commenter stated that 80 percent of most domestic violence victims and 55 percent of most sexual assault victims use the program to restore safety and stability in their lives would be heavily affected by limiting access to SNAP.

One commenter stated that the proposed rule would disproportionately affect communities of color who use public benefits and social services to make ends meet and work towards self-sufficiency. A commenter stated that the proposed rule would likely disproportionality cause Latinos to lose access to SNAP and Medicaid benefits, exacerbating existing health inequities, increasing instances of hunger and poverty among this population. Similarly, another commenter described

[406] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[407] *See, e.g., Ex parte Mitchell,* 256 F. 229 (N.D.N.Y. 1919) (referencing disease and disability as relevant to the public charge determination); *Ex parte Sakaguchi,* 277 F. 913, 916 (9th Cir. 1922) (taking into consideration that the alien was an able-bodied woman, among other factors, and finding that there wasn't evidence that she was likely to become a public charge); *Barlin* v. *Rodgers,* 191 F. 970, 974–977 (3d Cir. 1911) (sustaining the exclusion of three impoverished immigrants, the first because he had a ''rudimentary'' right hand affecting his ability to earn a living, the second because of poor appearance and ''stammering'' such that made the alien scarcely able to make himself understood, and the third because he was very small for his age); *United States ex rel. Canfora* v. *Williams,* 186 F. 354 (S.D.N.Y. 1911) (ruling that an amputated leg was sufficient to justify the exclusion of a sixty year old man even though the man had adult children who were able and willing to support him).

the benefits of access to SNAP for the Latino community and commented that a loss of SNAP benefits would cause more Latinos, including children, to experience poverty and suffer from hunger and malnutrition. Another commenter stated that including SNAP will harm college students, as SNAP is a critical resource for the many college students who struggle with food insecurity.

Other commenters provided information on individuals with specific medical conditions that need Medicaid, including treating thalassemia (a group of blood disorders) and cardiovascular disease. A commenter cited studies showing that people with opioid addiction who lacked Medicaid were half as likely to receive treatment as those covered by some form of insurance. A commenter said that parental mental health and substance abuse was a strong indicator of child mistreatment, and the services Medicaid provides to combat these issues help keep children safe.

Many commenters noted the negative impact of including the receipt of housing assistance in the public charge determination on a variety of groups, including infants and toddlers, women and single mothers, large and low-income families, Latinos, domestic violence survivors, agricultural workers, low-income communities, people of color, the Lesbian, Gay, Bisexual, Transgender Immigrants (LGBTQ) community, AAPI, elderly, minority groups, and disabled persons. Multiple commenters cited studies and addressed the specific costs of the rule for domestic violence survivors, arguing that a survivor's greatest unmet need is housing when recovering from abuse. Other commenters commented that the rule would make it more difficult for families with multiple children to obtain housing due to the prorated system.

Response: DHS appreciates the comments. DHS recognizes that some people currently in the United States do in fact depend on the government to meet their needs, and that this rule is likely to result in negative consequences for some of those people, and people like them. Such negative consequences are, to some extent, an inevitable consequence of more rigorous application of a statutory ground of inadmissibility that is targeted towards people who receive public benefits to meet their basic needs. DHS declines to modify the scope of the rule to accommodate all possible Federal and State policies supporting public benefits use by specific vulnerable populations. DHS notes that if an alien relied on public benefits for a limited period time to escape a dangerous situation, but no longer relies on such benefits, the alien should make that clear to DHS, so that DHS can incorporate into its totality of the circumstances assessment the fact of the alien's changed circumstances.

DHS recognizes that it is possible that the inclusion of benefits such as SNAP and Medicaid may impact in greater numbers communities of color, including Latinos and AAPI, as well as those with particular medical conditions that require public benefits for treatment, and therefore may impact the overall composition of immigration with respect to these groups. DHS also recognizes that consideration of the receipt of public benefits while the alien was a child may also deter some parents from applying for these benefits on behalf of their children. But this is not DHS's intention in promulgating this rule. Instead, with this rule, DHS seeks to better ensure that applicants for admission to the United States and applicants for adjustment of status who are subject to the public charge ground of inadmissibility are self-sufficient.[408]

As provided by Congress, health is a mandatory factor in the public charge inadmissibility determination.[409] However, DHS will not find an alien inadmissible on public charge grounds based solely on an alien's medical condition or disability.

DHS's public charge inadmissibility determination evaluates the totality of an alien's individual circumstances. This totality of the circumstances approach weighs all the positive and negative evidence related to an alien's age; health; family status; assets, resources, and financial status; education and skills; required affidavit of support; and any other factor or circumstance that may warrant consideration in the public charge inadmissibility determination.[410] If the factors establish, in the balance, that an alien is likely at any time in the future to become a public charge, he or she will be deemed inadmissible. As noted in precedent administrative decisions, determining the likelihood of an alien becoming a public charge involves ''consideration of all the factors bearing on the alien's ability or potential ability to be self-supporting'' [411] in the totality of the circumstances.[412]

DHS's view of self-sufficiency is that aliens subject to the public charge ground of inadmissibility must rely on their own capabilities and secure financial support, including from family members and sponsors, rather than seek and receive public benefits to meet their basic needs. Cash aid and non-cash benefits directed toward food and nutrition, housing, and healthcare account for significant Federal expenditure on low-income individuals and bear directly on self-sufficiency. Because of the nature of the public benefits that would be considered under this rule—which are generally means-tested and provide cash for income maintenance and for basic living needs such as food and nutrition, housing, and healthcare—DHS believes that receipt of such benefits may render a person a person with limited means to provide for his or her own basic living needs and who receives public benefits is not self-sufficient because his or her reliance.

DHS notes that this rule would not adversely impact certain victims of domestic and sexual abuse, as VAWA, T, and U applicants are generally not subject to the public charge inadmissibility determination, as set forth in 8 CFR 212.23.

Comment: Several commenters said that over 1.1 million noncitizens age 62 and older live in low- or moderate-income households. Other commenters stated that nearly seven million seniors age 65 and older are enrolled in both Medicare and Medicaid, and one in five Medicare beneficiaries relies on Medicaid to help them pay for Medicare premiums and cost-sharing. Several commenters said having health insurance is especially important for older adults because they have greater healthcare needs. This makes Medicare a lifeline for most seniors, providing coverage for hospital, doctors' visits, and prescription drugs, but many immigrant seniors are not eligible for Medicare.

A commenter stated this age standard would result in mistreatment of elders when trying to enter or stay in the United States and would undermine immigrants' access to essential healthcare, nutrition, and housing programs. A commenter stated low-income seniors also greatly benefit from programs such as HCV Program (Section 8) rental assistance and SNAP to meet their basic needs and if immigrant families are afraid to access nutrition assistance programs, older adults will be food insecure and at risk of unhealthy eating, which can cause or exacerbate other health conditions and

[408] *See* 8 U.S.C. 1601(2).

[409] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[410] *See* 8 CFR 212.22.

[411] *Matter of Vindman,* 16 I&N Dec. 131, 132 (Reg'l Comm'r 1977).

[412] *See, e.g., Matter of Vindman,* 16 I&N Dec. 131 (Reg'l Comm'r 1977); *Matter of Harutunian,* 14 I&N Dec. 583 (Reg'l Comm'r 1974).

unnecessarily burden the healthcare system.

Response: DHS recognizes that eligibility for certain public benefits depends not only on a person's financial need but also on a person's age. However, Congress did not specifically exclude aliens of certain ages from the public charge inadmissibility determination and in fact included age as a mandatory factor in section 212(a)(4) of the Act, 8 U.S.C. 1184(a)(4).[413] Accordingly, DHS proposes to consider the alien's age primarily in relation to employment or employability and secondarily to other factors as relevant to determining whether someone is likely to become a public charge. DHS notes that the public charge inadmissibility determination evaluates the alien's particular circumstances. DHS's totality of the circumstances standard involves weighing all the positive and negative considerations related to an alien's age; health; family status; assets, resources, and financial status; education and skills; required affidavit of support; and any other factor or circumstance that may warrant consideration in the public charge inadmissibility determination.[414] If the negative factors outweigh the positive factors, then the alien would be found to be inadmissible as likely to become a public charge; if the positive factors outweigh the negative factors, then the alien would not be found inadmissible as likely to become a public charge.

DHS also notes that receipt of Medicaid, even if received in conjunction with receipt of Medicare, would still be considered a public benefit in the totality of the circumstances for public charge inadmissibility.

Comment: One commenter indicated that the rule could allow a young adult to be deemed inadmissible as a public charge if at any point within the last year the person or a member of the household or certain members of the family received a few of these benefits for only a period of time. The commenter indicated that household definition leaves a very wide array of potential individuals who may receive a public benefit through no volition or interaction of the immigrant applicant but would, as a result, have an impact on the determination of admissibility for the immigrant's application including a child or a young family member. The commenter indicated that despite the applicant providing sufficient support and having no need for public benefits, that family member or the primary caregiver for the family member may facilitate the application for and receipt of public benefits for that child or in relation to the care for that child.

Response: The public charge inadmissibility determination evaluates an alien's particular circumstances. DHS is not considering public benefits received by other household members as part of an alien's public charge inadmissibility determination. DHS has further clarified this inclusions of a definition for receipt of public benefits which indicates that an alien's receipt, application for or certification for public benefits solely on behalf of another individual does not constitute receipt of, application for or certification for such alien. But if the alien is a listed beneficiary, the alien is considered to have received the public benefit.

DHS's totality of the circumstances standard weighs all the positive and negative considerations related to an alien's age; health; family status; assets, resources, and financial status; education and skills; required affidavit of support; and any other factor or circumstance that may warrant consideration in the public charge inadmissibility determination.[415]

In the definition of household,[416] DHS accounts for both (1) the persons whom the alien is supporting and (2) those persons who are contributing to the household, and thus the alien's assets and resources. DHS believes that an alien's ability to support a household is relevant to DHS's consideration of the alien's assets, resources, financial status, and family status. DHS believes this is an appropriate definition in the limited immigration context of public charge inadmissibility determinations. Public benefits received by household members do not count towards the alien's financial assets and income for purposes of the public charge inadmissibility determination.[417]

Comment: A commenter stated that the rule would deprive U.S. citizens who live in mixed-status households of their access to assistance programs for which they are eligible.

Response: DHS disagrees that the rule would deprive U.S. citizens of access to assistance programs for which they are eligible. This rule does not include consideration of public benefits received by U.S. citizens in the public charge inadmissibility determination. The valuation of the public benefits is an individual determination and receipt of public benefits by other members of a household including U.S. citizens will not be considered in an applicant's public charge inadmissibility determination. In addition, DHS notes that this rule does not restrict an alien's access to public benefits for which the alien is eligible. Rather, this rule explains the criteria that DHS will use to determine whether an alien subject to section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), has met his or her burden of demonstrating eligibility for the immigration benefit sought.

Receipt of Public Benefits by Children

Comment: Several commenters said a child's use of benefits should not impact their public charge inadmissibility determination, as public benefits are often vital to the development of children and for them to become productive members of society. Commenters also indicated that a child's use of benefits should not impact their immigration application once they come of age. These commenters cited research demonstrating that the use of these programs in childhood helps children complete their education and have higher incomes as adults, be healthy, have better educational opportunities, and become more likely to be economically secure and contribute to their communities as adults. Another commenter indicated that public benefits serve as crucial levers that reduce the intergenerational transmission of poverty. Commenters also noted that ''[b]ecause children do not decide whether or not to apply for benefits and because their financial situation as children is not necessarily indicative of their financial situation for life, children's receipt of benefits should not be counted in any public charge determination.'' Some commenters stated that considering an immigrant's past use of public benefits as a child in the public charge inadmissibility determination would deter immigrant parents from obtaining food and healthcare assistance for their children, and argued that this would result in adverse outcomes for the children themselves and impose significant costs on society. A commenter stated that low-income children with immigrant parents, including U.S. citizen children, are already less likely to receive Medicaid than those with U.S. born parents.

Many commenters cited to research indicating that the use of programs, such as SNAP, Medicaid, and CHIP, and

[413] *See* INA section 212(a)(4)(B), 8 U.S.C. 1182(a)(4)(B).

[414] *See* 8 CFR 212.22.

[415] *See* 8 CFR 212.22.

[416] *See* 8 CFR 212.21(d).

[417] *See* 8 CFR 212.22(b)(4)(ii), which provides that USCIS' considerations when assessing the alien's assets, resources, and financial status excludes any public benefits received by the alien as well as any public benefits received by another person of the household.

housing assistance in childhood, helps children complete their education and have higher incomes as adults, live in stable housing, receive needed health services and consume adequate and nutritious food, and fosters their future success in education and the workforce. A commenter noted the impact of this rule on their work to facilitate healthy brain development among children. A few commenters stated that multiple studies confirm early childhood or prenatal access to Medicaid and SNAP improves health and reduces reliance on cash assistance. The commenters stated that children with access to Medicaid have fewer absences from school, are more likely to graduate from high school and college, and are more likely to have higher paying jobs as adults. Another commenter stated that children with health insurance are more likely to have routine healthcare, improved health outcomes, and improved success in education. One commenter said that lack of access to affordable housing remains one of the main barriers to economic stability for many families and the proposed rule would further limit access to housing assistance for families with children. The commenter cited research that shows rental assistance for households with children results in significant positive effects for future child outcomes and family economic security. A few commenters stated this proposal could undermine the access to healthcare for children of immigrants or their aging family members.

Response: DHS recognizes that many of the public benefits programs aim to better future economic and health outcomes for minor recipients, and that parents may decide to disenroll their children from public benefits programs to avoid negative immigration consequences. However, this rule is aimed at better ensuring that aliens who are subject to the public charge ground of inadmissibility are self-sufficient.

DHS also recognizes that children who receive public benefits are not making the decisions to apply for such benefits. However, DHS notes that that Congress did not exclude children from the public charge ground of inadmissibility unless the child is seeking a status that Congress expressly exempted from public charge inadmissibility and, moreover, specifically required that DHS consider an applicant's age in the public charge inadmissibility determination. Nonetheless, as explained more fully in the discussion of Medicaid, DHS will not consider the receipt of Medicaid by children under the age of 21.

Military/First Responders

Comment: Some commenters supported the NPRM's proposal to exclude from the public charge determination any public benefits received by active duty service members and their families. Some commenters also discussed the impact of the rule on military families, including increasing food security for active military families and allowing them to focus on protecting the United States rather than on whether they will be able to feed their family. Commenters stated that too many military families and veterans depend on SNAP to make ends meet because their military pay is not enough to meet their basic needs. One commenter, citing to data from FY 2013, stated that current and former military members and their families redeemed approximately $104 million in SNAP benefits at commissaries—a 300 percent increase since 2007. The commenter further stated that for military families who do not have base-housing and live in high-cost areas, like those in California, accessing SNAP can be complicated and this has led military families across the country to turn out of desperation to food pantries and food banks—many operating on base or nearby military installations—for emergency food assistance. The commenter further stated that in recent years the Department of Defense (DOD) and the Department of Veterans Affairs (VA) have issued policies to address high rates of hunger among low-income military and veteran families, because military leaders understand that soldiers are less prepared to serve their country if they are hungry or worried about their families going hungry. They also know that when veterans are largely living in poverty with unmet basic needs, it is more difficult to convince young people who live in their communities to sign up.

A commenter also cited to 2013 USDA data, and reported that in that year, $103.6 million of groceries were purchased with SNAP benefits at military commissaries, and that between 2,000 and 22,000 military households received SNAP benefits. The commenter stated that a Department of Defense Education Activity (DoDEA) showed that in September 2015, 24 percent of 23,000 children in DoDEA schools were eligible for free meals, while 21 percent were eligible for reduced-price meals.

Commenters, citing the 2.4 million children from military families who were enrolled in Medicaid or CHIP, noted that many families with family members enlisted in the military benefitted from enrollment in Medicaid or CHIP, indicated that Medicaid enrollment leads to positive health outcomes.

Response: DHS acknowledges that military service members and their families who are applying for an immigration benefit for which admissibility is required and that is subject to section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), will be required to demonstrate that they are not likely at any time in the future to become a public charge. However, consistent with the NPRM, DHS's public charge analysis will exclude consideration of the receipt of any public benefits by active duty servicemembers, including those in the Ready Reserve of the U.S. Armed Forces, and their spouses and children. As noted in the NPRM, the U.S. Government is profoundly grateful for the unparalleled sacrifices of the members of our armed services and their families. Servicemembers who, during their service, receive public benefits, in no way burden the public; indeed, their sacrifices are vital to the public's safety and security. The DOD has advised DHS that many of the aliens who enlist in the military are early in their careers, and therefore, consistent with statutory pay authorities, earn relatively low salaries that are supplemented by certain allowances and tax advantages.[418] Although data limitations exist, evidence suggests that as a consequence of the unique compensation and tax structure afforded by Congress to aliens enlisting for military service, some active duty alien servicemembers, as well as their spouses and children, as defined in section 101(b) of the Act, may rely on SNAP[419] and other listed public

[418] *See, e.g.,* 37 U.S.C. 201–212, 401–439 (Basic Pay and Allowances Other than Travel and Transportation Allowances, respectively); Lawrence Kapp, Cong. Research Serv., Defense Primer: Regular Military Compensation 2 tbl.1 (Dec. 17, 2018), available at *https://fas.org/sgp/crs/natsec/IF10532.pdf* (reporting average regular military compensation of $41,384 at the E–1 level in 2018, comprised of $19,660 in average annual basic pay, plus allowances and tax advantage) (last visited July 26, 2019); Lawrence Kapp et al., Cong. Research Serv., RL33446, Military Pay: Key Questions and Answers 6–9 (2019), available at *https://fas.org/sgp/crs/natsec/RL33446.pdf* (describing types of military compensation and federal tax advantages) (last visited July 26, 2019).

[419] *See* U.S. Gov't Accountability Office, GAO–16–561, Military Personnel: DOD Needs More Complete Data on Active-Duty Servicemembers' Use of Food Assistance Programs (July 2016), available at *https://www.gao.gov/assets/680/678474.pdf* (reporting estimates ranging from 2,000 active duty servicemembers receiving SNAP to 22,000 such servicemembers receiving SNAP) (last visited July 26, 2019). Effective FY16, Congress implemented a recommendation by the Military Compensation and Retirement Modernization Commission to sunset DOD's Family Subsistence

Continued

benefits. As a result, the general standard included in the proposed rule could result in a finding of inadmissibility under section 212(a)(4) when such aliens apply for adjustment of status.

As noted in the NPRM, following consultation with DOD, DHS has concluded that such an outcome may give rise to concerns about servicemembers' immigration status or the immigration status of servicemembers' spouses and children as defined in section 101(b) of the Act, 8 U.S.C. 1101(b), which would reduce troop readiness and interfere significantly with U.S. Armed Forces recruitment efforts. This exclusion is consistent with DHS's longstanding policy of ensuring support for our military personnel who serve and sacrifice for our nation, and their families, as well as supporting military readiness and recruitment.

Accordingly, DHS has excluded the consideration of the receipt of all benefits listed in 8 CFR 212.21(b) from the public charge inadmissibility determination, when received by active duty servicemembers, including those in the Ready Reserve, and their spouses and children. If a service member has since retired or otherwise been discharged from military service, receipt of public benefits while in the service will not be counted in the public charge consideration. Only public benefits receipted after discharge from the military would be considered. Applicants that fall under this exclusion must submit proof that the servicemember is serving in active duty or the Ready Reserve. DHS believes this should minimize any impact to military readiness.

Comment: Some commenters suggested that the exemption that applies to individuals serving in the Armed Forces should apply to other individuals, such as veterans and stated that failure to include military veterans within this carve-out is arbitrary and capricious. The commenter stated that once an individual leaves active or reserve duty, upon the completion of his or her enlistment, is honorably discharged, and takes up a private job at the very same salary, the public benefit exemption would no longer apply and thus be ineligible for admissibility and adjustment of status. The commenter stated military service members should be not be subject to public charge the moment they depart the military. A commenter said the rule would have an unintended negative impact on veterans of the U.S. military who do not have permanent status because they have access to the public benefits outlined in the rule. The commenter stated that their need for access to benefits may be directly tied to injuries resulting from their service.

A commenter stated that while applying the proposed rule to servicemembers would have negative policy consequences, the DHS lacks legal authority to exempt the ''public charge'' analysis from a whole segment of the population. The commenter stated that the relevant statute regarding ''public charge'' applies to ''[a]ny alien,'' and DHS stated no basis on which it can exclude certain individuals from the generally applicable proposed definition of ''public charge.'' The commenter stated that the rule would almost certainly apply to servicemembers like the rest of the population and therefore DHS should abandon the rule.

Response: DHS appreciates the comments and certainly appreciates the sacrifices that veterans have made for the United States. Among other factors, current servicemembers have a unique pay structure implemented by Congress that may involve the use of public benefits, and DHS has accordingly excluded the public benefits as listed in the rule for active duty service members in order to limit a possible impact on military readiness. DHS does not believe the same considerations are presented for veterans, as they do not currently serve, are not directly affected by the military compensation structure, and have access to a specific benefits scheme that Congress has designed for them (and that is not designated in this rule). Further, in light of that unique salary and benefit scheme created by Congress for active service members and their families, DHS disagrees with the commenter that it lacks authority to exempt use of the designated public benefits for such individuals and families from the definition of public charge. Rather, DHS has determined that it would be unreasonable, and contrary to congressional intent, to include use of public benefits by such individuals within the definition, where doing so could undermine the careful salary and benefits structure established by Congress and negatively affect recruitment and readiness.

Comment: Some commenters suggested that the exemption that applies to individuals serving in the Armed Forces should apply to other individuals, such as members of the public who have jobs of comparable importance to national security. The commenter stated as an example that there is no exemption for non-uniform support members working for or on behalf of the U.S. military, those working for State or local law enforcement, those working for prisons, or working as firefighters or as emergency medical technicians. The commenter stated that there is no doubt the U.S. ''Government is profoundly grateful for the unparalleled sacrifices'' of police officers, firefighters, and emergency medical technicians, but the rule does not exclude the public benefits received from these individuals. Other commenters indicated that the failure to exempt first responders and veterans or other groups was irrational, because military service members are not the only ones serving in roles important to national security.

Response: DHS refers the commenters to the explanations above regarding this rule's treatment of active duty servicemembers, including those in the Ready Reserve, and their spouses and children. DHS recognizes that many professionals, including first responders, also provide important services for the public, and make sacrifices that are critical and worthy of our gratitude. However, DHS believes that Armed Forces members and their spouses and children are uniquely positioned in this context, and that DHS should not extend similar treatment to other categories of applicants based on their employment or public service.

b. Supplemental Security Income

Comment: Multiple commenters opposed the inclusion of SSI and stated that SSI supports children with disabilities, and that a child who begins receiving SSI is less likely to fall below the poverty line. The commenters stated that the inclusion of SSI in the public charge rule threatens the health, safety, and well-being of the children and families that receive it. One commenter stated that SSI benefits represented 1.4 percent of the Federal Budget in FY 2012, and there is no reason to believe that the complete data recited in the ''one analysis'' relied on by the DHS for 2017 would be any different. The commenter stated that SSI was 0.33 percent of GDP in the years 2011 to 2012, and expected to decline to 0.23 percent in 2037. Further, the commenter said 86 percent of SSI benefits are paid to the disabled, concluding that it is

Supplemental Allowance Program within the United States, Puerto Rico, the U.S. Virgin Islands, and Guam; SNAP reliance may have increased somewhat following termination of the program. *See* Public Law 114–92, div. A, section 602, 129 Stat. 726, 836 (Nov. 25, 2015); Military Comp. & Ret. Modernization Comm'n, Final Report 187 (Jan. 2015) (''The [Family Subsistence Supplemental Allowance Program] should be sunset in the United States, Puerto Rico, Guam, and other U.S. territories where SNAP or similar programs exist, thereby reducing the administrative costs of a duplicative program.'').

irrational to exclude individuals with disabilities by claiming that they are likely to become a public charge. In contrast, other commenters asserted that only U.S. citizens should receive SSI.

Response: DHS appreciates the comments, however, DHS has determined that it will consider SSI as described in the rule. DHS notes that this decision is consistent with the 1999 Interim Field Guidance, and that, as discussed in the NPRM, SSI represents one of the largest Federal expenditures for low-income people.[420] As provided in the NPRM, SSI was included as public benefit because it provides monthly income payments for people with limited resources, is financed through general revenues, and has high expenditures.[421] DHS has determined that considering SSI in the rule, consistent with the 1999 Interim Field Guidance, is important in ensuring that aliens are self-sufficient and rely on their own capabilities and the resources of their families, their sponsors, and private organizations.

c. Temporary Assistance for Needy Families

Comment: Several commenters opposed the inclusion of TANF in the rule. One commenter stated that TANF helps families achieve self-sufficiency through support that allows parents to send their children to high-quality child care programs, and that including consideration of TANF could therefore harm families. Some commenters stated that TANF is the only source of Federal cash assistance for families with children, and that research shows that children make up about 77 percent of recipients. The commenters went on to state that families use cash assistance to aid in achieving economic security and working towards upward mobility, and that the inclusion of TANF in the proposed rule will be detrimental to children during their developmental years. The commenters stated that families who disenroll from TANF would lose their eligibility to receive free school meals, which would result in hungry children, homeless and precariously housed families, sicker adults and children, and reduced access to behavioral health services. Another commenter indicated that while the majority of TANF recipients are children, there is a current decrease in children receiving cash assistance (under 25 percent of all poor families with children) and the rule would further restrict access. The commenter also indicated that the rule fails to recognize that States are increasingly choosing to provide TANF to working families who earn too much to qualify for the basic cash assistance programs and that research has shown that such policies, which ''make work pay,'' improve employment outcomes because they serve as an effective incentive for families to find and keep jobs.

Response: DHS appreciates the comments; however, DHS has determined that considering TANF in the rule, consistent with the 1999 Interim Field Guidance, is important in ensuring that aliens are self-sufficient and rely on their own capabilities and the resources of their families, their sponsors, and private organizations. As provided in the NPRM, TANF was included as public benefit because it provides monthly income payments for low-income families and is intended to foster self-sufficiency, economic stability for families with children and has high expenditures.[422]

Comment: Some commenters added that TANF helps families enroll their children in childcare, which is a lifeline for working families. A commenter explained that, while the Child Care and Development Fund (CCDF) is the primary source of public funding for child care, a state may transfer up to 30 percent of its TANF funds to CCDF, or directly allocate its TANF funds, to provide child care subsidies to families in need. The commenter went on to provide statistics on the number of children in child-care and discussed the child-care support that TANF provides for working families. The commenter also provided data on the number of children in childcare and that one in six children eligible for CCDF services gain access to quality care.

Response: States may transfer TANF funding to other benefits including childcare, but this not considered cash TANF.[423] As only the ''cash assistance for income maintenance'' portion of TANF is considered in the public charge inadmissibility determination, direct TANF spending on child care and transfers to CCDF are excluded from the definition of public benefit for purposes of this rule.

Comment: One commenter stated that TANF ''child-only'' grants should be exempted from the proposed rule as they support the needs of children raised by extended relatives without parents. The commenter indicated that unlike TANF family grants, ''child-only'' grants are based solely on the income of the child and are only to meet their needs whether outside or inside the foster care system. The commenter stated that many children living with relatives in foster care are only offered TANF child-only support, since many states do not routinely license relatives and the children are consequently ineligible for foster care maintenance payments.

Response: DHS appreciates the comments, but notes the ''child-only grants'' are based solely on the needs of the child (*i.e.,* does not take the adults' needs into account when calculating the assistance benefit)' as opposed to the income of the child.[424] TANF cash assistance provided to a child is considered a public benefit under this rule. States may fund a variety of child welfare activities using TANF funds, including services for family reunification, parenting education, in-home family services, and crisis intervention.[425] TANF is only considered in the public charge inadmissibility determination if it is in the form of cash assistance for income maintenance. Again, non-cash TANF funded services are not included in the rule. States may transfer TANF funding to other benefits including childcare, which is not being considered in the rule. However, as previously discussed, there is no public charge exemption for children, therefore, any cash benefit receipt, including TANF, by a child generally would still be considered as a public benefit in public charge inadmissibility determination.

d. State, Local and Tribal Cash Assistance

Comment: A commenter provided information on various Washington State programs designed to provide individuals and families with the resources and support. The commenter

[420] *See* Gene Falk et al., Cong. Research Serv., R45097, *Federal Spending on Benefits and Services for People with Low Income: In Brief* (2018), *available at https://fas.org/sgp/crs/misc/R45097.pdf* (last visited July 26, 2019).

[421] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51166 (proposed Oct. 10, 2018).

[422] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51166 (proposed Oct. 10, 2018).

[423] *See* PRWORA, Public Law 104–193 (Aug. 22, 1996). *See* HHS, Office of Family Assistance, 2014 Child Care Reauthorization and Opportunities for TANF and CCDF (Feb. 19, 2016), available at *https://www.acf.hhs.gov/ofa/resource/tanf-acf-im-2016-02-2014-child-care-reauthorization-and-opportunities-for-tanf-and-ccdf* (last visited July 26, 2019).

[424] See U.S. Department of Health and Human Services, Temporary Assistance For Needy Families, 12th Report to Congress Fiscal Years 2014 and 2015, available at *https://www.acf.hhs.gov/sites/default/files/ofa/12th_annual_tanf_report_to_congress_final.pdf* (last visited July 23, 2019).

[425] HHS, Child Welfare Information Gateway, Temporary assistance for Needy Families (TANF), available at *https://www.childwelfare.gov/topics/management/funding/program-areas/prevention/federal/nondedicated/tanf* (last visited July 26, 2019).

stated that in the FY 2017, approximately one in four Washington residents needed cash, food, child support, child care, and other services and that each day, more than two million individuals receive the support and resources they need from the state to transform their lives. The commenter stated that Washington invests general state funds to assist individuals and families who are ineligible for Federal programs to include lawfully present non-citizens who fail to meet federal eligibility qualifications established in the PRWORA. The commenter described the following programs: State Family Assistance; Food Assistance Program for Legal Immigrants; Aged, Blind, or Disabled Cash Assistance; Pregnant Women Assistance; Consolidated Emergency Assistance Program; Refugee Cash Assistance; Housing and Essential Needs Referral; Diversion Cash Assistance; and State Supplemental Payment. The commenter indicated that the rule would undermine the success of these programs that involve cash or non-monetized benefits and eligible applicants may refuse to receive these benefits.

Response: DHS appreciates the comments; however, DHS has determined that considering state cash assistance in the rule, consistent with the 1999 Interim Field Guidance, is important in ensuring that aliens are self-sufficient and rely on their own capabilities and the resources of their families, their sponsors, and private organizations. The programs listed by the commenter that provide cash assistance would be considered public benefits in the public charge inadmissibility determination even if the funding is provided by the state unless they are provided to individuals not subject to public charge such as Refugee Cash Assistance or are not for general income maintenance (*e.g.,* if they are not means-tested or if they are provided for some specific purpose that is not for food and nutrition, housing, or healthcare). For example, LIHEAP (Low Income Home Energy Assistance Program) and emergency disaster relief would not be considered as a public benefit in the public charge inadmissibility determination even though they may be considered as a cash or cash equivalent benefits.

e. Supplemental Nutrition Assistance Program

Comment: Many commenters stated that the rule's inclusion of public benefits such as SNAP affects other public benefits including children's ability to access other needed benefits, particularly at school. The commenters explained that some benefits received at school (*e.g.,* free school meals) are linked to enrollment in SNAP benefits and could be impacted. A commenter stated that the proposed rule is inhumane, affecting families' ability to access SNAP to get the adequate food and nutrition they need. The commenter stated that hunger and malnutrition affects a person's ability to focus, function, and fight off disease and that hunger is already a serious problem in the United States. The commenter stated that aiding the hunger epidemic through the consideration of SNAP is against the public interest and the progression of our society. A commenter said the onerous restrictions initially placed on immigrant participation in SNAP during the 1996 reforms were reversed at the next available opportunity—the 2002 Farm Bill—which illuminates the sound public policy of ensuring that every family living in the United States has access to the resources necessary to feed their children.[426] A commenter stated that only 40 percent of eligible citizen children living in households with immigrants received SNAP benefits after changes to immigration and welfare law in the 1990s.

Response: DHS appreciates the comments and recognizes the importance of SNAP. DHS also acknowledges that some people may choose to disenroll from SNAP. However, this rule does not change the eligibility requirements of SNAP and does not prohibit individuals from receiving SNAP. In addition, this rule does not include school lunch or breakfast programs in the definition of public benefit. Further, the expansion of SNAP provisions for children under 18 established by the 2002 Farm Bill,[427] is only applicable to the five-year waiting period; therefore children who become lawful permeant residents do not need to wait five years before being eligible for SNAP.[428] However, DHS will consider SNAP as part of the public charge inadmissibility determination. DHS has determined that considering SNAP is important in ensuring that aliens are self-sufficient and rely on their own capabilities and the resources of their families, their sponsors, and private organizations. DHS believes that even though children and schools may no longer benefit from direct certification for school nutrition programs, a child's disenrollment from SNAP due to this rule would likely have no effect on the child's eligibility for school nutrition programs, and would not stop the child and school from accessing these programs through existing enrollment processes other than direct certification. This rule would not prevent a child from applying for or receiving any school related nutrition program.

Comment: A couple of commenters said the rule would violate the prohibition in Section 8(b) of the Food and Nutrition Act from considering SNAP benefits as income or resources. For example, commenters stated that the inclusion of SNAP is inconsistent with the SNAP statute that states that ''the value of benefits that may be provided under this chapter shall not be considered income or resources for any purpose under any Federal, State, or local laws.'' Commenters also stated that the inclusion of SNAP is inconsistent with congressional intent to expand SNAP eligibility to immigrant children. Similarly, a commenter stated that SNAP should be excluded from the public charge definition because the legislative history of SNAP indicates that SNAP was intended to be supplemental in nature. The commenter suggested that it would be unreasonable to consider receipt of a supplemental benefit to be sufficient to render a person a public charge. Discussing the legislative history surrounding the past four Farm Bills, a commenter stated that SNAP enjoys bipartisan support and Congress has rejected efforts to reduce its reach. The commenter stated that the proposed rule would reduce benefits for low-income children of immigrant parents and that this was inconsistent with congressional intent. A commenter said the onerous restrictions initially placed on immigrant participation in SNAP during the 1996 reforms were reversed at the next available opportunity—the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill)—which illuminates the sound public policy of ensuring that every family living in the United States has access to the resources necessary to feed their children.

Response: DHS disagrees that the rule is contrary to congressional intent. The fact that Congress has expanded which aliens can receive certain public benefits does not indicate a congressional intent that those benefits should not be considered in determining public charge. The rule abides by the statutory requirement as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and is consistent with congressional policy statements relating to self-sufficiency in 8 U.S.C. 1601. In these policy statements, Congress confirmed that the

[427] *See* Public Law 107–171, section 4401, 116 Stat. 134, 333 (May 13, 2002).

[428] *See* 8 U.S.C. 1612(a)(2)(J).

immigration policy continues to be that, ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' [429]

Further, DHS disagrees that the inclusion of SNAP as one of the designated public benefits violates the Food and Nutrition Act of 2008. While Federal law allows certain qualified alien children under 18 to receive SNAP benefits,[430] this rule does not prohibit anyone from receiving a benefit for which they qualify. However, Congress did not prohibit the consideration of public benefits as part of any of the factors to be considered in the public charge inadmissibility determination. DHS believes the use of certain benefits is appropriate to consider in determining public charge inadmissibility. To implement Congress' requirement to administer the public charge ground of inadmissibility, DHS inevitably must consider benefits which individuals are eligible to receive, as did the 1999 Interim Field Guidance. DHS believes the rule strikes an appropriate balance as to which benefits are considered.

Further, DHS disagrees that the rule violates the restrictions in section 8(b) of the Food and Nutrition Act, 7 U.S.C. 2017(b). That section provides that the value of SNAP benefits ''shall not be considered income or resources for any purpose under any Federal, State, or local laws.'' [431] The rule does not consider SNAP as income or resources. The rule explicitly excludes the value of public benefits including SNAP from the evidence of income to be considered.[432] Likewise, the consideration of the assets is limited to cash assets and resources and other assets and resources that can be converted into cash within 12 months.[433] Assets and resources do not include SNAP benefits, which are not cash, and selling SNAP benefits is illegal.[434]

Comment: Several commenters said that this rule conflicts with USDA's 1999 input as part of the 1999 proposed rule,[435] which advised that special nutrition programs should not be considered in public charge analysis. A commenter cited to the 1999 Interim Field Guidance, and stated that historically, the receipt of SNAP benefits (or the typical use of Medicaid) does not indicate that an immigrant is or is likely to become primarily dependent on the Government for subsistence. The commenter stated that to qualify for benefits, a SNAP household's income generally must be at or below 130 percent of FPG, the household's net monthly income (after deductions for expenses like housing and childcare) must be less than or equal to 100 percent of the FPG, and its assets must fall below limits identified in Federal regulations. The commenter further stated that the average monthly benefit per household is $253, and the average monthly benefit per person is $125 per month, or $1.40 per meal.

Response: As indicated in the proposed rule, DHS determined that receipt of SNAP is relevant to the determination of whether or not the alien is self-sufficient, and therefore not likely to become a public charge. The 1999 proposed rule, and the associated letters, related to a proposed definition of public charge that this rule would change. Furthermore, while INS consulted with the relevant public benefit granting agencies in 1999, DHS was not bound by those agencies' recommendations, but adopted them based on its interpretation of the term public charge, as well as certain public policy objectives articulated in that rule. DHS believes including the program is consistent with Congress' intention that aliens should be self-sufficient.[436] DHS recognizes that some public benefits have higher income thresholds than the income thresholds that this rule identifies as most relevant to the totality of the circumstances determination. However, the general income threshold of 125 percent of the FPG in the public charge totality of the circumstances determination is just one factor; DHS will not exclude consideration of any benefit that does not match that threshold.

Comment: One commenter noted that the rule is inconsistent with SNAP eligibility. Commenters stated that the proposed rule undermines congressional intent and the longstanding Federal commitment to helping those who struggle to have enough healthy food. Commenters stated that the proposed rule is inconsistent with clear congressional intent regarding eligibility for means-tested programs because it undermines those very rules set by Congress in law. One commenter stated that ''Congress has made explicit choices to expand eligibility (or permit states to do so),'' and increase immigrant access to programs like SNAP, CHIP and Medicaid, and therefore, ''[t]he administration must defer to [c]ongressional intent on this issue.''

Response: DHS does not agree that the inclusion of SNAP as a public benefit considered in the public charge inadmissibility determination is inconsistent with congressional intent. The rule intends to abide by the statutory requirement as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and consistent with congressional statements relating to self-sufficiency in 8 U.S.C. 1601: Specifically, that, ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' [437] As discussed in the NPRM, benefits directed toward food and nutrition, housing, and healthcare are directly relevant to public charge inadmissibility determinations, because a person who needs the public's assistance to provide for these basic necessities is not self-sufficient.[438] In addition, these benefits account for significant Federal expenditure on low-income individuals and bear directly on self-sufficiency, as discussed in the NPRM.[439]

Comment: A commenter stated that the proposed rule's characterization of individuals receiving SNAP benefits even for modest periods of time as a public charge is inconsistent with extensive research showing that SNAP provides supplemental assistance to a large number of workers, both while they are employed in low-paying jobs and during brief periods of unemployment. The commenter stated that most non-disabled adults who participate in SNAP, including eligible immigrants, work in a typical month or within a year of that month. Specifically, the commenter asserted that over half of the individuals who

[429] *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

[430] *See* 8 U.S.C. 1612(a)(2)(J).

[431] Congress has also exempted children under 18 from sponsor deeming requirements for purposes of SNAP receipt, 7 U.S.C. 2014(i)(2)(E), but this provision does not affect the core reimbursement obligation. In the latter respect, this provision is materially different than the CHIPRA provision regarding Medicaid for children under 21 and pregnant women, discussed above.

[432] *See* 8 CFR 212.22(b)(4)(ii)(A) & (C) (''excluding any income from public benefits'').

[433] *See* 8 CFR 212.22(b)(4)(ii)(D) & (E).

[434] *See* 7 U.S.C. 2024(b).

[435] *See* Inadmissibility and Deportability on Public Charge Grounds, 64 FR 28,676, 28,688 (proposed May 26, 1999).

[436] *See* 8 U.S.C. 1601(1).

[437] *See* Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

[438] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51159 (proposed Oct. 10, 2018).

[439] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51166 (proposed Oct. 10, 2018).

were participating in SNAP in a typical month in mid-2012 were working in that month, and 74 percent worked in the year before or after that month. Similarly, many other commenters stated that the large majority of SNAP recipients who can work do work.

Response: DHS recognizes that people who are working may also lack self-sufficiency. The person's employment does not negate that the person is receiving the public benefit and the employment is not reimbursing the public benefit-granting agency for the cost of the public benefit. Under this rule, DHS would not treat past receipt of SNAP—or any other benefit—as outcome-dispositive. Instead, will assess such past receipt in the totality of the circumstances, to determine whether the alien is likely to become a public charge in the future.

CalFresh

Comment: A commenter stated that one in ten Californians receive nutrition assistance through CalFresh, which is California's SNAP program. The commenter stated that CalFresh is California's food stamp program and increases the food buying power in low income households. The commenter stated that if this proposed rule is enacted, school districts will see more children coming to school hungry because noncitizen families, regardless of whether the rule would affect their situation, will be afraid to apply for food stamps, either by deciding not to enroll, or by disenrolling current recipients.

Response: As CalFresh is the Federally-funded SNAP program under the State of California, it would be considered as a public benefit under this rule. As discussed with respect to SNAP generally, CalFresh is relevant to the determination of whether or not the alien is self-sufficient, and therefore not likely to become a public charge. DHS understands that some people may disenroll from SNAP/CalFresh and other SNAP funded State benefits. However, this rule does not change the eligibility requirements for these benefits and DHS believes that the inclusion of State SNAP benefits is consistent with congressional statements relating to self-sufficiency in 8 U.S.C. 1601.

f. Housing

Comment: Commenters opposed including project-based Section 8 housing in the definition of public charge, because the vouchers can help ease the burden of rent in high-cost cities, help alleviate homelessness, promote economic stability, allow the flexibility for families to pay for other necessities, and promote self-sufficiency. Commenters also provided information and data on the benefit of the programs. Many of these commenters stated that housing is a basic necessity and is or should be a human right. Several commenters discussed the administrative burden and costs the potential rule will have on housing providers, including local rule makers, housing agencies, and private landlords who administer public vouchers, such as the dissemination of information to tenants and providing them with evidentiary information. Other commenters raised concerns that DHS did not sufficiently address the potential costs to the housing market, including the inundation of homeless shelters, and the loss of Government funds going to the private market. A commenter raised concerns that the rule will divert funds from direct housing and resident services to help U.S. Department of Housing and Urban Development (HUD) residents understand the new rule.

Response: DHS appreciates the comments and recognizes the importance of housing programs. DHS has determined that considering housing programs, such as Section 8 Vouchers, Section 8 Rental Assistance and public housing, in the rule is important in ensuring that aliens are self-sufficient and rely on their own capabilities and the resources of their families, their sponsors, and private organizations. These programs have high expenditure and relate to the basic living need of housing, and therefore the receipt of such housing related public benefit suggests a lack of self-sufficiency.[440] DHS will therefore consider the housing programs listed in the rule in the public charge inadmissibility determination. The rule intends to abide by the statutory requirement as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and be consistent with congressional statements relating to self-sufficiency in 8 U.S.C. 1601. As Congress indicated, the immigration policies continue to be that, ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' [441] However, housing programs that provide mortgage assistance or credits will not be considered in the public charge inadmissibility determination.

Comment: A commenter stated that receipt of a housing subsidy does not on its own accurately measure self-sufficiency, citing that 34 percent of assisted households are working and contributing to their housing costs. The commenter also stated that housing programs do not constitute an incentive for immigration. The average number of months a household spends on an agency waiting list before being admitted to the public housing or housing choice voucher program is 18 and 32, respectively. A commenter also stated that rental assistance is best understood as a supplemental benefit that reduces housing costs for low-income households but does not provide support for all of an individual's basic needs, instead recipients are generally required to provide housing costs up to 30 percent of their income. A commenter stated that a small share of individuals and households eligible for housing assistance actually receive it because of local housing conditions, wait list sizes, and preferences, DHS will not be able to predict that someone seeking status adjustment or lawful entry is likely to receive housing benefits.

Response: DHS understands that there are many conditions that may affect whether a person ultimately receives public housing. As previously indicated, DHS has determined that considering housing programs, such as Section 8 Vouchers, Section 8 Rental Assistance, and public housing, in the rule is important in ensuring that aliens are self-sufficient and rely on their own capabilities and the resources of their families, their sponsors, and private organizations. As previously indicated, the past receipt of one public benefit will not on its own make a person inadmissible based on public charge grounds. Instead, DHS would review all the factors in the totality of the circumstances.

Comment: Some commenters stated that, by including housing programs, the rule directly contradicts the mission of public housing as public housing programs are meant to serve families and provide for housing.

Response: DHS appreciates that the mission of public housing is to provide low-income affordable housing to families. DHS also has a mission to abide by congressional mandates to review the inadmissibility of all aliens including based on public charge and congressional statements relating to self-sufficiency in 8 U.S.C. 1601.

Comment: A commenter stated that the rule would waste affordable housing

[440] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51167 (proposed Oct. 10, 2018).

[441] *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

resources, including subsidized rental housing programs such as Low-Income Housing Tax Credit (LIHTC) housing, Section 515 rural housing, and Section 514/516 farm labor housing, leading to especially severe, negative impacts in rural California, and the commenter stated that the rule would further destabilize the farmworker population in our agricultural regions. The commenter indicated that from 1964 to 2004, Section 514 and 516 housing programs managed by USDA financed nearly 35,000 homes for farmworkers and rehabilitated thousands more and that that in the period that followed, farmworker housing development continued to be backed by annual Federal appropriations in the tens of millions of dollars. The commenter stated that housing programs have had varying eligibility requirements that have allowed individuals with a variety of immigration statuses and mixed-status families to secure stable, affordable housing; and the rule would therefore lead to significant dislocation of immigrant families, away from housing that was built precisely for their use.

Response: This rule does not include LIHTC housing, Section 515 rural housing, and Section 514/516 farm labor housing as public benefits. Further, although the rule may affect whether individuals apply for housing, the rules does not change the eligibility requirements for any public benefit. DHS also notes that under 20 CFR 655.122(d)(1), the employer must provide housing at no cost to the H–2A workers (temporary workers performing agricultural services), and those workers in corresponding employment who are not reasonably able to return to their residence within the same day. Further, under 20 CFR 655.122(d)(4), if public housing provided for migrant agricultural workers under the auspices of a local, county, or State government is secured by the employer, the employer must pay any charges normally required for use of the public housing units directly to the housing's management. DHS would not consider such housing under the definition of public benefit as the employer is required by regulation to pay for any associated costs.

Comment: A commenter said data refuted the notion that immigrant families rely disproportionately on all forms of public assistance, citing a study indicating that just 4.2 percent of immigrant households with children utilize housing assistance as compared to 5.3 percent of U.S.-born households. A couple of commenters cited research showing that most able-bodied adults receiving rental assistance are employed, arguing that they are therefore self-sufficient.

Response: DHS appreciates the comment and recognizes that the availability of public benefits for aliens is limited. The purpose of the public charge rule is, however, to ensure that those seeking admission to or adjustment of status in the United States do not become public charges by using the public benefits in the future. The public charge inadmissibility determination is correspondingly one of an alien's likelihood of becoming a public charge through receipt of benefits in the future even if the person is employed. Further, as previously indicated, DHS recognizes that people receiving public benefit may nonetheless be working, but as they are receiving public benefits, such aliens are not self-sufficient. Therefore, DHS will continue to consider the public benefits as listed in the rule.

Comment: A commenter stated that DHS should specify in its rule that individuals in mixed-status families who are not recipients of Federal financial housing assistance do not receive a public benefit for public charge determination purposes.

Response: DHS will not consider a person who lives in any one of the listed housing programs as receiving public benefits unless the public benefit-granting agency actually designated the benefit for the applicant as a beneficiary, such as in a contract, lease, or other documentation.

Comment: A commenter stated that including housing to the public charge determination will cause recipients of public housing to be treated differently due to their immigration status, in contradiction to the Fair Housing Act [442] of 1968's prohibition against discrimination.

Response: DHS does not believe that the rule is contrary to the antidiscrimination provisions of the Fair Housing Act.[443] The antidiscrimination provisions prohibit discrimination on grounds covered by the Fair Housing Act by lenders, property sellers, and others covered by that law. In contrast, this rule is applicable in the immigration context where an alien must establish that he or she is admissible and is not inadmissible as likely at any time in the future to become a public charge under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4).

Comment: A few commenters asked whether homeownership programs are included under the rule.

Response: The rule does not consider homeownership programs, such as the Housing Choice Voucher Homeownership program,[444] in the public charge inadmissibility determination. DHS will only consider public housing benefits as listed in the rule.

Comment: A commenter requested that DHS add benefits received pursuant to Project Rental Assistance Contracts (PRAC), USDA rental assistance projects, or all HUD benefits to the public benefits definition.

Response: DHS appreciates the comment, however, DHS will not include additional housing programs. The programs listed by the commenters have low expenditures.[445]

In addition, DHS has removed references to 42 U.S.C. 1437u, the Family Self-sufficiency program, and 24 CFR part 402 Section 8 Project-Based Contract Renewal, which is a program associated with housing but is not itself a housing program.

Comment: A commenter associated with the City of Los Angeles reported that the beneficiaries of many city housing programs and policies will be directly negatively impacted by the proposed public charge rule. The

[442] *See* 42 U.S.C. 3604.

[443] *See* Title VIII (Fair Housing Act, as amended) of the Civil Rights Act of 1968, Public Law 90–284, 82 Stat. 73 (April 11, 1968) (codified in 42 U.S.C. 3601–19).

[444] *See* 24 CFR part 982, subpart M, 24 CFR 982.625–982.643. *See* also *HUD.gov,* Homeownership Vouchers, available at *https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/homeownership* (last visited April 19, 2019).

[445] For example, Supportive Housing for the Elderly, the 2019 Request for Outlays is $659,000,000, *see* HUD, Housing, Housing For The Elderly (Section 202), 2019 Summary Statement and Initiatives, available at *https://www.hud.gov/sites/dfiles/CFO/documents/25%20-%20FY19CJ%20-%20HSNG%20-%20Housing%20for%20the%20Elderly%20%28Section%20202%29%20-%20Updated.pdf* (last visited May 31, 2019); for Supportive Housing for Persons with Disabilities, the 2019 Request for Outlays is $188,000,000, Housing, Housing For Persons With Disabilities (Section 811), 2019 Summary Statement and Initiatives, available at *https://www.hud.gov/sites/dfiles/CFO/documents/26%20-%20FY19CJ%20-%20HSNG%20-%20Housing%20for%20Persons%20with%20Disabilities%20%28Section%20811%29%20-%20Updated.pdf* (last visited May 31, 2019); for Housing for Persons With AIDS (HOPWA), the 2019 Request for Outlays is $353,448,000, *see* Community Planning And Development Housing Opportunities For Persons With Aids 2019 Summary Statement And Initiatives, available at *https://www.hud.gov/sites/dfiles/CFO/documents/17%20-%20FY19CJ%20-%20CPD%20-%20Housing%20Opportunities%20for%20Persons%20with%20AIDS%20%28HOPWA%29.pdf* (last visited May 31, 2019); and for USDA Multi-Family Housing Rental Assistance, the 2019 appropriated funds is $1,331,400,000, *see* FY 2019 Appropriated Funds, available at *https://www.rd.usda.gov/newsroom/fy2019-appropriated-funding* (last visited May 31, 2019).

commenter cited programs such as permanent support housing, including Section 8 Vouchers; Housing Opportunities for Persons With HIV/AIDS; Domestic Violence Shelter Operations; and Family Source Center services. The commenter indicated that the rule will either dissuade immigrants who legally qualify for public assistance from seeking the necessary services or lead to high level of disenrollment. The commenter indicated that some program officials could not confidently offer aliens clear guidance on the immigration consequences of accessing certain services. The commenter stated that the rulemaking would exacerbate homelessness and has already led to a ''chilling effect.'' The commenter also stated that the proposed rule was inconsistent with the commenter's commitment to ensure fair housing for its residents, and threatens its ability to enforce housing rights for local residents. The commenter stated that such commitment includes a requirement by HUD to certify that it would affirmatively further fair housing.

Response: The public charge rule does not prevent aliens from obtaining benefits they are legally entitled to under PRWORA. Given Congress' strong interest in an immigrant's self-sufficiency [446] and based on the fact that Congress did not exempt the receipt of such benefits from consideration for purposes of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4),[447] DHS will consider public benefits as listed in the rule. DHS notes that other housing programs not listed in the rule, such as Section 202 Supportive Housing for the Elderly, Section 811 Supporting Housing for Person with Disabilities, Housing Opportunities for Persons With AIDS (HOPWA), USDA Multi-Family Housing Rentals, and home loan and grant programs, will not be considered in the public charge inadmissibility determination.

Comment: A commenter asked whether the following benefits received as part of a lead paint abatement program would be considered public benefits for purposes of public charge; any stipend received as part of the program, including stipends or gift cards that are offered to encourage families to get their children tested for lead; the use of a city-operated lead safe house to which families may move during renovation of their home to remove lead; or receipt of HUD grant funds used to pay a landlord of a rental unit to rehabilitate a unit that has been found to have poisoned a child. The commenter indicated that many of the funds used for lead abatement programs are HUD grant dollars, and to the extent that these payments are made available based upon the income of the renter, they could have an impact on the renter from a public charge standpoint.

Response: DHS will not consider any subsidies or grants provided to test for lead paint or to ameliorate homes with lead paint issues in the public charge determination. DHS will only consider those public housing programs enumerated in 8 CFR 212.21(b). HUD's Lead-Based Paint and Lead Hazard Reduction Demonstration Grant Programs are regulated under 24 CFR part 35, and do not fall under the list of enumerated benefits. Therefore, subsidies or grants for lead abatement programs are not considered a public benefit for purpose of the public charge inadmissibility determination.

g. Institutionalization

Comment: A commenter asked that institutionalization for long-term care be removed as a consideration in the public charge determination because the country has made progress with deinstitutionalization over the past several administrations. The commenter also stated that there is no evidence that people with significant disabilities are taking advantage of the Medicaid system. The commenter stated that the rule's potential effects on individuals with disabilities created an implication that individuals with disabilities were not welcomed citizens of the United States, and stated that this was an ''appalling message.'' A commenter stated that despite deinstitutionalized supports and services becoming more and more prevalent, most people with disabilities receiving any Medicaid supports must first prove that they are at risk of institutionalization. The commenter stated that the requirement to prove risk of institutionalization applies to virtually every individual with an intellectual and/or developmental disability in the United States regardless of immigration status. The commenter stated that inclusion of institutionalization in the public charge rule would thus automatically cast a mark against a person with a disability under the proposed rule.

Response: DHS appreciates the comments. DHS does not believe that all individuals with an intellectual or developmental disability will necessarily be institutionalized, be likely to be institutionalized, or be inadmissible based on public charge grounds. As explained in the NPRM,[448] the U.S. Government subsidizes health insurance, which pays for expenses associated with the institutionalization. The receipt of these benefits to provide for the cost of institutionalization indicates a lack of self-sufficiency in satisfying basic living needs of food and nutrition, housing, and healthcare. Additionally, institutions are residential facilities that assume the total care of the basic living requirements of individuals who are admitted, including room and board. However, DHS understands that the language in the NPRM could be interpreted as inclusive of other public benefits not listed in the rule, such as Social Security retirement benefits or Medicare. Therefore, DHS has removed the reference to long-term institutionalization within the definition of public benefit, as the long-term institutionalization benefits that DHS has in the past considered, and intends to consider under this rule, are already part of the public benefit definition, *i.e.,* TANF, SSI, and Medicaid.

Further, DHS disagrees that continuing to consider institutionalization for long-term care at government expense indicates that the United States does not welcome people with disabilities. DHS reiterates that a child or a person who is severely disabled or who has a severe medical condition and who lives in a long-term care facility at government expense would not be found inadmissible on the public charge ground solely on account of the past institutionalization. Instead, DHS will, in the totality of the circumstances, take into account whether there are sufficient assets and resources to provide for his or her future care in a privately-financed setting, including resources provided by guardians or relatives who may have the ability to support the alien and provide for the alien's future care.

Comment: One commenter stated that most of the population would eventually require long-term care in nursing homes. A commenter stated that including benefits provided for institutionalization is a virtually blanket conclusion that all immigrants are ''likely'' to become public charges, because a huge percentage of aging individuals in the United States will ultimately require some form of institutional care. The commenter cited to data that, according to the commenter, indicated nursing homes alone will ultimately care for 35 percent of the population. The commenter said

[446] As expressed in 8 U.S.C. 1601.

[447] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[448] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51171–72 (proposed Oct. 10, 2018).

considering these services as public benefits would render all immigrants inadmissible. A commenter stated that institutionalization cannot be predicted and asked what would happen if an alien previously deemed admissible later became disabled, but documented that they will not need benefits at any time in the future.

Response: DHS understands that people may need long-term care with age; however, DHS does not believe that everyone will need to be supported by the Government. For example, an alien or his or her family may have sufficient assets or resources to ensure that the alien has the necessary care, even in a circumstance where the alien cannot work or must be institutionalized. Or the alien could have adequate insurance to support institutionalization for long-term care, whether through a private insurer or through Medicare.

The public charge inadmissibility determination calls for a determination that it is more likely than not, in the totality of the circumstances, that the alien will become a public charge. For this reason, DHS would consider it unreasonable to assume, for purposes of the public charge determination, that all individuals will eventually live in nursing homes subsidized by the government. USCIS will not deny a person based on public charge solely because of a remote possibility that a person will need such care in advanced age. DHS also clarifies that the public charge inadmissibility determination does not necessarily involve a review of whether the person has actually received a public benefit after DHS has made its determination. DHS further understands that the language in the regulation may indicate that other public benefits not otherwise listed that may be used to fund institutionalization, including State benefits, Social Security retirement benefits, SSDI, or Medicare. When referring to public benefits used for long-term care at government expense, the 1999 Interim Guidance listed SSI, TANF, and Medicaid as examples of public benefits for long-term institutionalization at government expense that would be considered in the public charge inadmissibility determination.[449] Likewise, under this rule, DHS would consider such benefits as part of long-term institutionalization at Government expense and did not intend to consider other benefits may be used such as Social Security retirement benefits, SSDI, Medicare or veteran's benefits. Social Security retirement benefits, SSDI, Medicare and veteran's benefits are considered earned benefits in that individuals pay into the programs as part of their employment and must work for a certain period of time before being eligible. Therefore, DHS is removing the provision for public benefits for long-term care at government expense as a separate provision in the definition of public benefits. Because the benefits considered for institutionalization under the rule are already within the rest of the list in the public benefit definition, DHS does not believe the additional provision is necessary and its deletion avoids confusion with other benefits that are not considered in the rule. Further, when a person is institutionalized and the person or a relative is paying for any cost associated with the institutionalization without the use of public benefits, DHS would not consider the institutionalization as a public benefit being received. DHS notes that institutionalization would otherwise be generally be considered as part of the health factor as described in the rule.

h. Medicaid

Comment: Many commenters stated that Medicaid should not be considered in public charge determinations. Commenters stated that the rule contradicts one of PRWORA's main policies, which extends Medicaid benefits to immigrants, as well as other laws that allow certain children and pregnant women to access Medicaid without a waiting period. One commenter stated that DHS should exempt up to two years of Medicaid when the individual has shown past ability and earning potential. The commenter did not provide a reason for the proposed two-year period, but stated that when a person applies for health insurance on the Affordable Care Act (ACA) marketplace, and is eligible for Medicaid, ''the marketplace automatically forwards an application on their behalf to Medicaid, even if they never intended to apply for Medicaid, leaving them with no choice in the matter at all!'' The commenter did not provide evidence to support his statement regarding how the ACA marketplace works. Some commenters supported the inclusion of Medicaid in the rule.

Response: DHS will continue to consider Medicaid. DHS agrees that Medicaid is beneficial to those who receive it. DHS, however, seeks to better ensure that applicants for admission to the United States and applicants for adjustment to lawful permanent resident status, who are subject to the public charge ground of inadmissibility or are nonimmigrants applying for an extension of stay or change of status, are self-sufficient and do not rely on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, sponsors, and private organizations.[450] Further as previously discussed, the public charge inadmissibility rule is not inconsistent with PRWORA, nor does it contravene or overrule PRWORA.[451]

As indicated in Table 10 of the NPRM,[452] the total Federal expenditure for the Medicaid program overall is by far larger than any other program for low-income people.[453] In addition, the focus of this public charge rule is to ensure self-sufficiency that covers the basic necessities of life, such as food and nutrition, housing, and healthcare.[454] Medicaid is a federal benefits program that provides for a person's health insurance to cover the costs of healthcare, which, is a basic necessity of life that is directly relevant to public charge.

However, DHS credits the many comments that DHS received regarding the receipt of Medicaid and CHIP by children and pregnant women, as well as the states that have expanded their Medicaid programs to allow access to such groups without a waiting period. DHS has decided to exclude consideration of Medicaid received by all aliens under the age of 21. The age limit of 21 for exempting Medicaid receipt from consideration reflects Congressional intent to allow states to extend coverage to this population (along with pregnant women as discussed below) without requiring them to wait five years as required by PRWORA, and without triggering a reimbursement requirement for the alien's sponsor under an affidavit of

[449] *See* Inadmissibility and Deportability on Public Charge Grounds, 64 FR 28689 (May 26, 1999).

[450] *See* 8 U.S.C. 1601(2).

[451] *See* Part III, Section D, Comments Regarding Legal Authority/Inconsistency with Congressional Intent.

[452] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51160 (Oct. 10, 2018).

[453] *See* Table 26–1 Policy, Net Budget Authority by Function, Category, and Program, available at *https://www.whitehouse.gov/wp-content/uploads/2018/02/26-1-fy2019.pdf* (last visited July 26, 2019). Expenditure amounts are net outlays unless otherwise noted. *See also* Gene Falk et al., Cong. Research Serv., R45097, Federal Spending on Benefits and Services for People with Low Income: In Brief (2018), *available at https://fas.org/sgp/crs/misc/R45097.pdf* (last visited July 26, 2019). Note however that neither HHS nor DHS are able to disaggregate emergency and non-emergency Medicaid expenditures. Therefore, this rule considers overall Medicaid expenditures.

[454] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51159 (proposed Oct. 10, 2018).

support.[455] The age limit also aligns with the limit most states offer free public education to children, and provides appropriate certainty to educators, parents, and children with respect to use of health care programs by children.[456]

DHS recognizes Congress did not exclude children from the public charge determination. But as noted in the proposed rule, the fact that an alien received public benefits as a child is a relevant consideration when determining the likelihood that the alien will receive public benefits in the future. As alien children approach or reach adulthood, they may age out of eligibility for certain benefits, choose to disenroll from such benefits (for which their parents may have enrolled them), or increase their chances of becoming self-sufficient depending upon whether they acquire education and skills, secure employment, and accumulate assets and resources. As a consequence, past receipt of public benefits as a child may be less indicative of future receipt, as compared to past receipt as an adult.

DHS recognizes that Medicaid and CHIP benefits for children also provide for other services or funding for in-school health services and serve as an important way to ensure that children receive the vaccines needed to protect public health and welfare. In addition, children may be enrolled in Medicaid through the school system or other programs which are required by law to provide services which may affect school budgets.

In sum, while children are not exempt from public charge inadmissibility, there are strong legal and policy reasons to assume that Congress did not intend DHS to treat receipt of Medicaid by alien children under the age of 21 in the same way as receipt of Medicaid by adult aliens. Congress expressly authorized states to expand Medicaid eligibility for aliens under the age of 21 without a waiting period, and expressly provided that receipt of such Medicaid would not trigger a reimbursement application under an affidavit of support. Finally, Medicaid also funds the delivery of certain services through the educational system, which DHS intends to exempt. Therefore, DHS believes that it is appropriate to exclude Medicaid for individuals under the age of 21 from the public benefit definition.

In addition, and consistent with the foregoing, DHS has decided to exempt Medicaid received by pregnant aliens during pregnancy and during the 60-day period beginning on the last day of the pregnancy. This exemption aligns the rule with the exclusion of CHIP from consideration, as CHIP also provides coverage to pregnant women and children, and ensures parity under this rule for this population across two Federal benefits (Medicaid and CHIP). It also aligns the rule with the special treatment that Congress afforded children under 21 and pregnant women in under 42 U.S.C. 1396b(v)(4). Again, that authority allows states to extend coverage to pregnant women, and children under the age of 21, without regard to the 5-year limit under PRWORA, and without imposing reimbursement obligations on an alien's sponsor through an affidavit of support (as discussed above). DHS believes that Medicaid received by pregnant aliens, while providing a short-term benefit for the alien herself, in many cases ultimately benefits the U.S. citizen child(ren) who is born to such alien.

DHS appreciates the suggestion to incorporate a two-year ''exemption period'' for Medicaid. However, DHS will not include a two-year period in the rule. Although DHS agrees that through the health insurance marketplace, an eligible person may be *referred* for Medicaid eligibility, DHS understands that generally the referral must still be approved by the State and accepted by the potential beneficiary.[457] The person has a choice in accepting Medicaid through the health insurance marketplace. In addition, all individuals may voluntarily disenroll from Medicaid at any time.[458] As DHS will only consider Medicaid received after the effective date of the rule, and requires the alien to be likely to receive Medicaid (or other designated public benefits) above the threshold in order for the alien to be likely to become a public charge, DHS does not believe that a two-year ''exemption period'' is necessary.

Comment: Some commenters said the durational limits on the use of Medicaid did not align with how Medicaid recipients use the program, and said that health insurance should be treated differently than other welfare programs. A commenter stated that the proposed 12-month threshold for Medicaid would produce absurd results when applied to a real-world context. The commenter stated that some treatments and services are intensive and span months, if not years. For example, a Medicaid enrollee with cancer could have a debilitating year-long treatment regimen. The proposed rule would force such an individual into an impossible situation where continued treatment would count against them for immigration purposes. Some commenters said insurance through programs like Medicaid reduces the likelihood that an individual will become bankrupt, and that the proposed rule may cause previously self-sufficient individuals to become reliant on government assistance. One commenter stated that individuals may be enrolled in Medicaid by hospitals without their knowledge if they are in an accident or presented to the ER with a serious health condition. The commenter said that at times, the patients do not even know that they are being enrolled in Medicaid and just think they are being enrolled into a sliding scale program. The commenter stated that looking at past receipt of Medicaid is too complicated and unhelpful in determining if a person may become a public charge, and recommended that if DHS insists in including Medicaid then the period of time should be reduced to a look back of maximum 12 months.

Response: DHS disagrees that Medicaid as health insurance should be treated differently. Medicaid has a large federal expenditure impact, similar to other public benefit programs included in the rule.[459] DHS believes the benefit programs considered in the public charge determination are appropriate as they directly relate to self-sufficiency, since they are providing basic necessities of life such as food and nutrition, housing, and healthcare. Because of the nature of the public benefits that would be considered under this rule—which are generally means-tested and provide cash for income maintenance and for basic living needs such as food and nutrition, housing, and

[455] Children's Health Insurance Program Reauthorization Act of 2009, Pub. L. 111–3, section 214, 123 Stat. 8, 56 (Feb. 4, 2009) (Permitting States to Ensure Coverage Without a 5-Year Delay of Certain Children and Pregnant Women Under the Medicaid Program and CHIP) (codified as amended at 42 U.S.C. 1396B(v)(4)).

[456] State laws generally provide a maximum age limit for free public education. The limit ranges between 17 (Alabama) and 26 (Texas). As of 2017, 25 states allow for free public education until age 21. Department of Education, National Center for Education Statistics, Table 5.1 Compulsory school attendance laws, minimum and maximum age limits for required free education, by state: 2017 *https://nces.ed.gov/programs/statereform/tab5_1.asp* (last visited July 17, 2019)

[457] *See* Kalman Rupp and Gerald F. Riley, State Medicaid Eligibility and Enrollment Policies and Rates of Medicaid Participation among Disabled Supplemental Security Income Recipients, Social Security Bulletin, Vol. 76 No. 3, 2016, available at *https://www.ssa.gov/policy/docs/ssb/v76n3/v76n3p17.html (last visited June 14, 2019).*

[458] *See* CMS, Medicare-Medicaid Plan Enrollment and Disenrollment Guidance (June 14, 2013), available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMPFinalEnrollGuidance.pdf* (last visited July 26, 2019).

[459] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51160 (proposed Oct. 10, 2018).

healthcare—DHS believes that receipt of such benefits is an important factor to consider, in the totality of the circumstances, when making a public charge determination. This is because a person with limited means to satisfy basic living needs who uses government assistance to fulfill these needs frequently will be dependent on such assistance to such an extent that the person is not self-sufficient. Medicaid, as a government subsidized health-insurance program, provides means to ensure sufficient healthcare. Regarding the concern that individuals may be enrolled in Medicaid without their knowledge when receiving emergency room services, DHS notes that the rule excludes consideration of emergency Medicaid. Additionally, individuals who are enrolled in Medicaid receive documentation informing them of their enrollment and may at any time disenroll from the public benefit.

DHS acknowledges the positive outcomes associated with public benefits programs, but the goals of programs such as Medicaid are different from the objectives of immigration in admission of aliens into the United States. The rule, therefore, abides by the statutory requirement as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and is consistent with congressional statements relating to self-sufficiency in 8 U.S.C. 1601. As Congress indicated, the immigration policy continues to be that, ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' [460] Therefore, the public charge inadmissibility ground and this rule serve to ensure that those coming to the United States will be self-sufficient.

Comment: One commenter opposed including Medicaid in the definition of public benefit and stated that such inclusion will harm the ability of disabled individuals to access reasonable accommodations. The commenter stated that such inclusion will result in individuals disenrolling from Medicaid and may adversely affect individuals' ability to obtain proof of disability from a doctor that is necessary to secure reasonable accommodations in housing. The commenter noted that such an individual, potentially with the assistance of social service or other organizations serving the individual, would have to find an alternative means of proving the disability. The commenter stated that costs and delays associated with obtaining such proof ''would lead to fewer tenants being allowed to bring forward the defenses to which they are legally entitled, and would lead to further evictions in the greater Boston area.''

Response: DHS recognizes that an individual who disenrolls from Medicaid (or foregoes initial enrollment) as a consequence of this rule may face additional challenges in providing proof of disability for purposes of reasonable accommodation. As noted by the commenter, however, Medicaid is not a precondition to obtaining such proof of disability. An alien who relies on Medicaid for healthcare (including potential documentation of disabilities) for the period of time that meets the requisite threshold (more than 12 months in the aggregate during any 36-month period) may be found to be a public charge, notwithstanding that such outcome may have negative downstream effects for such alien or others.

Comment: A couple of commenters said there was no reason to distinguish between private and public health insurance in making a determination about self-sufficiency, and that private insurance for working-class people is often subsidized by the government through such mechanisms as special tax treatment for employer-provided insurance and refundable tax credits for private health insurance plans under the ACA.

Response: DHS appreciates the comments but disagrees. Medicaid can impose substantial costs on multiple levels of government and generally indicates a lack of ability to be self-sufficient in satisfying a basic living need, *i.e.,* healthcare. As noted in the NPRM, by at least one measure, this program entails some of the largest overall Federal expenditure for low-income people, by far. Although DHS agrees that government subsidies for private health insurance plans may also be amenable to consideration for public charge purposes, DHS believes it is a reasonable approach to only designate Medicaid at this time.

Comment: Several commenters remarked that states have implemented programs, such as Medicaid Buy-In programs, to allow individuals with disabilities to retain the necessary Medicaid coverage while participating in the labor force. A commenter stated that Medicaid is one of many government programs that provide targeted assistance to individuals with disabilities. The commenter provided the example of New York, which created a Medicaid Buy-In Program for Working People with Disabilities specifically to allow working people with disabilities to earn more income without risk of losing their health insurance. The commenter stated that many people qualify for Medicaid because an injury or disability has made them unable to work. Medicaid often covers services that are unavailable through private insurance, such as medical equipment, long-term care, and certain specialist care services. The commenter stated that the NPRM undermines the goals of these programs by broadly including ''health'' as a factor in the public charge determination and by heavily weighting receipt of health-related benefits as a negative factor in public charge determinations without distinguishing Medicaid recipients with disabilities.

Response: DHS appreciates that some people may be eligible for Medicaid based on other eligibility criteria or a higher income threshold, however, such Medicaid programs would also be included within the definition of public benefit for the purposes of the public charge inadmissibility determination. DHS does not intend to undermine the goals of Medicaid or Medicaid Buy-In programs in this rule. However, Congress provided for the mandatory factors, including health.[461] The interpretation of the public charge provision has long included consideration of the alien's receipt of government-funded healthcare programs.[462] Medicaid Buy-In programs are optional state Medicaid programs for workers with disabilities who have earnings in excess of traditional Medicaid rules.[463] These programs are still using the same source of government funding; the main difference is that they contain different eligibility requirements, such as a higher income threshold. Further, DHS, as previously discussed, understands that people may be employed and still receive public benefits and are therefore not self-sufficient. Aliens should be

[460] *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

[461] *See* INA section 212(a)(4)(B), 8 U.S.C. 1182(a)(4)(B).

[462] *See, e.g., Ex parte Nunez,* 93 F.2d 41 (9th Cir. 1937).

[463] *See* Medicaid.gov, Medicaid Employment Initiatives, available at *https://www.medicaid.gov/medicaid/ltss/employment/index.html* (last visited June 24, 2019). *See also* for example, New York State, Medicaid Buy-in Program for Working People with Disabilities, available at *https://www.health.ny.gov/health_care/medicaid/program/buy_in/index.htm* (last visited June 24, 2019). In order to qualify under the New York State program, a person must have a disability as defined by SSA, be engaged in paid work, and have a gross income that may be as high as about $63,492 for an individuals and $86,575 for a couple, among other requirements.

obtaining private health insurance other than Medicaid in order to establish self-sufficiency.

Comment: A commenter indicated that the rule is unclear on the meaning of Medicaid and unclear whether programs that are funded only by the state and provided under the auspices of Medi-Cal would be considered Medicaid for the purposes of a public charge analysis.

Another commenter stated that Medicaid is a Federal-State program; it is funded jointly by the Federal Government and the States, and each state operates its own program within broad Federal guidelines. The commenter indicated that States have numerous options as to the people and benefits they cover and a great deal of flexibility in designing and administering their programs. The commenter stated that consequently, Medicaid eligibility and benefits vary widely from state to state. For example, the commenter stated that Wisconsin is the only non-expansion state to cover childless adults at any income level. The commenter further stated that immigration authorities would have no way of predicting which states individuals would likely live in throughout their lives and therefore would not know which income thresholds would be relevant to consider when making a public charge determination, potentially leading them to assume that most people could end up using Medicaid at some point.

Response: Medicaid is a Federal-State partnership under which the Federal Government provides matching funds to states for certain expenditures at varying percentages (depending on the state). The form of Medicaid covered by this rule is any Medicaid program operated under the authority of Title XIX of the Social Security Act Amendments of 1965 (Pub. L. 89–97), for which the state seeks reimbursement from the Federal Government. In other words, any Medicaid benefit for which a state seeks reimbursement from the Federal Government will be considered in the public charge determination regardless of which state administers the program. Medi-Cal is how the State of California delivers Medicaid to its residents.[464] Any Medi-Cal receipt will therefore be considered in the totality of the circumstances in the public charge inadmissibility determination, unless the Medi-Cal is provided to the alien under a state-only authority at no expense to the Federal Government. Medicaid administered by other states will also be considered in the public charge inadmissibility determination to the same extent as described above, regardless of the name used for Medicaid in such state. A state medical insurance program, funded exclusively by the state, is not included in the definition of public benefit under 8 CFR 212.21(b), and will not be considered as a public benefit in the public charge inadmissibility determination. To the extent that States give the same name to their Federal Medicaid program and the state-only funded health insurance program, aliens will not be required to report the receipt of the state-only funded health insurance. USCIS would assume that any Medicaid identified on the Form I–944 is Federal Medicaid.

Comment: A commenter agreed with the exception for school-based services, but said it underscores the need for clarification stating that public benefit programs and services provided to school children by public school systems will not be considered in immigration status determinations for a family member or member of the household. Moreover, the commenter said further clarification is needed that any application, documentation, or verification information collected by a public school for program eligibility, allocation, or qualification purposes would not be requested or subject to disclosure by the local education agencies or the student and their parents or guardians for DHS public charge consideration.

Response: DHS reiterates that only the public benefits listed in 8 CFR 212.21(b) are considered public benefits for purposes of the public charge inadmissibility determination. DHS also reiterates that under this rule, Medicaid-funded school-based benefits provided to children who are at or below the oldest age of children eligible for secondary education as determined under State law are not considered public benefits for purposes of the public charge determination, as are Medicaid-funded IDEA programs and Medicaid for children under the age of 21 are not included the are definition of public benefit. Additionally, public benefits received by household members are not considered in an alien's public charge inadmissibility determination.[465] Confidentiality or non-disclosure provisions relating to applications for or receipt of certain public benefits programs are generally governed by laws relating to the specific public benefits program and are not within the scope of this regulation. Further, as part of the public charge inadmissibility determination, DHS does not intend to request information from schools that was collected by such school for program eligibility, allocation, or qualification purposes. Instead the students, or students' parents or guardians would provide documentation related to any Medicaid or SNAP, or other public benefit, application, documentation, or verification information collected by a public school for program eligibility, allocation, or qualification purposes.

Individuals With Disabilities Education Act

Comment: Multiple commenters stated that children with special healthcare needs (disabilities) depend on Medicaid, and that while the proposed rule includes exceptions for services funded by Medicaid but provided through IDEA, no plan has been put forward that would enable this carve-out to work in practice.

Many commenters discussed the positive effects of children being enrolled in Medicaid and the ''chilling effect'' or disenrollment associated with the proposed rule, and warned that decreased participation in Medicaid would lead to decreased utilization of preventative services, worse health outcomes for families and children, and significant economic costs. Many commenters said the proposed rule's exemption of school-based health services was insufficient given the larger repercussions of the ''chilling effect'' and the likelihood that many children would be disenrolled. Some commenters indicated that under IDEA, schools serve as a health care provider reimbursed by Medicaid but are not eligible for reimbursement if a family chooses not to enroll their child. A commenter provided data on the funding school districts receive from Medicaid for school-based health services, and the numbers of students who benefit from these programs. The commenters pointed out that this funding is tied to the number of Medicaid-eligible students enrolled. Schools said they already struggle to receive consent for school-based, Medicaid-reimbursable services, and warned that the proposed rule would exacerbate this problem. A commenter expressed concern that, even though medically necessary special education services provided to eligible children at school would be excluded under the rule, the fear of being labelled a public charge would cause some immigrant

[464] *Ca.gov*, Medi-Cal, available at *https://www.dhcs.ca.gov/services/Medi-cal/pages/default.aspx* (last visited Mar. 29, 2019).

[465] If a household member is obtaining public benefits, however, that amount will not be counted toward the household's annual gross income determinations. *See* 8 CFR 212.22(b)(4)(ii)(A).

parents to refrain from securing these services for children. A few commenters were concerned that the proposed rule would worsen health outcomes, increase food insecurity, and reduce educational attainment.

A commenter supported the exclusion of benefits under IDEA, but stated that it remained concerned about these services being used against parents who refuse to sign a specific consent form. Multiple commenters stated that children with special healthcare needs, including children with disabilities, depend on Medicaid. These commenters indicated that children with special needs cannot and do not receive Medicaid for educational services alone and the exclusion of Medicaid-funded IDEA services will likely do little to encourage families who are fearful of participating in Medicaid to maintain their enrollment. A commenter stated that IDEA funding is often insufficient and requires states to rely on Medicaid to fill funding gaps. The commenter added that if schools lost Medicaid funding, it could result in special education and even general education services being withheld and the loss of school nurses, whose salaries are subsidized by Medicaid. (Special education assistance programs, such as the New Jersey Special Education Medicaid Initiative addressed by one of the commenters, are school-based Medicaid reimbursement programs that allow school districts to obtain federal reimbursement of actual costs of Medicaid covered services under the IDEA).[466] One commenter who generally supported the rule stated opposition to the Medicaid exclusion under IDEA and recommended that all disabilities should be individually assessed.

Response: DHS recognizes the public benefits listed in the rule may be associated with other programs and that eligibility for other programs or reimbursements to organizations may be dependent or automatically provided based on the receipt of one of the enumerated public benefits. DHS also understands that it is possible that a parent would not be aware of which services in an Individualized Education Plan or any other education plan set up by a school for a child with disabilities are reimbursed by Medicaid or a different funding source. Parents may not receive notification that Medicaid was billed for services provided at school. In addition, DHS recognizes that Medicaid's assistance programs go beyond mere special education assistance under IDEA for Medicaid covered benefits and that school-based programs also include services such as dental and vision services, (for example under the Early Periodic Screening Diagnostic and Treatment (EPSDT)) benefit or other preventative services.[467] DHS believes that by excluding any Medicaid received by an alien under the age of 21 (as well as any and all CHIP benefits), and retaining the exemptions for (1) services or benefits funded by Medicaid but provided under the IDEA and for (2) school-based benefits provided to children who are at or below the oldest age of children eligible for secondary education, DHS has effectively addressed many of the objections that commenters raised related to the potential indirect effects of this rule on school funding. With these changes, DHS believes that it has created a workable framework for purposes of the public charge assessment and the benefits these programs provide for school-age children.

Comment: A commenter stated that DHS's reasoning for excluding a program like IDEA should apply to the other benefits DHS proposes adding to the public charge determination. For example, according to the commenter, the proposed rule stated or implied that DHS proposed to exclude IDEA to avoid discriminating against people with disabilities. The commenter stated that DHS should consider other ways the proposed rule discriminates against vulnerable populations. Some commenters specifically requested that public benefits received by individuals with disabilities be excluded or that DHS exclude Medicaid and SNAP. Several commenters reasoned that individuals with disabilities rely on non-cash benefits disproportionately, often due to their disability, in order to continue working, stay healthy, and remain independent and productive members of the community.

Response: As indicated in the NPRM, DHS excluded services provided under IDEA that are generally funded in whole or in part by Medicaid to ensure that schools continue to receive financial resources to cover the cost of special education and related services which they would be legally required to provide at no cost regardless of the outcomes of the rulemaking.[468] But DHS also recognizes that Congress did not exclude applicants with disabilities or other medical conditions in the public charge inadmissibility statute.[469] DHS considers any disability or other medical condition in the public charge inadmissibility determination to the extent the alien's health makes the alien more likely than not to become a public charge at any time in the future. USCIS' consideration of health-related issues will be largely limited to those conditions that are identified on the Form I–693 and affect an applicant's ability to work, attend school, or otherwise care for himself or herself. As noted in the proposed rule, after assessing Federal statutes and regulations protecting individuals with disabilities from discrimination, DHS believes that this rule's treatment of disability in the public charge context is not inconsistent with such statutes and regulations.[470]

Comment: A commenter stated that many of its members are childcare providers and child-care center teachers who raised questions about whether or not certain child-specific services through Medicaid and CHIP would be excluded. The commenter stated that children received essential services through these programs, including the EPSDT benefit, which is a federally mandated benefit, and ensures coverage for developmental assessments for infants and young children with the routine and preventive care services they need to grow into healthy adults.

Response: The EPSDT benefit is not a separately funded Medicaid program, but an integral part of the Medicaid benefit for children, as described in section 1905(r) of the Social Security Act. As EPSDT is a Medicaid program, and DHS determined that any services provided to aliens under the age of 21 based on Medicaid and CHIP will not be considered as part of the public charge determination, any benefits under EPSDT would also not be considered in the public charge inadmissibility determination.

Emergency Services Exclusion

Comment: A commenter opposed the exclusion of emergency services, stating that the failure to provide financially for the receipt of emergency services was a strong indicator of a lack of self-reliance. Another commenter stated that emergency Medicaid's applicability to births creates an immigration incentive by advertising a service, which will ultimately assist aliens' immigration process (by providing them with a new U.S. citizen as a family member). The commenter further stated that DHS

[466] *See* 20 U.S.C. 1400 *et seq.*

[467] Medicaid payments for necessary health services are covered under section 1905R of the Social Security Act, 42 U.S.C. part 441, Subpart B.

[468] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51170 (proposed Oct. 10, 2018). These services are typically not income-based.

[469] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[470] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184 (proposed Oct. 10, 2018).

misconstrued 8 U.S.C. 1611(b), and did not consistently recognize the distinction in legislative intent to provide benefits to aliens that may nevertheless be considered as negative factors in a public charge determination. In contrast, some commenters supported the exclusion of emergency Medicaid. Some commenters indicated that immigrants would still be reluctant to access emergency services because many will not be aware that emergency services are excluded, or may not know if someone in their household was experiencing a true medical emergency.

Response: DHS appreciates and understands the commenters' concerns. However, DHS will exclude emergency Medicaid benefits in the rule, consistent with the policy underlying the PRWORA exclusion for care and services that are necessary for the treatment of an emergency medical condition. In 8 U.S.C. 1611(b), Congress specifically excluded this category of benefit from the definition of public benefits and as a result from allows non-qualified aliens to receive such emergency public benefits. DHS did not propose to designate any public benefits that are not defined as public benefits in PRWORA, because those exclusions may reflect a congressional judgment regarding the importance of ensuring that those benefits remain available to otherwise eligible aliens. DHS prefers to avoid any appearance of interfering with aliens' willingness or ability to access such public benefits. Accordingly, DHS excludes receipt of Medicaid under these provisions if the State determines that the relevant treatment falls under ''emergency medical conditions.'' [471]

Comment: A commenter stated that hospitals are compelled to provide emergency services due to their mission and laws like the Emergency Medical Treatment and Active Labor Act (EMTALA), but those services will go uncompensated if patients are disenrolled from Medicaid due to the chilling effect. A commenter stated that the emergency services exemption would not be uniformly applied across states, resulting in hospitals bearing the unpaid costs of medical care. One commenter said different states will make different determinations about what constitutes an emergency, and this uncertainty will cause individuals with chronic, involuntary medical conditions to be denied admission or avoid treatment out of fear.

Response: DHS understands that the states determine whether a medical condition would be determined to be an emergency for purposes of Medicaid and that determination may be inconsistent throughout states. However, DHS does not have the authority to determine whether a medical condition is an emergency or whether a state must provide Medicaid for a particular medical condition. Congress enacted the EMTALA to ensure public access to emergency services regardless of ability to pay.[472] Medicare-participating hospitals that offer emergency services must provide a medical screening examination and provide stabilizing treatment regardless of an individual's ability to pay.[473] DHS acknowledges that increased use of emergency rooms and emergent care as a method of primary healthcare due to delayed treatment is possible and there is a potential for increases in uncompensated care in which a treatment or service is not paid for by an insurer or patient. However, DHS does not have specific estimates on the increase cost for such services.

Vaccinations

Comment: Commenters indicated that the public charge rule would make immigrant families afraid to seek health-care, including vaccinations against communicable diseases, and therefore, endanger the U.S. population. The commenters stated that mass disenrollment from Medicaid would greatly restrict access to vaccines, which would result in adverse effects for the immigrant and general population, and would harm the public and the national security of the United States. For example, a commenter stated that in the event of a novel influenza outbreak, a critical first step would be to get individuals access to healthcare, which requires trust in governmental public health authorities. The commenter indicated that engaging with the public health system was critical to ensuring robust immunization to protect the population overall; if a subset of the community were fearful to access government healthcare services, regardless of whether a specific type of service qualified for a narrow exception, it would have a significant impact on the country's ability to protect and promote the public health. Another commenter indicated that its health department anticipated that promulgation of the rule, as written in the NPRM, will result in decreased utilization of children's healthcare, including vaccinations, which will increase the risk for vaccine preventable diseases. According to the commenter, these effects will pose an immediate risk to the health of individual immigrants and is also likely result in increased transmission of tuberculosis or other infectious diseases, increasing the likelihood of an outbreak.

Some commenters stated that since many immigrants live in communities alongside people of the same national origin, reduced vaccinations could result in unvaccinated or under-vaccinated clusters of individuals. Commenters warned that research shows that uninsured individuals are much less likely to be vaccinated. One commenter stated that a recent study found that even a five percent reduction in vaccine coverage could trigger a significant measles outbreak. A commenter stated that many immigrant families were already cancelling appointments for flu vaccinations, and referred to a Centers for Disease Control and Prevention (CDC) estimate of the number of flu-related deaths in 2018 to underscore the severity of this issue. A commenter indicated that the proposal will cause worse health outcomes, increased use of emergency departments, and increases in communicable diseases due to less vaccination. Another commenter stated that the rule would increase the incidence of childhood diseases like chickenpox, measles, mumps and rubella and deter parents from vaccinating their children.

Response: With this rulemaking, DHS does not intend to restrict the access of vaccines for children or adults or intend to discourage individuals from obtaining the necessary vaccines to prevent vaccine-preventable diseases. The purpose of this rulemaking is to ensure that those seeking admission to the United States are self-sufficient and rely on themselves or family and friends for support instead of relying on the government for subsistence. As noted above, this final rule does not consider receipt of Medicaid by a child under age 21, or during a person's pregnancy, to constitute receipt of public benefits. This should address a substantial portion, though not all, of the vaccinations issue.

Vaccinations obtained through public benefits programs are not considered public benefits under 8 CFR 212.21(b), although if an alien enrolls in Medicaid for the purpose of obtaining vaccines, the Medicaid itself qualifies as a public

[471] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51169 (proposed Oct. 10, 2018).

[472] *See CMS.gov,* Emergency Medical Treatment & Labor Act (EMTALA), available at *https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/index.html* (last visited May 31, 2019).

[473] *See CMS.gov,* Emergency Medical Treatment & Labor Act (EMTALA), available at *https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/index.html* (last visited May 31, 2019).

benefit. DHS also notes that free or low cost vaccines are available to children who are not insured or underinsured through the Vaccines for Children (VFC) Program.[474] In addition, local health centers and state health departments provide preventive services that include vaccines that may be offered on a sliding scale fee based on income.[475] Therefore, DHS believes that vaccines would still be available for children and adults even if they disenroll from Medicaid.

Substance Abuse

Comment: Several commenters stated that the proposed rule would also discourage people from utilizing substance abuse disorder treatment services for which Medicaid is the largest insurer.

Response: DHS does not intend to discourage people from utilizing substance abuse disorder treatment services. DHS acknowledges however that, once this rule is effective, individuals may choose to disenroll from public benefits or not seek to receive such public benefits. DHS would like to note that local health centers and state health departments may provide certain health services addressing substance abuse and mental disorders.[476] Additionally, state-funded rehabilitation centers may offer affordable options, even if an individual disenrolls from Medicaid.[477] Benefits from local and state health departments or state-funded rehabilitation centers are generally not considered public benefits under this rule, unless they are obtained through Medicaid. Therefore, DHS believes that substance abuse disorder treatment will continue to be available to individuals even if they disenroll from Medicaid.

i. Medicare, Medicare Part D Low Income Subsidy

Comment: Commenters opposed DHS's proposal to include the Medicare Part D Low Income Subsidy (Medicare Part D LIS) in the definition of public benefit. Commenters stated that inclusion of the Medicare Part D LIS may result in greater poverty and sickness, lack of access for seniors to prescription drugs, health services, worse health outcomes for Medicare enrollees and higher costs for Medicare non-drug spending. Commenters stated that Medicare Part D LIS helps seniors with chronic conditions, including breast cancer. Commenters also stated the rule, by including Medicare Part D LIS, targets disabled people, who use the program at higher rates than the general population. Commenters stated that the rule would force ''millions'' of seniors to disenroll from Medicare Part D, making it harder to afford necessary prescriptions. A commenter indicated that low- and moderate-income seniors who have been paying into Social Security like all other taxpayers would not be able access Medicare Part D subsidies. Commenters stated that prescription medication is very expensive and seniors who cannot afford having their prescriptions filled will end up in emergency rooms which will only cost their communities even more.

A commenter indicated that the Medicare Part D LIS program has higher financial eligibility thresholds than cash welfare programs and is available to more than the indigent, making it a bad indicator of dependence on the government. Citing a Kaiser Family Foundation report,[478] the commenter stated that individuals with income up to 150 percent of the FPL, and countable assets of $14,100 for an individual or $28,150 for a couple, qualify for Medicare Part D LIS in 2018. The commenter further stated that the scope of Medicare Part D LIS is limited to assistance in the cost of drugs which does not indicate dependence on government subsistence.

Commenters indicated that most non-citizen Medicare enrollees are lawful permanent residents, but that individuals who are ''lawfully present'' (*e.g.,* immigrants with TPS) and have a ten-year work history or have end-stage renal disease (ESRD) may also be eligible. A commenter indicated that individuals over the age of 65 and young individuals with disabilities who meet the income and employment guidelines are eligible for Medicare Part D LIS. A commenter stated that it is difficult to see any purpose to a rule that would deny admission to long term elderly residents who have worked and paid taxes for 10 or more years for using a benefit as modest as the Medicare Part D LIS.

A commenter stated that the effect of the proposed rule may to increase the costs, which according to the commenter was not considered in the NPRM, paid for under Medicare Part A and B or C because the increased medication use and adherence achieved through expanded drug coverage for seniors have been associated with decreased spending for nondrug medical care and reduced hospitalization rates among Medicare enrollees. The commenter stated that the rule would adversely affect Massachusetts where 74 percent of Medicare enrollees in Massachusetts were enrolled in Part D plans, and 35 percent of Medicare Part D recipients also receive the LIS.

Several commenters stated that immigrants contribute more into the Medicare system than they take out of it, and pay more out of pocket for care than citizens, thus subsidizing the system. Commenters stated that the Medicare Part D LIS may be more heavily supported by general revenues, but funding for the entire Medicare Part D program comes mostly from general revenues, with premiums covering about one-quarter of all costs. The commenter provided data intended to show that for 2019, Medicare's actuaries estimate that Medicare Part D plans will receive direct subsidy payments averaging $296 per enrollee overall and $2,337 for enrollees receiving the LIS; employers are expected to receive, on average, $553 for retirees in employer-subsidy plans. The commenter stated that the average Medicare Part D LIS beneficiary is receiving added government assisted benefits of only $1,784 per year compared to retirees in employer plans, which would be less than the 15 percent of FPG threshold that would have applied under the proposed rule had the Medicare Part D LIS been considered a ''monetized'' benefit. Commenters stated that almost one in three Medicare beneficiaries enrolled in Medicare Part D prescription drug coverage get ''extra help'' with their premiums, out-of-pocket prescription costs, copays or percentage of the drug's costs through LIS. The commenter further stated that one in five people with Medicare (11.7 million) rely on Medicaid to afford their monthly Medicare Part B premiums or cost-sharing. Nearly 12 million older adults and people with disabilities are enrolled in both Medicare and Medicaid. A commenter stated that ''Extra Help'' is estimated to be worth approximately

[474] *See* CDC, Vaccines For Children (VFC), available at *https://www.cdc.gov/vaccines/programs/vfc/index.html* (last visited May 15, 2019). *See* also CDC, VFC Detailed Questions and Answers for Parents, available at *https://www.cdc.gov/vaccines/programs/vfc/parents/qa-detailed.html#eligibility* (last visited May 15, 2019).

[475] *See* HHS, vaccines.gov, How to Pay, available at *https://www.vaccines.gov/getting/pay* (last visited May 15, 2019).

[476] *See* Substance Abuse and Mental Health Services Administration (SAMHSA) *https://www.samhsa.gov/find-treatment* (last visited July 22, 2019).

[477] *See* SAMHSA, Directory of Single State Agencies for Substance Abuse Services (Dec. 16, 2016), *https://www.samhsa.gov/sites/default/files/ssadirectory.pdf* (last visited June 4, 2019).

[478] *See* Kaiser Family Foundation, Medicare Part D: An Overview of the Medicare Part D Prescription Drug Benefit (Oct. 12, 2018), *https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/* (last visited July 26, 2019).

$4,000 per year per individual which is a substantial support for medications that are often necessary to prevent disease or manage a chronic illness. The commenter stated that to forego needed medications due to cost will not only be a harm to an elderly person or someone living with a permanent disability, but to our overall healthcare system that will be burdened with more costly hospital-based and emergency care.

However, another commenter agreed with DHS's assertion that utilization of Medicare Part D LIS was an indicator of a lack of ability to remain self-sufficient in covering medical costs.

Response: DHS appreciates the comments and recognizes the importance of Medicare and the Medicare Part D LIS, as well as the heightened eligibility threshold for those programs. Someone who is not entitled to Medicare Part A and/or Part B is not eligible for Medicare Part D or the LIS.[479] In general, to be eligible for premium-free Medicare Part A, a person must be age 65 or older and worked (or the spouse worked) and paid Medicare taxes for at least 10 years.[480] A person must be a U.S. resident and either a citizen or an alien lawfully admitted for lawful permanent residence who has resided in the United States continuously for the five-year period immediately preceding the month the application is filed in order to qualify for Medicare Part B and, therefore, the associated Medicare Part D. An individual who is not a United States citizen or is not lawfully present in the United States is not eligible for Medicare Part D and may not enroll in a Medicare Part D plan.[481]

In addition, the Medicare Part D LIS lowers the premium and cost-sharing amounts owed by Medicare Part D plan enrollees; as such, individuals not enrolled in a Medicare Part D plan are not able to access the benefits of the subsidy. While included in the NPRM because of the large Federal expenditure,[482] Medicare Part D prescription drug coverage only provides medical prescription coverage, and not health insurance as a whole. Since 2006, it has been available to all Medicare recipients regardless of income, health status, or prescription drug usage.[483] DHS agrees with the commenters and removed Medicare Part D subsidies from consideration in the public charge inadmissibility determination. DHS also notes that it has not designated any other aspect of Medicare for consideration in the public charge inadmissibility determination. However, any receive of Medicaid as a subsidy for Medicare would be considered receipt of a public benefit in the public charge inadmissibility determination.

Comment: A commenter stated that in order to mitigate the negative public health consequences associated with deterring use of public health insurance benefits, Medicaid and Medicare Part D LIS should comprise a separate set of programs that may only be given ''minimal negative weight'' in the totality of the circumstances, whether they are currently received at the time of application or were received at some point in the 36 months prior to application and for whatever factor in the totality of circumstances their receipt is being considered. The commenter stated that this would mean that a person could not be determined to be a public charge when receiving or having received those benefits in the 36 months prior to applying without also having a heavily weighted negative factor present in his or her case. The commenter stated that with this modification in place, noncitizens applying for visas, lawful permanent resident status, or other status could expect to financially ''rehabilitate'' themselves without fear that receipt of public benefits in the remote past might weigh negatively against them. Additionally, the commenter indicated that with this change, the rule would effectively make receiving public health insurance benefits the ''lightest'' negative factor to be considered and provide noncitizens with assurance that seeking coverage will have only a small impact on their admissibility which would mitigate the deterrent effect of considering receipt of these benefits.

Response: As provided in the previous response, DHS is not including Medicare Part D LIS in the definition of public benefit and therefore, there is no need to address the weight given to Medicare Part D LIS. With respect to Medicaid, DHS refers the commenter to the specific discussion above regarding the basis for considering Medicaid receipt. If an alien reports past Medicaid receipt as part of an adjustment of status application, the alien can also show that the alien is no longer receiving Medicaid and explain why the alien's past receipt of Medicaid does not make it more likely than not that the alien will receive any public benefit in the future.

j. Additional Considerations

Exhaustive List

Comment: An individual commenter stated that the agency should emphasize, in light of future congressional action, that the list outlined in the proposed rule is not exhaustive and any definition of public benefit would be best left to agency discretion, or be defined in a separate rule. A commenter stated that the list in the rule is hardly exhaustive when it comes to potential programs. The commenter stated that by one count, there are a total of 89 separate means-tested welfare programs spread across 14 departments and agencies, paid for by the Federal Government. The commenter provided examples including that more than $30 billion is spent annually by the Federal Government on Refundable Premium Assistance and cost-sharing tax credits to assist low-income people with buying health insurance and named other public benefits. The commenter stated that States also spend some $6 billion annually on their own as part of their Medicaid General Assistance programs and another $34 billion on other programs to help low-income people receive care, particularly at hospitals. The commenter stated that the vast number of overlapping and linked welfare programs means that recipients seldom use just one program.

In contrast, a commenter stated that the inclusion of a ''catch-all'' provision could leave the rule open to constitutional challenges. Additionally, other commenters stated that DHS should not allow public benefits that are not explicitly enumerated in the rule to be weighted negatively in the totality of the circumstances review. Commenters opposed to a ''catch-all'' provision suggested that its inclusion would remove the certainty an exhaustive list provides and would introduce a great potential for confusion as well as call into question whether the members of the regulated public have had sufficient notice that a certain benefit may be considered negatively in a public charge determination analysis, thus triggering due process concerns. Several commenters said they opposed the future inclusion of any ''unenumerated

[479] The Centers For Medicare And Medicaid Services, Guidance To States On The Low-Income Subsidy (February 2009), available at *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/Downloads/StateLISGuidance021009.pdf* (last visited July 26, 2019).

[480] *See* HHS, Who is eligible for Medicare?, available at *https://www.hhs.gov/answers/medicare-and-medicaid/who-is-elibible-for-medicare/index.html#main-content* (last visited June 25, 2019).

[481] *See* 42 CFR 423.30.

[482] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51172 (proposed Oct. 10, 2018).

[483] *See* Medicare.gov, How to get drug coverage, available at *https://www.medicare.gov/drug-coverage-part-d/how-to-get-drug-coverage* (last visited June 14, 2019).

benefits'' into the scope of the proposed rule since the proposed rule already improperly considers non-cash benefits and because the addition of any more programs would increase harm to individuals, families, and communities. A commenter stated that DHS's request for public comment to expand the list of other benefits in the totality of circumstances was a ''catch-all provision'' that would allow the agency to consider all benefits an alien receives, regardless of whether they are listed in the regulation or not. Other commenters wrote that it is highly likely that individuals using the benefits outlined in the proposed rule are also using additional benefits not included in the rule.

Response: For clarity and consistency, DHS has specifically listed the public benefits that will be considered. The list of designated benefits is exhaustive, avoiding the Constitutional concerns raised by the commenters that may arguably come with a non-exhaustive list. Indicating that the list is non-exhaustive would add vagueness and confusion as to what public benefits would be considered. This does not preclude DHS from updating the list of benefits through future regulatory action. DHS believes that the rule is adequately protective as drafted.

Additional Programs

Comment: Many commenters opposed the inclusion of any additional programs in the rule. Commenters stated that the inclusion of additional programs would lead to further negative health impacts on families and children.

Response: DHS appreciates the comments. DHS has not designated additional public benefits for consideration under this final rule.

Comment: A commenter asked that public benefits provided by State and local governments to non-qualified aliens under authority of PRWORA be specifically included in the codified list. The commenter said these benefits are provided from ''appropriated funds'' and with few exceptions are accessed on an individualized basis using means-tested criteria. A commenter said its state had created a program called Alien Emergency Medical Program, which was designed to offer coverage to newly arrived immigrants, or those who had resided in-state for less than five years. The commenter said the proposed rule would target those who qualify for the program.

Response: A state medical insurance program that is not included in the rule's definition of public benefit will not be considered as a public benefit in the public charge inadmissibility determination. DHS understands that the Washington State Alien Emergency Medical Program [484] is separate from Medicaid and is funded by Washington State, and is not a program listed in the public benefit definition in the rule. Further, emergency Medicaid is also not considered a public benefit for purposes of the public charge inadmissibility determination. Therefore, the Washington State Alien Emergency Medical Program would not be considered a public benefit for purposes of the public charge inadmissibility determination.

Dependents

Comment: A commenter indicated the new regulations should include welfare use by dependents. The commenter indicated that the very idea of self-sufficiency means that people can provide for themselves and their children and spouses without assistance from taxpayers. The commenter indicated that excluding the children's benefits including Medicaid, WIC, and free school lunch, from not being considered for public charge is like having an income tax that excludes all income from second jobs, investments, and rental properties. The commenter analyzed the 2014 public-use SIPP data and indicated that in 39 percent of immigrant-headed households (legal and illegal) receiving TANF, only the children receive the payments. The commenter indicated that much of the immigrant welfare use of this program would be missed if dependents are not considered. Another commenter stated that any receipt of means-tested anti-poverty benefits by immigrants or their dependents should count toward the public charge determination. Other commenters stated that DHS should never attribute to an alien applicant the receipt of benefits by the alien's dependents, including U.S. citizen children. The commenters stated that considering receipt of benefits by an alien's U.S. citizen children could give rise to constitutional issues.

Response: DHS appreciates the comments. DHS believes that the rule addresses self-sufficiency adequately without introducing consideration of a third party's receipt of public benefits, potentially to include U.S. citizen third parties such as non-custodial children. In consideration of these issues, as well as the many comments regarding the potential effects of the rule on U.S. citizen children, DHS respectfully declines to expand the rule in this manner. DHS notes that although an inadmissibility determination is made for each person individually, the alien's income is reviewed in terms of the household, and the alien's family status is considered as well, as the statute requires. The ultimate question under this rule, however, is whether the alien (rather than his or her dependents) is likely to receive public benefits in the future above the applicable threshold.

Tax Credits

Comment: Some commenters stated that non-citizens should be unable to benefit from the EITC or the Additional Child Tax Credit (ACTC). Similarly, a few commenters said the exclusion of the refundable tax credits is problematic since the refundable portion of EITC and ACTC cost over $80 billion combined in 2016. The commenters asserted that these tax credits meet the definition of a means-tested anti-poverty benefit.

In contrast, another commenter stated that the receipt of EITC and Child Tax Credit (CTC) credits, which are funded through TANF and are actually employment incentives, should be explicitly exempted from the rule in order to eliminate possible misconceptions and prevent immigrants from failing to file their income tax returns out of fear of being disqualified from future citizenship. Another commenter said inclusion of EITC would punish hardworking immigrants.

Response: DHS appreciates the comments regarding the EITC, ACTC, and CTC. Only public benefits as defined in 8 CFR 212.21(b) will be considered in the public charge inadmissibility determination. Although EITC and ACTC benefits provide what may be considered cash assistance, DHS did not propose to include EITC or ACTC as public benefits in the public charge inadmissibility determination. DHS is not including tax credits because many people with moderate incomes and high incomes are eligible for these tax credits, and the tax system is structured in such a way as to encourage taxpayers to claim and maximize all tax credits for which they are eligible. In addition, DHS is unable to determine how much of the taxpayer's refund is attributable to any one tax credit, as compared to other aspects of the tax return (such as non-designated credits or deductions) or to any one person, as opposed to a spouse filing jointly. Finally, these tax credits may be combined with other tax credits between spouses. One spouse may be a U.S. citizen and the tax return may be filed jointly. Therefore, DHS would not

[484] *See* Washington State Department of Social and Health Services, Alien Emergency Medical Program, available at *https://www.dshs.wa.gov/esa/community-services-offices/alien-emergency-medical-programs* (last visited July 22, 2019).

be able to determine whether the alien or the U.S. citizen received the tax credit. DHS has revised the regulatory text to make clear that ''cash assistance for income maintenance'' does not include any tax credit programs.

Comment: One commenter stated that DHS should exempt up to two years of the ACA premium subsidy, also known as the Premium Tax Credit (PTC), usage when the individual has shown past ability and earning potential. In addition, the commenter indicated that the ACA premium subsidies are applied based on income levels without the individual choosing to apply for the subsidies. Another commenter suggested that DHS should not consider PTC for purchasing individual market coverage in a public charge determination at all. One commenter stated that, in addition to continuing to exclude exchange programs such as ACTC under the ACA [485] from public charge consideration, DHS should clarify the interaction between applications for exchange programs and other potentially impacted benefits. The commenter explained that marketplaces are required by law to feature a uniform application process for Medicaid and non-Medicaid health programs and stated that this could cause confusion because an individual attempting to apply for exchange insurance and programs could inadvertently be seen as a ''Medicaid applicant.''

In contrast, some commenters suggested that DHS should reconsider whether immigrants wishing to reside in the United States will have the ability to support themselves, and any subsequently born children, without using benefits like subsidies under the ACA. Another commenter indicated that serious consideration should be given to adding subsidies that underwrite more than 50 percent of premium costs to the list in 8 CFR 212.21(b). The commenter stated that these benefits are provided from appropriated funds and, with few exceptions, are accessed on an individualized basis using means-tested criteria.

Response: DHS has decided not to consider ACA subsidies or health insurance received through the health insurance marketplace outside of Medicaid as public benefits in the public charge inadmissibility determination, due to the complexity of assessing the value of the benefit and the higher income eligibility thresholds associated with the benefit, as compared to the eligibility thresholds for other benefits. As discussed in section III.R of this preamble, DHS has added a heavily weighted positive factor for private health insurance appropriate to the expected period of admission. This heavily weighted positive factor would not apply in the case of a plan for which the alien receives subsidies in the form of premium tax credits.

Special Supplemental Nutrition Program for Women, Infants, and Children

Comment: Many comments opposed the potential inclusion of WIC, stating that consideration of benefits such as WIC would have a negative impact on the health and nutrition of families and individuals. Some commenters indicated that families and individuals should not have to choose between benefits such as WIC and an immigration status. Other commenters stated that programs like WIC help provide essential nutrition to children, pregnant women, and mothers, and result in improved health outcomes. Commenters provided anecdotes about how they or their family members' access to WIC helped them or their children thrive and become productive members of American society. Several commenters provided rationale, research, or data relating to important public health goals and the benefits of WIC enrollment, including the reduction or prevention of preterm birth and infant mortality, iron deficiency anemia, malnourishment, as well as increases in breastfeeding rates and hemoglobin levels of enrolled children. Other commenters provided that the WIC food package with its nutritional value increased public health, specifically for Hispanics who have lived in the United States for less than five years. Sourcing research articles and studies, some commenters described that WIC's 2009 food package changes lead to a modest decline in severe childhood obesity among young children, and that children who received SNAP or Medicaid were more likely to finish high school and grow up to be successful adults.

A commenter stated that the reduction in programs like WIC will end up costing taxpayers much more than they might save in the short term, as healthcare costs will increase. Commenters stated that a decrease in WIC participation will have short and long-term economic implications. The commenters stated that for every dollar spent on WIC there is an associated savings in Medicaid costs during the first 60 days after birth from $1.77 to $3.13 for newborns and mothers, and $2.84 to $3.90 for newborns alone. Additionally, the commenters provided further examples of Medicaid cost-savings associated with WIC.

Another commenter cited to data and stated that 74.9 percent of WIC participants are adjunctively eligible for SNAP and Medicaid, thereby reducing initial certification requirements and paperwork. Commenters added that the decreased participation in Medicaid or SNAP among WIC families would have a significant impact on WIC's certification process because income certification through adjunctive eligibility was more efficient than income screening involving pay stubs and other financial documents. The commenters, citing data and multiple studies, provided a state's estimate that income screening with financial documents costs $12.50 per participant, whereas the income screening with adjunctive eligibility is $3.75 per participant. The commenters stated that the increased costs would place a strain on WIC's state budgets, which would undercut WIC's efforts to improve efficiency, streamline certification processes, and focus WIC services on its core public health mission.

Other commenters said Congress has never sought to inhibit WIC's ability to serve immigrant populations due to the overriding public interest in promoting access to health services and nutrition assistance. A commenter noted that participating clients can only spend a maximum of five years on this program and receive limited benefits (only supplemental foods) not qualifying them a public charge. Some commenters said the rule would impact their ability to serve eligible WIC participants.

In contrast, some commenters suggested that USCIS reconsider whether immigrants wishing to reside in the United States will have the ability to support themselves, and any subsequently born children, without using benefits like WIC. The commenter said these benefits are provided from ''appropriated funds'' and with few exceptions are accessed on an individualized basis using means-tested criteria.

Response: WIC was not included in the public benefits designated for consideration in public charge inadmissibility determinations. Only public benefits as defined in 8 CFR 212.21(b) will be considered in a public charge inadmissibility determination. DHS understands that aliens subject to the public charge inadmissibility ground may choose to disenroll from public benefits, even if the benefit is not listed in 8 CFR 212.21(b). However, this rule does not, and cannot, preclude individuals from requesting or receiving

[485] Patient Protection and Affordable Care Act, Public Law 111–148, Section 1401(a), 124 Stat. 119, 213 (2010) (codified at 26 U.S.C. 36B).

any public benefits for which they qualify. As discussed in the NPRM, benefits directed toward food and nutrition, housing, and healthcare are directly relevant to public charge inadmissibility determinations, because a person who needs the public's assistance to provide for these basic necessities is not self-sufficient.[486] WIC [487] provides federal grants to States for supplemental foods, healthcare referrals, and nutrition education for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age five who are found to be at nutritional risk.[488] But overall expenditures for WIC are low, and WIC is authorized under the Child Nutrition Act of 1966,[489] which is excluded under the limitations for qualified aliens from federal means-tested public benefits. Therefore, DHS believes WIC is appropriately excluded.

Additionally, as discussed later in DHS's responses to comments related to the economic analysis and in the economic analysis itself, DHS agrees that some entities, such as State and local governments or other businesses and organizations would incur costs related to the changes commenters identify. However, these costs are considered to be indirect costs of the rule since this rule does not directly regulate these entities and does not require them to make changes to their business processes or programs. Therefore, DHS considers these indirect costs as qualitative, unquantified effects of the final rule since it is unclear how many entities will choose to make administrative changes to their business processes and the cost of making such changes. DHS agrees that there could be WIC applicants who are not adjunctively eligible due to disenrollment from Medicaid or SNAP although an individual who is a member of a family in which a pregnant woman or infant is certified as eligible to receive Medicaid may be deemed adjunctively eligible for WIC. DHS notes that households receiving WIC would be adjunctively eligible only through noncitizen participation in SNAP or Medicaid for those age 21 and over (or receiving Medicaid while pregnant) which would only apply to a very small percentage of households receiving WIC. Any costs associated with changes in adjunctive eligibility would be a consequence of DHS's decision to designate SNAP, which DHS has explained earlier in this preamble.

School Breakfast/Lunch Programs

Comment: A few commenters recommended that DHS include the National School Lunch Program (NSLP) and School Breakfast Program (SBP) for purposes of a public charge determination. The commenters stated that receiving public benefits indicates a person is not self-sufficient. Some commenters suggested that USCIS reconsider whether immigrants wishing to reside in the United States will have the ability to support themselves, and any subsequently born children, without using benefits from the NSLP. The commenter said these benefits are provided from ''appropriated funds'' and with few exceptions are accessed on an individualized basis using means-tested criteria. A commenter stated that in their local school district, hundreds of families had not reapplied for free/reduced meal program, which resulted in tens of thousands of dollars in lost revenue to its food service program, a negative impact to the farming community, and children who are hungry at school who cannot perform well. The commenter indicated that families were fearful of government assistance and the risk of being separated from their families or deported. A commenter stated that Federal nutrition assistance programs play a vital role in improving the nutritional well-being and food security of targeted segments of the United States population. The commenter stated that the California Department of Education Nutrition Services Division administers the NSLP, SBP, Seamless Summer Option, Afterschool Meal Supplement, Special Milk Program, Child and Adult Care Food Program, Summer Food Service Program, and the Fresh Fruit and Vegetable Program, which provide nutrition for low-income children. The commenter provided the number of children receiving benefits under the programs and indicated that the rule could create confusion and a chilling effect on families' perception that participating in any health and nutrition program will jeopardize their immigration status. A commenter stated that children who qualify for SNAP, or live with a child who receives SNAP, are automatically qualified for free meals under the NSLP ''direct certification'' under 42 U.S.C. 1758(b)(12) and that when a family disenrolls a child from the SNAP benefits, the school district may be unable to ''directly certify'' that child or his/her siblings for free meal status.

Response: Although school lunch programs provide for nutrition similar to SNAP, these benefits account for a relatively low overall expenditure, are specific to children in a school setting, and are administered by schools. In addition, assistance or benefits under the National School Lunch Act, (NSLP and the SBP) [490] and the Child Nutrition Act of 1966 are excluded under the limitations for qualified aliens from federal means-tested public benefits.[491] Under 8 U.S.C. 1613, qualified aliens are generally not eligible for ''means-tested public benefits'' until after five years of entry. However, the child nutrition programs, including the NSLP, are excluded from this ineligibility. In addition, the law prescribes that a person who receives free public education benefits under State or local law shall not be ineligible to receive benefits provided under the school lunch program under the Richard B. Russell National School Lunch Act [492] or the SBP under section 4 of the Child Nutrition Act of 1966 [493] on the basis of citizenship, alienage, or immigration status.[494] Therefore, DHS believes the NSLP is appropriately excluded. In addition, the other school related nutrition programs mentioned by the commenter, including Seamless Summer Option, Afterschool Meal Supplement, Special Milk Program, Child and Adult Care Food Program, Summer Food Service Program, and the Fresh Fruit and Vegetable Program, would not be considered public benefits under the public charge inadmissibility determination.

Further, DHS understands that a child may no longer automatically enroll in the school lunch programs or be automatically certified for the school programs. However, the child would

[486] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51159 (proposed Oct. 10, 2018).

[487] *See Lewis* v. *Thompson,* 252 F.3d 567, 583 (2d Cir 2001). Although WIC may provide benefits to a pregnant woman's whose unborn child would otherwise be eligible for public benefits after birth based on U.S. citizenship, at least one circuit has determined that the denial of prenatal care to an unqualified alien pregnant woman had a rational basis and therefore did not violate equal protection. The court indicated that there were ''three rationales for the denial of prenatal care to unqualified alien pregnant mothers: deterrence of illegal immigration, self-sufficiency, and cost savings. The first alone suffices for rational basis review.''

[488] *See* USDA, Food and Nutrition Service, Special Supplemental Nutrition Program for Women, Infants, and Children, available at *https://www.fns.usda.gov/wic/women-infants-and-children-wic* (last visited June 14, 2019).

[489] *See* Public Law 104–193, section 423, 110 Stat. 2105, 2271–2247 (Aug. 22, 1996).

[490] *See* USDA, The School Breakfast Program, available at *https://fns-prod.azureedge.net/sites/default/files/sbp/SBPfactsheet.pdf* (last visited July 26, 2019).

[491] *See* Public Law 104–193, Section 403, 110 Stat. 2105, 2266 (Aug. 22, 1996) (codified at 8 U.S.C. 1613(c)(2)(D)).

[492] *See* 42 U.S.C. 1751 *et seq.*

[493] *See* 42 U.S.C. 1773.

[494] *See* 8 U.S.C. 1615.

still qualify for the programs based on the eligibility criteria and this rule does not change the programs' eligibility criteria or restrict who may apply for the programs.

State and Local Benefits

Comment: Referring to the PRWORA definition of public benefits,[495] a commenter asked that public benefits include State and local governments' public benefits provided to non-qualified aliens under the authority of PRWORA. This commenter also referenced federal and state retirement, health, disability, postsecondary education, and unemployment benefits, indicating that the eligibility for these benefits is generally determined using individualized adjudications of need, typically means-based. The commenter advised that in order to avoid APA challenges to the codification or arbitrary exclusions, DHS should include all of the statutory benefits that can be accessed individually by needy persons. In contrast, other commenters stated that benefits funded by states should not be included in public charge determinations.

Response: While the proposed rule included state and local and tribal cash benefits for income maintenance, DHS excluded state, local, and tribal non-cash benefits from consideration in the public charge inadmissibility determination because of the number of public benefits that exist and the administrative burden such a rule would have imposed on DHS and the state and local public benefit granting agencies. In addition, including all state and local benefits would add vagueness and confusion as to what public benefits would be considered. Consistent with the proposed rule, DHS will continue to exclude state, local, and tribal benefits that are not cash-benefits for these reasons. Further, DHS would not consider federal and state retirement, Social Security retirement benefits, Social Security Disability, postsecondary education, or unemployment benefits as public benefits under the public charge inadmissibility determination as these are considered to be earned benefits through the person's employment and specific tax deductions.

Head Start

Comment: A few commenters asked that DHS include Head Start, because this program also qualifies as a means-tested federal program and goes toward a person's self-sufficiency. In contrast, a commenter objected to the proposed rule based on the commenter's assessment that programs such as Head Start and WIC will be impacted by the proposed changes and their ''chilling effect.'' Commenters indicated that participation in Head Start programs has been shown to result in better educational and health outcomes as well as lower rates of incarceration, ultimately saving local, state, and federal tax dollars. A commenter stated that in Michigan farmworker families one or both parents work and receive low wages enough to for their children to qualify for Head Start.

Response: DHS appreciates the comments and understands other programs also provide for nutrition and healthcare. DHS believes that the focus of the rule is best served in considering certain general benefits directed toward food and nutrition, housing, and healthcare that have high expenditures. DHS has decided to continue to exclude Head Start. DHS notes that when Congress reauthorized the Improving Head Start for School Readiness Act,[496] in 2007, it focused, in part, on ways to make Head Start services more accessible to migrant and seasonal farmworker families. Because both parents typically work in the fields, Migrant and Seasonal Head Start (MSHS) programs offer 12 weeks to year-round, full-day services to accommodate local agricultural industries and harvest season workers. To be eligible for MSHS services, a family's income must come primarily from agricultural work and the family must be eligible otherwise for Head Start services (*i.e.,* poverty, homelessness, or foster care).[497] Head Start also has a low expenditure in comparison to other benefits. Therefore, DHS believes Head Start is appropriately excluded.

Healthy Start, The Emergency Food Assistance Program, and Similar Programs

Comment: A few commenters asked that DHS include Healthy Start. The commenters stated that this program also qualify as a means-tested federal program and illustrates a person's lack of self-sufficiency. Some commenters asked that DHS include The Emergency Food Assistance Program (TEFAP), as this program also qualifies as a means-tested federal program and illustrates a person's lack of self-sufficiency. Commenters made similar points with respect to additional programs, such as programs that provide grants to localities or organizations to alleviate homelessness, programs that provide supplemental nutrition assistance to specific populations, and programs that provide low-income energy assistance or weatherization assistance.[498] Some commenters recommended that DHS exclude these and similar programs to avoid a range of costs that might be incurred by individuals, communities, and government agencies, if DHS included some or all of these programs.

Response: As stated earlier in this section, DHS believes that the focus of the rule is best served in considering certain general benefits directed toward food and nutrition, housing, and healthcare, which have high expenditures, and generally excluding emergency services or support. None of these programs have overall expenditures approaching the levels of the other listed benefits, and some provide emergency services or support, or involve providing funding to organizations, without an individual enrollment mechanism. In the interest of administrability, DHS will not consider these benefits at this time.

Pell Grants

Comment: Although several commenters were generally pleased that the proposed rule did not include public education benefits such as Pell Grants or other financial aid, one commenter stated that fear and confusion generated by the rule could deter greater numbers of immigrant youth or children of immigrants eligible for federal and state-funded aid programs from applying to college. A commenter indicated that the proposed rule could effect changes in the U.S. talent pipeline that would ultimately undermine our nation's global competitiveness and regional growth, and indicated that a highly educated workforce spurs economic growth and strengthens state and local economies. The commenter stated that the rule would discourage and may decrease the number of U.S.-citizen youth with non-U.S. citizen parents, lawful permanent residents, and undocumented immigrant youth who are long-term residents of the United States from completing college degrees and pursuing areas of national need

[495] Includes public benefits ''provided by appropriated funds of the United States'' or ''a state or local government.'' 8 U.S.C. 1611(c)(1), 1621(c)(1).

[496] *See* Public Law 110–134, 121 Stat. 1363 (Dec. 12, 2007).

[497] *See* Office of Head Start Administration for Children and Families U.S. Department of Health and Human Services, Migrant And Seasonal Head Start Report To Congress (no date), available at *https://eclkc.ohs.acf.hhs.gov/sites/default/files/pdf/migrant-seasonal-congress-report-2009-2011.pdf* (last visited July 26, 2019).

[498] Such as LIHEAP and Weatherization Assistance Program (WAP).

particularly true in the fields of science, technology, engineering, and mathematics (STEM). Another commenter requested that DHS explicitly exclude Title IV federal student aid programs from the list of those considered for a public charge determination.

Response: Pell grants and student aid programs will not be considered in the public charge inadmissibility determination. As previously discussed, DHS's list of public benefits included in the regulation is an exhaustive list and only those benefits listed will be considered in a public charge inadmissibility determination. The focus of the rule is public benefits programs that provide cash assistance for income maintenance or support food nutrition, housing and healthcare with a relatively high overall expenditure. Pell grants and student aid programs are education-based and DHS is not considering them in the public charge inadmissibility determination. DHS decided to not include a list of those benefits that are not considered for public charge purposes because they are too numerous and benefits programs may change over time.

Children's Health Insurance Program

Comment: A commenter asked that USCIS consider the inclusion of additional welfare programs such as CHIP. Some commenters noted that CHIP ought to be part of a public benefit determination because it is still part of determining an applicant's overall self-sufficiency. Another commenter stated that CHIP should be included in the public charge determination for consistency purposes, because CHIP is a form of government support and applying consistent standards ensures the Government's goal of promoting self-sufficiency.

In contrast, numerous commenters requested that CHIP be explicitly exempt from public charge; these commenters cited to studies and indicated that millions of children and thousands of pregnant women rely on the program for health coverage. Others also discussed the importance and benefits of CHIP for children, such as providing vaccinations; keeping children healthy; reducing the rate of uninsured children across the United States; and improving children's health, education, and outcomes later in life; as well as long-term economic benefits into adulthood such as job attainment and paying more in taxes. Several commenters stated that CHIP provided a critical link for children who have experienced abuse or who are in homes where domestic violence is present to overcome trauma and address physical injuries inflicted by their abusers.

Many commenters generally warned that CHIP should not be included in public charge assessments because doing so would cause significant harm, including serious health consequences, costly long-term expenses for health care providers and patients, and food insecurity in children, which is especially detrimental to the health, educational performance, development, and well-being of children. A commenter stated that including CHIP would lead to parents having to choose between their child's health, and the public charge determination and immigration status. Numerous commenters said including CHIP in public charge assessments would be contrary to Congress' explicit intent in expanding coverage to lawfully present children and pregnant women for public health, economic, and social benefits. A commenter stated that the higher income thresholds for Medicaid and the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) state option represents a clear intent by Congress to ensure that pregnant immigrant women have access to the medical services necessary to ensure a healthy pregnancy and positive birth outcomes. Other commenters stated that including CHIP, a benefit explicitly created for working families, in public charge assessments would be contrary to the historical meaning of public charge as a person who depends on the government rather than working. Many commenters stated that Congress and states have historically demonstrated a high level of commitment to promoting health for lower-income children through CHIP, with 49 states now electing to cover children though CHIPRA and the Legal Immigrant Children's Health Improvement Act (ICHIA).

Commenters stated that penalizing the use of CHIP undercuts the sound public policies many states have put in place to ensure basic healthcare services are available to immigrants to protect their health and to promote healthy communities. Another commenter cited a study indicating that the inclusion of CHIP in the final rule would have significant public health and economic ramifications, including lower rates of healthcare utilization and poorer health among immigrants and their dependents as well as higher uncompensated care costs to federally qualified health centers and public hospitals. Many commenters stated that including CHIP in a public charge determination would lead to many parents of eligible children foregoing CHIP benefits and some commenters cited data on the number of people who would disenroll from CHIP. Many commenters suggested that those foregoing CHIP coverage due to the rule, may visit emergency departments for care that could have otherwise been obtained in a primary care setting and would cause a rise in the number of uninsured people and charity care, thereby transferring the financial burden to hospitals, and forcing hospitals to reduce the healthcare services that they are able to provide to communities.

Several commenters stated that by including CHIP, USCIS would be able to specifically target families with children who may be eligible for CHIP even if the family surpasses the 125 percent of the FPL standard laid out in the proposal. Numerous commenters stated that CHIP addresses a critical coverage gap, targeting working families that earn too much to be eligible for Medicaid but cannot afford traditional private insurance. Commenters stated that making the receipt of CHIP coverage a negative factor in the public charge test, or including it in the definition of ''public charge,'' would place coverage for children out of reach. Other commenters stated that including CHIP in the final rule will create additional financial pressures on working families, and would penalize those who are moving toward self-sufficiency, as they do not qualify for Medicaid due to their increased income. A few commenters stated that past use of CHIP is not a predictor of future dependence on the Government for subsistence as an adult.

Many commenters stated that DHS's reasons for not including CHIP in the proposed rule have nothing to do with a public charge determination because CHIP does not involve the same level of expenditures as other programs; commenters stated that government expenditures are irrelevant to the assessment of whether an individual may become a public charge. Some stated that DHS's reasons for not including CHIP indicates that DHS recognizes that immigrants do not over-utilize the CHIP program and, thus, including CHIP in the final rule would only serve the purpose of denying immigrant children a benefit that supports their basic health needs. Other commenters stated that Federal CHIP funding is capped and, thus, reduced spending in states with larger immigrant populations will not reduce overall Federal spending, but will disadvantage those states relative to states with a smaller immigrant population. Another commenter stated that while the proposal exempts CHIP, it was unclear what would happen to beneficiaries in states that have opted to implement

CHIP as part of a Medicaid expansion rather than a separate program.

Response: DHS appreciates the comments and recognizes the importance of CHIP. DHS determined that it will not include CHIP in the public charge inadmissibility determination. States can use CHIP funding to cover children at higher incomes under CHIP.[499] CHIP enrollees have a higher income and states have greater flexibility in the benefit package provided.[500] An individual must be ineligible for Medicaid to quality for CHIP. CHIP primarily covers children, including lawfully residing children, and in a handful of states and covers pregnant women.[501] Eligible families have higher incomes (between 133–400 percent FPL).[502] In addition, states (and in turn the Federal Government) tend to spend less per person on CHIP than on Medicaid because the families have a higher income and thus fewer healthcare needs, and because children are less expensive to cover. Overall expenditures are also lower than Medicaid.[503] Finally, exclusion of CHIP is consistent with this rule's changes with respect to Medicaid received by a child under the age of 21 and receipt during an alien's pregnancy. Therefore, DHS believes it is appropriate to exclude CHIP from the public benefit definition in the public charge inadmissibility determination.

Disaster Supplemental Nutrition Assistance

Comment: A commenter recommended that Disaster Supplemental Nutrition Assistance (D–SNAP) should be excluded from the public charge determination to allow families or persons who have experienced a catastrophic disaster, such as a fire or a hurricane, to receive D–SNAP benefits without fear of being subject to a public charge inadmissibility determination.

Response: D–SNAP and other emergency disaster relief assistance programs are not included in the rule. DHS also notes that, as provided in the NPRM, not all cash assistance would qualify as cash assistance for income maintenance under the proposed rule. For instance, DHS would not consider Stafford Act disaster assistance, including financial assistance provided to individuals and households under the Federal Emergency Management Agency's Individuals and Households Program, 42 U.S.C. 5174, as cash assistance for income maintenance. The same would hold true for comparable disaster assistance provided by State, local, or tribal governments.

Social Security Disability Insurance

Comment: A commenter stated that the rule should not consider Social Security Disability Insurance (SSDI) as part of the public charge inadmissibility determination because SSDI is an earned benefit which may be a parent of a child.

Response: DHS will only consider those public benefits as listed in the rule. SSDI is not one of the benefits listed under the definition of public benefits for purposes of public charge inadmissibility and therefore will not be considered as part of the rule.

3. Likely at Any Time To Become a Public Charge

Comment: A commenter stated that DHS interprets ''likely at any time to become a public charge'' to mean ''likely at any time in the future to receive one or more public benefits. . . based on the totality of the circumstances,'' and DHS does not propose to establish a per se policy whereby an alien is likely to become a public charge if the alien is receiving benefits at the time of the application. The commenters stated that DHS's reasoning is ''less than transparent'' and conflicts with both pre-1999 practice and statutory interpretation. A commenter stated that Congress could have added the phrase ''in the future'' but has repeatedly declined to do so.

Response: DHS disagrees with the commenter that the interpretation of ''likely at any time in the future'' conflicts with the statutory wording and pre-1999 practice. As explained in the NPRM,[504] the language of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), requires a predictive assessment. Terms such as ''become'' and ''likely at any time'' indicate that the assessment should be based on factors that tend to reasonably show that the burden of supporting the alien is likely to be cast on the public.[505] As established in the NPRM, case law supports this view and is therefore consistent with the pre-1999 approach to public charge and the definition of ''likely at any time in the future to become a public charge'' as added to 8 CFR 212.21(c).[506] While Congress could have added ''in the future,'' Congress' wording of the public charge provision clearly indicates prospective determination; DHS added the words to clarify that any time is prospective and forward looking.[507]

Comment: Commenters stated that the proposed rule is impermissibly vague by failing to define ''likely'' as the term is used in ''likely to become a public charge.'' One commenter indicated that DHS failed to define ''likely'' although it used the term throughout the entire rule. The commenter indicated that DHS used a specific dollar amount for purposes of the public charge determination, yet, DHS failed to provide a threshold amount for adjudicators to use to assess the likeliness of becoming a public charge in the future. Additionally, the commenter also indicated that although DHS provided numerous statistics on benefits use rates, DHS never clarified what likelihood is high enough to justify a denial.[508] Therefore, the commenter suggested defining the term ''likely'' as a ''probability of becoming a public charge equal to or greater than 75 percent.''

Response: DHS appreciates the comment and agrees that the meaning of likely at any time in the future to become a public charge needs clarification. However, DHS will not

[499] CHIP-funded Medicaid coverage generally can be used for children whose income is above the Medicaid income standard in effect in the state in 1997, when the CHIP program was first established.

[500] Medicaid.gov, CHIP Eligibility, available at *https://www.medicaid.gov/chip/eligibility-standards/index.html* (last visited June 13, 2019).

[501] *See* Medicaid.gov, Medicaid and CHIP Coverage of Lawfully Residing Children and Pregnant Women, available at *https://www.medicaid.gov/medicaid/outreach-and-enrollment/lawfully-residing/index.html* (last visited June 13, 2019).

[502] *See* Medicaid.gov, Medicaid, Children's Health Insurance Program, & Basic Health Program Eligibility Levels, available at *https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-eligibility-levels/index.html* (last visited July 27, 2019).

[503] *See* U.S. Dep't of Health and Human Servs. (HHS), Centers for Medicare & Medicaid (CMS), Expenditure Reports from MBES/CBES. Available at *https://www.medicaid.gov/medicaid/finance/state-expenditure-reporting/expenditure-reports/index.html* (last visited July 27, 2019). For a list of federal expenditures by program, *see* FY 2016 data from table 2 of Gene Falk et al., Cong. Research Serv., R45097, Federal Spending on Benefits and Services for People with Low Income: In Brief (2018), available at *https://fas.org/sgp/crs/misc/R45097.pdf* (last visited July 27, 2019).

[504] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51174–75, 51178–79 (proposed Oct. 10, 2018).

[505] *See, e.g., Matter of Martinez-Lopez,* 10 I&N Dec. 421 (Att'y Gen. 1964).

[506] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51174–75, 51178–79 (proposed Oct. 10, 2018).

[507] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51174–75, 51178–79 (proposed Oct. 10, 2018).

[508] The commenter referred to a 1999 Central Intelligence Agency study in which was concluded that NATO military officers did not interpret the words ''likely'' or ''unlikely'' in a consistent manner showing a wide variation. *See* Richard J. Heuer, Jr., Psychology of Intelligence Analysis, Central Intelligence Agency (1999), p. 155, *https://www.cia.gov/library/center-for-the-study-of-intelligence/csi-publications/books-and-monographs/psychology-of-intelligence-analysis/PsychofIntelNew.pdf* (last visited July 26, 2019).

accept the suggestion that likely at any time to become a public charge means a 75 percent likelihood that the alien would become a public charge at any time in the future. As with other key terms in the statute, Congress did not define or otherwise describe what it meant by likely at any time to become a public charge. DHS believes likely in the context of likely at any time to become a public charge is best considered as probable, *i.e.,* more likely than not. Although, as the commenter noted, the term ''likely'' has been inconsistently defined in some contexts,[509] equating likely at any time to more likely than not is nonetheless consistent with the approach many courts have taken in the determining the meaning of likely.[510] DHS believes that defining likely at any time to mean ''more likely than not'' is consistent with how the DHS regulations implementing withholding of removal and deferral of removal under the Convention Against Torture have used ''more likely than not'' interchangeably with ''likely to.'' [511]

Therefore, DHS has amended the definition of likely to become a public charge at 212.21(c) to clarify that a person is likely to become a public charge if it is ''more likely than not'' that the individual at any time in the future will receive one or more public benefits, as defined in 8 CFR 212.21(b), based on the totality of the alien's circumstances.[512]

4. Household

Comment: Several commenters expressed concern with the new definition of ''household.'' A commenter stated that this new definition is designed to apply to as many people as possible and would be the most expansive definition of ''household'' within the Executive Branch. A few commenters asserted that the proposed rule rejects both the HHS and the IRS definitions of ''dependent'' and ''household'' in favor of arbitrary standards set by DHS. Another commenter indicated that different agencies have their own definition of a ''household,'' which leads to variance and an uneven application of the law.

Response: DHS disagrees that the definition of household would be the most expansive in the Executive Branch or that it acts as a penalty. As discussed in the NPRM,[513] the poverty guidelines do not define who should be considered part of the household, and different agencies and programs have different standards for determining household size.[514] For example, and as explained in the NPRM,[515] SNAP uses the term ''household'' and includes everyone who lives together and purchases and prepares meals together, which is more expansive than the definition that DHS is adopting. DHS further disagrees that the standard is arbitrary. However, DHS does agree that different agencies have their own definition of household as discussed in the NPRM.

Furthermore, as discussed in the NPRM, DHS is not fully adopting the IRS definition of ''dependent.'' [516] That definition would generally require some type of relationship to the person filing (including step and foster children and their children) whether or not the dependent is living with the person filing and the amount of support being provided by the person filing (over 50 percent).[517] For tax purposes, dependents may include U.S. citizens, U.S. resident aliens, U.S. nationals, and residents of Canada or Mexico.[518] DHS's definition would adopt the IRS consideration of the amount of support being provided to the individuals (50 percent) as the threshold for considering an individual as part of the household in the public charge determination, rather than consider any support being provided.[519] As discussed in the NPRM, DHS believes that the ''at least 50 percent of financial support'' threshold as used by the IRS is reasonable to apply to the determination of who belongs in an alien's household, without regard to whether these individuals physically reside in the alien's home. This would include those individuals the alien may not have a legal responsibility to support but may nonetheless be supporting. DHS believes that an alien's ability to support a household is relevant to DHS's consideration of the alien's assets, resources, financial status, and family status.

Comment: Several commenters expressed concern with the definition classifying people as household members if the alien contributes 50 percent or more to their financial support. A commenter said that this requirement is vague and too expansive, asserting that many families live in

[509] For example, a review of state laws on determining when sex offenders are ''likely'' to reoffend found that ''states vary greatly on how they define likely'' with some states define it as greater than 50 percent or substantially probable while others have expressly rejected standard based on percentages. Jefferson C. Knighton, Daniel C. Murrie, Marcus T. Boccaccini, & Darrel B. Turner, *How Likely is 'Likely to Reoffend' in Civil Sex Offender Commitment Trials,* 38 Law & Hum, Behav. 293, 294–96 (2014). N.B. DHS is referencing sex offender statutes to show the lack of clarity in defining the word likely; DHS is not implying, in any way, any similarity between those who commit sexual crimes to those who are subject to public charge.

[510] *See, e.g., Southwest Sunsites, Inc.* v. *F.T.C.,* 785 F.2d 1431 (9th Cir.) (''First, the FTC must show probable, not possible, deception ('*likely* to mislead,' not '*tendency and capacity* to mislead').'' (emphasis in the original)), *cert. denied,* 479 U.S. 828 (1986); *Fermin* v. *Pfizer Inc.,* 215 F. Supp. 3d 209, 211 (E.D.N.Y. 2016) (''The term 'likely' indicates that deception must be probable, not just possible.''); *Siderca, S.A.I.C.* v. *United States,* 28 C.I.T. 1782, 350 F. Supp.2d 1223, 1226 (Ct. Int'l Trade 2004) (''The common meaning of 'likely' is 'probable,' or, to put it another way, 'more likely than not.'''); *In re G.H.,* 781 NW2d 438, 445 (Neb. 2010) (holding that '' 'probable,' in other words, more likely than not'' satisfies the ''likely to engage in repeat acts of sexual violence'' standard under Nebraska law.).

[511] *Compare* 8 CFR 208.16(c)(4) (''If the immigration judge determines that the alien is *more likely than not* to be tortured in the country of removal, the alien is entitled to protection under the Convention Against Torture.'') *with* 8 CFR 208.17(b)(2) (''The immigration judge shall also inform the alien that removal has been deferred only to the country in which it has been determined that the alien is *likely* to be tortured, and that the alien may be removed at any time to another country where he or she is not likely to be tortured.'') (emphasis added). *See generally Matter of Chawathe,* 25 I&N Dec. 369, 376 (2010) (discussing the more likely than not standard).

[512] This change clarifies the definition of likely to become a public charge, but it does not alter the burden that adjustment applicants bear in demonstrating that they are admissible. As with any other ground of inadmissibility, an applicant for adjustment of status still has the burden of demonstrating that he or she is clearly and beyond doubt entitled to be admitted to the United States and is not inadmissible. *See Matter of Bett,* 26 I&N Dec. 437, 440 (BIA 2014). Adjustment applicants have the burden to show that they clearly and beyond doubt satisfy the standard of not being more likely than not to become a public charge in the future. *See generally House* v. *Bell,* 547 U.S. 518, 538 (2006) (discussing habeas petitioner's burden of showing ''more likely than not'' with the standard of ''no reasonable juror would find him guilty beyond a reasonable doubt.'')

[513] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51176 (proposed Oct. 10, 2018).

[514] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51176 (proposed Oct. 10, 2018), discussing Annual Update of the HHS Poverty Guidelines, 83 FR 2642 (Jan. 18, 2018). *See also* HHS Annual Update of the HHS Poverty Guidelines, 84 FR 1167 (Feb. 1, 2019).

[515] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51176 (proposed Oct. 10, 2018).

[516] *See* 26 U.S.C. 152; *see also* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51176 (proposed Oct. 10, 2018), discussing IRS Publication 501 (Jan 2, 2018), *available at https://www.irs.gov/pub/irs-pdf/p501.pdf* (last visited May 8, 2019).

[517] S*ee* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51176 (proposed Oct. 10, 2018), discussing IRS Publication 501 (Jan 2, 2018), *available at https://www.irs.gov/pub/irs-pdf/p501.pdf.*

[518] S*ee* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51176 (proposed Oct. 10, 2018), discussing IRS Publication 501 (Jan 2, 2018), *available at https://www.irs.gov/pub/irs-pdf/p501.pdf.*

[519] *See* Internal Revenue Serv., *Dependency Exemptions, available at https://apps.irs.gov/app/vita/content/globalmedia/4491_dependency_exemptions.pdf* (last visited July 26, 2017); *see also* Internal Revenue Serv., *Table 2: Dependency Exemption for Qualifying Relative, available at https://apps.irs.gov/app/vita/content/globalmedia/table_2_dependency_exemption_relative_4012.pdf* (last visited July 26, 2018).

extended family and close friend housing that share the cost of utilities, transportation, food, etc., which can lead to difficult miscalculations of this 50 percent threshold. Similarly, one commenter stated that household size is not predictive of a person's propensity to become a public charge, but is instead the natural consequence of working people pooling together their resources to support each other. Other commenters provided the example that many immigrants provide financial support to family members who remain in their countries of origin and in some countries, as little as $100 a month can constitute more than 50 percent of an individual's financial support, which would mean that the person should be counted as part of the immigrant's household size, which would drive up the earnings they would need to meet the threshold by much higher amounts. Multiple commenters asserted that immigrants could be penalized for providing family support to a sibling with disability or parents to whom they have no legal obligation. A commenter said the definition could cause harm to larger households who must show larger incomes or resources to support the larger numbers being counted, regardless of the reality of the financial benefits that households may be providing to society. This commenter also stated that it could be especially harmful to immigrant families who often care for extended family members in cases of emergencies without being legally required to do so.

Response: As explained in the NPRM,[520] DHS considers an alien's household size not only as part of the alien's asset, resources, and financial status but also for purposes of the family status. As is the case with all of the factors and consideration, DHS will consider the impact of the household size as part of the totality of the circumstances.[521] Therefore, having support from other household members may be a positive consideration while having assets below the 125 percent threshold for the household size may be a negative consideration because it indicates that an alien may be likely to become a public charge. For these reasons, DHS considers the household size a relevant consideration in the public charge assessment and predictive of the likelihood, within the totality of the circumstances, that an alien will become a public charge. DHS recognizes that multiple individuals in the household may be working to support the household.

With the definition of household, DHS aims to account for both the persons whom the alien is supporting and those who are contributing to the household to support the alien, and thus to the alien's assets and resources.[522] DHS will consider any of the family members supported, including those who are supported outside the United States and listed on Form I–944. DHS clearly outlined in the regulatory provision who is included in the definition of household and therefore DHS does not agree that the definition is vague or too expansive, but agrees that it may be, depending on the specific circumstances of the household, either over-or under-inclusive.

Comment: Commenters stated that, although the receipt of benefits by U.S. citizen children would not be a negative factor to their noncitizen parent's application, the mere fact that the children are in the household would be a downward factor for determining overall household income. Another commenter stated that children should not be included in the household calculation because most support agreements or orders do not contain information to determine whether a potential amount is 50 percent of the financial support of a child. A commenter stated that verifying which individuals provide to the applicant at least 50 percent of their financial support requires a fact-intensive review of not only cash support, but non-cash support such as room and board or payment of utilities that may only be partly attributable to the noncitizen. The commenters said this overly complicates the household size assessment, particularly as compared to the relatively straightforward determination used for the current Form I–864.

Response: As indicated in the NPRM, as part of the description of the definition of household and family status [523] research and data have shown that the number of household members may affect the likelihood of receipt of public benefits. However, the number of household members may also positively affect the financial status and household, depending on the alien's and household's circumstances, include other member's employment and financial contributions to the household. Therefore, DHS disagrees with the commenters that children would be considered a downward factor for determining overall household income. DHS's definition of household member adopts the IRS consideration of the amount of support being provided to individuals (50 percent) as the threshold for considering an individual as part of the household. Therefore, DHS will retain the standard as proposed.

Comment: Several commenters remarked that this assessment would have a disproportionally negative impact on immigrant women, asserting that immigrant women are more likely than immigrant men to have one of more children living in the same household, and therefore, more likely to have a large household. Some commenters stated this requirement directly imposes on an immigrant woman's bodily autonomy and agency, particularly if or when to have children, by counting having a large family against them as part of the public charge determination. A commenter discussed the definition's impact on domestic and sexual violence survivors, asserting that this population could be penalized for providing continuing support to former partners or family members if they were involuntarily coerced into providing such support or have ceased living with them due to abuse. The commenter added that the rule could penalize victims who often seek the help of family members to alleviate housing and childcare expenses and strengthen their ties to the United States.

Response: DHS is implementing a statutory ground of inadmissibility provided by Congress; the goal of the rule is not to penalize but to ensure that those coming to the United States are self-sufficient and not likely depend on public resources. DHS also incorporated exceptions provided by Congress, including those applicable to battered spouses and children.[524] Therefore, DHS disagrees that the rule penalizes domestic and sexual violence survivors. As it is the case for all, the public charge assessment will be made in the totality of the circumstance to determine whether an applicant is likely, at any time in the future, to become a public charge.

Comment: A commenter said the definition does not allow for the exclusion of the alien's household members who are not intending to immigrate within six months of the immigrant's application, which holds the applicant fiscally responsible for an individual that they will not be living with for at least 6 months after immigrating to the United States.

[520] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51175 (proposed Oct. 10, 2018).

[521] *See* 8 CFR 212.22(a).

[522] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51177 (proposed Oct. 10, 2018).

[523] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51176–51178, 51184 (proposed Oct. 10, 2018).

[524] *See* 8 CFR 212.23.

Response: As explained in the NPRM, for purposes of the household definition, DHS will take into consideration both individuals living in the alien's home and individuals not living in the alien's home, including aliens living outside the United States, for whom the alien, and or the alien's parents or legal guardians are providing, or are required to provide, at least 50 percent of financial support.[525] DHS therefore does not focus on the location of the financially supported person, but on the fact that the person is receiving more than 50 percent of financial support from the applicant, rendering those funds unavailable to the applicant for his or her own support and self-sufficiency.

Comment: A commenter expressed their opposition to the NPRM assertion that ''the receipt of non-cash benefits generally increased as family size increased.'' This commenter referenced Table 17 in the NPRM, which the commenter stated indicated that non-cash benefit usage is higher among families of three (22.3 percent) than families of four (20.7 percent). The same commenter cited information claiming that among noncitizens in ''nonfamily households'' (*i.e.,* individuals), 2.7 percent received cash assistance and that number steadily decreased in larger households with only 1.8 percent of noncitizens in families of five or more receiving any cash benefit.

Response: DHS appreciates the comment. DHS acknowledges that certain data were not statistically significant, which in some cases was a consequence of small sample sizes. The statistics cited regarding non-cash benefit use among families of sizes three and four were not statistically significantly different from each other, so DHS would not conclude that one is higher or lower. Among noncitizens, the results that were statistically significant showed a lower rate of non-cash benefit use among nonfamily households, and a higher rate of non-cash benefit use among those with a family size bigger than five, compared with those having family sizes of two, three, and four. Among citizens, those having family sizes of two were shown to have a lower rate of non-cash benefit use than those with larger families. These findings suggest a generally higher rate of non-cash benefit use as family size increases. Regarding the rates of cash benefit use, the estimates cited for nonfamily households and those with families of size five or more were not statistically significantly different. The estimates of cash benefit use among noncitizens in Table 17 in the NPRM had high variance, indicating only that the rates were about one to three percent across family size groups. Therefore, DHS believes that the data properly reflects that receipt of noncash benefits generally increases with an increase in family size.

Comment: A commenter stated that the rule ''contravenes PRWORA and IIRIRA by drastically limiting how a sponsor's income is considered as part of the public charge analysis—even though the sponsor's commitment is legally enforceable.'' The commenter stated that only considering the sponsor's income if (i) the sponsor physically lives with the noncitizen, or (ii) ''the sponsor is already contributing 50 percent or more of the alien's financial support,'' has no basis in either PRWORA or IIRIRA and ''would run contrary to the basic logic undergirding the sponsor affidavit provisions of both laws'' because under PRWORA and IIRIRA, a sponsor must have an income of at least 125 percent of the FPL, and both the sponsored noncitizen and benefit-granting agencies may legally enforce the affidavit of support as the sponsor's promise to maintain a noncitizen above 125 percent of the FPL. In addition, the commenter noted that PRWORA requires benefit-granting agencies to include a sponsor's income when determining whether a sponsored noncitizen is income-eligible for means-tested benefits. The commenter asserted that discounting the value of an affidavit of support in the public charge determination unless the sponsor is closely related to or lives with the noncitizen, would ignore the legally enforceable nature of the sponsor's promise and that the sponsor's income is deemed that of the noncitizen.

Response: DHS disagrees that the rule contravenes PRWORA and IIRIRA with respect to the manner in which DHS will consider a sponsor's income. DHS neither proposed any changes to how the sponsor's income is considered with respect to the enforceable affidavit of support, nor changed any applicable deeming rules. In addition, the INA requires a distinct public charge assessment for admission and adjustment of status even where an alien has an affidavit of support. Under this rule, the affidavit of support, where required, will still have to comply with the requirements of section 213A of the Act, 8 U.S.C. 1183a, and 8 CFR part 213a.

As noted previously, Congress set forth the mandatory factors that DHS must consider in the public charge inadmissibility determination—these factors include the alien's assets, resources, and financial status. While the affidavit of support is required for most family-based applications and some employment-based applications, it is set apart from those factors, and *may* be considered in a public charge inadmissibility determination as a separate consideration.[526] This indicates that Congress intended for the affidavit of support and the public charge determination to serve similar, but not identical functions.

As discussed in the NPRM, DHS chose a definition of household that takes into account the definitions used by benefit-granting agencies and that captures individuals who are financially interdependent with the alien. In considering gross household income, USCIS will also consider any monthly or annual income from individuals who are not included in the alien's household, where the support to the household has been provided to the household on a continuing monthly or yearly basis during the most recent calendar year.[527] Accordingly, if the sponsor is already providing 50 percent or more of financial support or is otherwise providing income on a monthly or annual basis to the alien that the alien will rely on to meet the income threshold, the sponsor's income or payments would be included in the consideration of the alien's assets, resources, and financial status.[528] DHS

[525] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51176 (proposed Oct. 10, 2018).

[526] *See* INA section 212(a)(4)(B)(i) & (ii), 8 U.S.C. 1182(a)(4)(B)(i) & (ii).

[527] *See* 8 CFR 212.22(b)(4)(i)(B).

[528] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51177 (proposed Oct. 10, 2018). (''For example, when a child, as defined in INA section 101(b), 8 U.S.C. 1101(b)(1), is filing for adjustment of status as the child of a U.S. citizen or lawful permanent resident, the affidavit of support sponsor would also be the parent. Because the parent is part of the household, the parent's income would be included as part of the household income. The parent's income would be reviewed as part of the assets, resources, and financial status factor based on the total household size. However, for example, if there is a cosponsor, who is the alien's cousin and who is not physically residing with the alien, then the cousin would not be counted as part of the household and his or her income would not be included as part of the assets, resources or financial status unless the sponsor is already contributing 50 percent or more of the alien's financial support. In addition, if the sponsor is a member of the alien's household and included in the calculation of the 125 percent of the FPG, DHS would only count the sponsor's income once for purposes of determining the alien's total household assets and resources. A sponsor's income as reported on the affidavit of support would be added to the income of the other members of the alien's household. The sponsor's income that is added to the alien's total household assets and resources would not be increased because the sponsor also submitted an affidavit of support promising to support the alien at least 125 percent of the FPG for the sponsor's household size. For example, assuming the alien and sponsor's

Continued

declines to otherwise deem the sponsor's income to the alien in the public charge context, as this kind of automatic deeming would essentially render meaningless the public charge determination for any alien with an affidavit of support. DHS does not believe Congress would have retained the public charge ground of inadmissibility, had it intended such a result.

H. Public Charge Inadmissibility Determination Based on Totality of Circumstances

Comment: Many commenters expressed general concern about the discretion that government workers would be given when making public charge determinations, which would result in inconsistent and unfair public charge inadmissibility determinations. One commenter noted that the rule change gives too much discretion to officers in making inadmissibility determinations. Another commenter noted that because the rule relies on officer discretion, there will be inconsistent adjudications and the rule is thus arbitrary and capricious. The commenter further stated that this proposed standard is also arbitrary and capricious because the required officer evaluation would be burdensome and inefficient. A commenter provided an estimate on the number of people adversely affected by the rule based on the factors.

Several commenters stated that the ''totality of circumstances'' test would require adjudicators to weigh a potentially unlimited number of ''factors,'' and expressed confusion regarding the difference between ''factors'' and ''considerations'' under the proposed rule. A commenter noted that ''[a]s a result, there could be an infinite number of factors that adjudicators could possibly assess, resulting in public charge determinations [that] will inevitably vary from adjudicator to adjudicator even when faced with very similarly situated cases.'' Two commenters stated that the proposed rule is not quantitative and the ''totality of circumstances'' test to determine public charge admissibility is vague and ambiguous. An individual commenter suggested that DHS remove the totality of circumstances language to ensure the rule will operate as intended and will not lead to inconsistent results.

An individual commenter stated that the existing statutory framework directs an adjudicator to consider an immigrant's personal and financial circumstances to determine the likelihood that they will become dependent on the government in the future, which is easily demonstrated by their employment prospects and the existence of support systems. However, the commenter stated that the proposed positive and negative weighted factor system was unworkable and provided no guidance on how these factors would be weighted. The commenter also stated that DHS should allow immigrants to prove themselves sufficient after immigrating. A commenter suggested DHS provide written documentation of the public charge determination and reasoning to the applicant and his/her legal representative. A few commenters described the proposed rule as extremely vague and open-ended regarding the issues that will be considered. The commenters also stated that DHS fails to state how it will measure the weighted factors. A commenter stated the alien must show by a preponderance of the evidence that he or she is eligible for the benefit sought but that the rule requires too high a standard of proof with respect to the applicant demonstrating he or she will not become a public charge.

Some commenters stated that the proposed rule contained vague standards, required adjudicators to consider a broad range of factors, and afforded such adjudicators significant discretion. The commenters stated that as a consequence, outcomes will be dependent on the particular adjudicator making the decision. Commenters indicated that they were especially concerned that this lack of predictability will make it nearly impossible for attorneys to adequately advise their clients. Commenters stated that such unpredictability would lead to a chilling effect with respect to aliens' use of public benefits.

Commenters stated that granting USCIS officers the discretion to evaluate the totality of circumstances would be inefficient, as they would require new training to evaluate criteria, such as credit reports, and that other agencies, such as DOL, already have education and skills criteria for work visas.

Response: DHS disagrees with the assertion that the rule provides too much discretion to adjudicators as a result of the totality of the circumstances approach and that the framework will lead to unfair and inconsistent determinations. DHS acknowledges the complexity of this rule. This final rule is intended to provide greater clarification in response to comments. As with any new regulation, the regulated public may need to read and become familiar with the regulation to understand how it applies. DHS will also issue guidance, and may further revise such guidance as necessary after it has gained experience with the new regulatory regime.

As explained in the NPRM, section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), provides that an alien who, ''in the opinion of'' the Secretary is likely to become a public charge is inadmissible.[529] The Government has long interpreted the phrase ''in the opinion of'' as describing an assessment that is subjective and discretionary in nature.[530] While authorizing this subjective, discretionary assessment, however, Congress also mandated that the public charge determination consider, at a minimum, the alien's age, health, family status, assets, resources, financial status, education, and skills. Consideration of these mandatory factors requires a case-by-case determination based on the totality of the alien's circumstances. This final rule will result in officers conducting a full analysis of the factors set forth in the statute and in this rule, and weighing all evidence submitted in the totality of the circumstances. Both the proposed rule and this final rule adequately explain how the criteria are to be applied and what evidence should be considered.

Unlike the 1999 Interim Field Guidance, which failed to interpret the statutory factors and provided no direction to adjudicators on how to consider them, this final rule is clear about the legal standard and evidentiary burden aliens must meet to demonstrate that they are not likely at any time in the future to become a public charge. In addition, USCIS will be conducting training for adjudicators and, as necessary, issuing sub-regulatory guidance to ensure consistency in adjudications. However, to the extent that each alien's individual circumstances constitute a unique fact

household sizes are the same, if the sponsor's total income reported on the affidavit of support is 250 percent of the FPG for the household size, that income would be added to the alien's assets and resources; the alien's total household income would then be at least 250 percent of the FPG, which constitutes a heavily weighted positive factor.'').

[529] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[530] *See Matter of Harutunian,* 14 I&N Dec. 583, 588 (Reg'l Cmm'r 1974) (''[T]he determination of whether an alien falls into that category [as likely to become a public charge] rests within the discretion of the consular officers or the Commissioner . . . Congress inserted the words 'in the opinion of' (the consul or the Attorney General) with the manifest intention of putting borderline adverse determinations beyond the reach of judicial review.'' (citation omitted)); *Matter of Martinez-Lopez,* 10 I&N Dec. 409, 421 (Att'y Gen. 1962) (''[U]nder the statutory language the question for visa purposes seems to depend entirely on the consular officer's subjective opinion.'').

pattern, outcomes in public charge determinations will appropriately vary. In addition, DHS disagrees that public charge determinations will be burdensome and inefficient. USCIS will take care to effectively examine the evidence presented to determine whether the alien is likely to become a public charge at any time in the future, consistent with the statute.

DHS also disagrees that the standard used to determine public charge inadmissibility is too high. While the commenter is correct that, in general, an applicant applying for an immigration benefit must demonstrate eligibility by a preponderance of the evidence,[531] DHS has not changed that standard of proof with respect to applications subject to a public charge inadmissibility determination. Those applicants will still, unless otherwise specified, be required to show by a preponderance of the evidence that they are not likely at any time to become a public charge. DHS has defined likely at any time to become a public charge in this final rule as more likely than not at any time in the future to become a public charge. Therefore, applicants subject to a public charge inadmissibility determination will need to demonstrate by a preponderance of the evidence that that they are not more likely than not at any time in the future to become a public charge.

Additionally, the public charge inadmissibility analysis is a prospective determination, as evidenced by the words ''likely at any time to become'' a public charge. Moreover, aliens subject to the public charge ground of inadmissibility must demonstrate that they are not likely at any time to become a public charge at the time of their application or a visa, admission, or adjustment of status. Therefore, DHS will not adopt the commenter's suggestion that an alien subject to the public charge ground of inadmissibility should be allowed to wait until after immigrating to the United States to demonstrate that he or she is likely at any time to become a public charge and thereby avoid becoming inadmissible on public charge grounds at the time of admission as an immigrant.

DHS also believes that the rule provides a clear framework for considering the mandatory factors in a public charge inadmissibility determination in the totality of the circumstances. DHS acknowledges, however, that the adjudication of public charge inadmissibility is complex and that the determination of the likelihood at any time in the future to become a public charge is not governed by clear data regarding whether any given alien subject to this determination is more likely than not to receive public benefits for more than 12 months in the aggregate in a 36-month period at any time in the future, and therefore would be inadmissible when weighing all factors in the totality of the alien's circumstances.

To address these concerns, USCIS plans to take several steps. For one, to provide its officers with a solid foundation and knowledge on public charge inadmissibility determinations, USCIS plans to issue policy guidance in its USCIS Policy Manual (*https://www.uscis.gov/policy-manual*), which will include information from the NPRM and this final rule and can be accessed by potential applicants. In its policy guidance, USCIS will direct officers to determine:

- Whether the alien is more likely than not to receive one or more public benefits, as defined in 8 CFR 212.21(b), at any time in the future; and
- Whether the alien's likely receipt of one or more of the enumerated public benefits is more likely than not to exceed 12 months in the aggregate within any 36 month period (such that, for instance, receipt of two benefits in one month counts as two months) at any time in the future.

In making this determination, there is no bright-line test that USCIS officers will administer. For instance, past or current receipt of public benefits may make an alien a public charge at present, but past or current receipt of public benefits, alone, is insufficient to sustain a finding that an alien is likely to become a public charge at any point in the future.

Instead, there must be a nexus between the alien's circumstances and the alien's future likelihood of becoming a public charge. The mere presence of any one enumerated circumstance, alone, is not outcome determinative.[532] USCIS, therefore, will evaluate all of the alien's facts, circumstances, and evidence to determine whether factors in the analysis are *positive* or *negative.* Any factor that *decreases* the alien's future likelihood of receiving one or more public benefits above the 12 months in the aggregate in a 36-month period threshold is *positive.* Any factor that *increases* the alien's future likelihood of an alien receiving one or more public benefits above the 12 aggregate months in a 36-month period threshold is *negative.*

USCIS will then weigh all factors individually and cumulatively. USCIS will assess the *weighted degree* to which each factor is *negative* or *positive*—the extent to which the factor affects the likelihood that the alien *will* or *will not* receive one or more public benefits above the threshold. Certain enumerated factors will weigh heavily in favor of finding that an alien is not likely to become a public charge or finding that an alien is likely to become a public charge. But, for example, depending on the alien's specific circumstances, a heavily weighted negative factor can be outweighed by a heavily weighted positive factor or some combination of positive factors in the totality of the circumstances. Otherwise, the weight given to an individual factor not designated a heavily weighted factor depends on the particular facts and circumstances of each case and the relationship of the individual factor to other factors in the analysis. Multiple factors operating together will carry more weight to the extent those factors in tandem show that the alien is more or less likely than not to become a public charge.

USCIS' totality of circumstances assessment will focus on, for instance, the following considerations:

- *Ability to Earn a Living*—The ability of the alien to earn sufficient income to pay for basic living needs (*i.e.,* food and nutrition, housing, and healthcare), as evidenced or impacted by, for example, the alien's age, health, work history, current employment status, future employment prospects, education, and skills;
- *Sufficiency of Income, Assets, and Resources*—The sufficiency of the alien's household's income, assets, and resources to meet basic living needs (*i.e.,* food and nutrition, housing and healthcare);
- *Sufficiency and Obligation of Sponsorship*—The legal sufficiency of the affidavit of support, if required, and the likelihood that a sponsor would actually provide the statutorily-required amount of financial support to the alien, and other related considerations;
- *Ability to Overcome Receipt of Public Benefits or Certification or Approval to Receive Public Benefits Above the Designated Threshold*—The ability of the alien to overcome receipt of, or certification or approval to receive, one or more public benefits for more than 12 months in the aggregate in any 36-month period beginning no

[531] *See Matter of Chawathe,* 25 I&N Dec. 369, 375 (2010) (''Except where a different standard is specified by law, a petitioner or applicant in administrative immigration proceedings must prove by a preponderance of evidence that he or she is eligible for the benefit sought.'') (citations omitted).

[532] Except that the absence of a sufficient affidavit of support, where required, will lead to an inadmissibility finding. *See* INA section 212(a)(4)(C), (D), 8 U.S.C. 1182(a)(4)(C), (D).

earlier than 36 months before the application for admission or adjustment of status.

Assessing an alien's ability to overcome the heavily weighted negative factor for recent receipt of, or certification or approval to receive, one or more public benefits above the designated threshold, in particular, will depend on the totality of the alien's circumstances and the existence of positive factors that alone or in combination could outweigh this heavily weighted negative factor such that the alien would not be likely to become a public charge at any time in the future. For example, the alien's assets and resources being at or above 250 percent of the FPG, the alien being healthy and between the ages of 18 and 61, the alien being currently employed, and evidence that the alien has disenrolled or requested to disenroll from public benefits could play a significant role in outweighing recent receipt of, or certification or approval to receive, public benefits above the designated threshold. Where a factor includes more than one consideration, including evidence related to such considerations, DHS will consider all evidence presented by the alien in the totality of the circumstances. For example, DHS will consider income above 125 percent and a good credit score and report as positive considerations in the totality of the circumstances.

If USCIS finds that the alien's positive factors outweigh the alien's negative factors, such that the alien is not likely to receive one or more public benefits above the designated threshold at any time in the future, then USCIS will conclude that the alien is not inadmissible as likely to become a public charge. On the other hand, if USCIS finds that the alien's negative factors outweigh the alien's positive factors, such that the alien is more likely than not to receive one or more public benefits above the designated threshold at any time in the future, then USCIS will find that the alien is inadmissible as likely to become a public charge.

USCIS, as with other applications, will notify applicants of deficiencies in their applications with respect to public charge inadmissibility in accordance with the principles outlined in 8 CFR 103.2 and USCIS policy in regard to notices, RFEs or NOIDs, and denials.[533] If USCIS denies an alien's application for adjustment of status on public charge grounds under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), USCIS will explain why the negative factors outweigh the positive factors based on the alien's individual circumstances in making the alien more likely than not to receive one or more public benefits above the designated threshold at any time in the future.

Furthermore, to ensure consistency and quality control, USCIS will provide training to officers and continue to monitor adjudications. As is the case for any adjudication at USCIS, USCIS will apply its general quality control processes for adjudications involving public charge assessments. USCIS continues its ongoing data collection efforts on its adjudications as well as other information relevant to the adjudication, to continually assess and improve the adjudication processes, procedures and training.

However, DHS notes that officer discretion is not a new concept in USCIS immigration benefits adjudications. Several benefits provided under the Act are discretionary in nature, and involve an assessment and weighting of positive and negative factors. For example, an alien's adjustment of status application to that of lawful permanent resident under section 245 of the Act, 8 U.S.C. 1255, requires the officer to weigh all positive and negative factors in the alien's case to ultimately determine whether lawful permanent resident status should be granted as a matter of discretion.[534] DHS disagrees with commenters' characterization that the rule overall, the proposed framework for the public charge determination, and individual factors, as published in the NPRM, lack required specificity or are impermissibly vague. When creating implementing regulations under the APA, an agency must provide notice that, among other things, articulates the terms or substance of the proposed rule, or a description of the subjects and issues involved. A notice of proposed rulemaking must contain sufficient factual details and rationale to permit interested parties to comment meaningfully. An agency is accorded broad deference in selecting the level of generality at which it may articulate regulations but a regulation is not deemed vague simply because it may contain a factor that is difficult to prove; it may be deemed vague or lacking in specificity if it is unclear as to what fact must be proven.[535] The NPRM and this rule both make abundantly clear what an alien must prove. DHS not only ensured that the public had a meaningful opportunity to comment by clearly articulating which factors USCIS will consider as part of the totality of the circumstances standard, but also by illustrating the application of the public charge determination framework and its factors in the preamble and in Table 33 of the NPRM.[536]

DHS also disagrees that the rule requires a high standard of proof. Congress established the mandatory factors that must be considered as part of the public charge determination and DHS is providing guidance on how to assess these factors.[537] Additionally, Congress established clear burdens and standards of proof relating to grounds of inadmissibility in immigration proceedings. The alien always has the burden to show that he or she is eligible for an immigration benefit and that he or she is not inadmissible.[538] In general, an alien must show by a preponderance of the evidence that he or she is eligible for the benefit sought.[539]

Finally, DHS understands that commenters believe that the submission of Form I–864 provides a method for objective public charge inadmissibility analysis and that the totality of the circumstances approach is inefficient because of training needs and because other agencies, such as the DOL, already evaluate education and skills criteria. It is true that the practical focus of DHS

[533] *See* USCIS Policy Memorandum Issuance of Certain RFEs and NOIDs; Revisions to *Adjudicator's Field Manual* (*AFM*) Chapter 10.5(a), Chapter 10.5(b), PM–602–0163 (Jul. 13, 2018) (*https://www.uscis.gov/sites/default/files/USCIS/Laws/Memoranda/AFM_10_Standards_for_RFEs_and_NOIDs_FINAL2.pdf* (last visited June 21, 2019).

DHS notes that the failure to submit a completed Form I–944, Declaration of Self-Sufficiency or Form I–864, Affidavit of Support with the Form I–485, Application to Register or Adjust Status, when required, may result in a rejection or a denial of the Form I–485 without a prior RFE or NOID. *See* 8 CFR 103.2(a)(7), (b)(8)(ii).

[534] *See* INA section 245, 8 U.S.C. 1255; *see also* USCIS Policy Manual Guidance on Adjustment of Status under INA section 245, Volume 7, Part B, 245(a) Adjustment.

[535] *See F.C.C.* v. *Fox Television Stations, Inc.,* 567 U.S. 239, 253 (2012); *see also Connally* v. *General Constr. Co.,* 269 U.S. 385, 391 (1926).

[536] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51211 (proposed Oct. 10, 2018).

[537] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[538] *See* INA section 291, 8 U.S.C. 1361; 8 CFR 103.2(b)(1) (''An applicant or petitioner must establish that he or she is eligible for the requested benefit.''); *Matter of Brantigan,* 11 I&N Dec. 493 (BIA 1966).

[539] *See Matter of Bett,* 26 I&N Dec. 437, 440 (BIA 2014) (''To be eligible for adjustment of status, an applicant has the burden to show that he is clearly and beyond doubt entitled to be admitted to the United States and is not inadmissible under section 212(a) of the Act.''); *Matter of Chawathe,* 25 I&N Dec. 369, 375 (2010) (''Except where a different standard is specified by law, a petitioner or applicant in administrative immigration proceedings must prove by a preponderance of evidence that he or she is eligible for the benefit sought.'') (citations omitted). *See also Kirong* v. *Mukasey,* 529 F.3d 800, 803–804 (8th Cir. 2008) (concluding that as an applicant for adjustment of status, the alien is put into the position of an alien seeking admission and must prove that he or she is clearly and beyond doubt admissible).

in a public charge inadmissibility determination previously had been primarily on the sufficiency of an affidavit of support submitted on the alien's behalf. DHS, however, clarified the relationship between the Form I–864 and a public charge inadmissibility determination in the NPRM.[540] As explained in the NPRM, given that the statute [541] differentiates between the affidavit of support requirement and the mandatory factors of the public charge assessment, DHS considers it inconsistent with the statutory language to solely use the affidavit of support as a means to determine public charge inadmissibility. Similarly, while certain employment-based immigrant categories are required to obtain labor certifications from the DOL and to submit evidence of job qualifications, these requirements focus on an alien's ability to meet qualifications of the job offered and the employer's ability to pay the proffered wages [542] rather than an alien's likelihood of becoming a public charge because of age, health, financial status, education, skills, etc. Therefore, DOL's assessments and certifications obtained by DOL are not redundant to or a suitable substitute for public charge determinations.

Comment: Several commenters stated that, although the proposed rule acknowledges that the public charge determination is intended to be prospective, the proposed criteria are actually retrospective and offered without any evidence that they are relevant to the determination of whether an immigrant will become dependent on the Government for support in the future. Some commenters stated that the proposed rule completely ignores an individual's ability to learn, work, develop skills, and support himself or herself and his or her family. Several commenters recommended that DHS conduct research about the probability that an individual would be self-sufficient or not based on the weighted factors included in the public charge determination.

One commenter agreed with the use of data in Table 33 on the Totality of Circumstances Framework for Public Charge Determinations in the NPRM,[543] but this commenter and many others stated that positive and negative weighted factors are not treated the same, as there is an extensive list of negative factors and a short list of positive factors. Therefore, these commenters believed that it would appear more likely an applicant could be disqualified based on weighted negative factors even if their application contains both positive and negative factors. Several commenters cited the MPI's analysis of American Community Survey (ACS) data from 2012–2016, that identified immigrants that are lawful permanent residents with fewer than five years of residency in the United States. The study showed that a significant number of these lawful permanent residents would have one or more negative factors counted against them, indicating substantial reduction in the number of potential green cards issued if the proposed rule was finalized.

Multiple commenters stated that, in order to improve one's education and skills and to be self-sufficient, it is often necessary to draw on short-term supportive services, but drawing on such means-tested public benefits would be a negative consideration in the totality of the circumstances test. Thus, the rule sets up a contradictory situation in which individuals attempting to strengthen their positive factors may instead add to the negative factors for their case. A commenter stated that the weighted factors used in the ''totality of circumstances'' test to determine inadmissibility is the ''only interpretation that would be consistent with the governing statutory language and established methods of statutory construction.''

Response: DHS disagrees that it is at all problematic for DHS to consider events in the alien's past as part of a prospective inadmissibility determination. As explained in the NPRM, DHS's proposed totality of the circumstances standard involves the weighing of positive and negative considerations in relation to the alien's age, health, financial assets, education and skills as well as the required affidavit of support and any other factor that warrants consideration in the alien's case. The totality of the circumstances approach, including consideration of events and circumstances in the alien's past, is consistent with the approach taken by the former INS, the BIA, and Article III case law.[544] Thus, although these factors may require some retrospective evaluation at the time of adjustment of status, Congress and courts deemed the alien's past as relevant to the alien's likelihood of becoming a public charge.[545] DHS also discussed, in detail, the relevance of each factor in the public charge determination and supported its finding with relevant data. DHS, therefore, disagrees that it failed to provide a reasonable explanation why the factors are relevant.

Finally, although section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), lists required factors that must be considered, it does not preclude USCIS from considering other considerations relevant in an applicant's case. DHS agrees that officers will encounter various circumstances not specifically accounted for in the regulation, but plans to give officers the necessary tools through guidance and training to fairly adjudicate such cases, and believes that officers are able to exercise their judgment appropriately. As noted above, Congress specifically provided for the agency's discretion to account for all aspects in an individual's case.[546] DHS disagrees with the commenters that indicated that positive and negative factors are not treated equally because DHS in its regulations listed more negative factors than positive ones. Although having more negative factors may be a basis for finding a person inadmissible based on public charge, the number of negative factors does not by itself lead to a conclusion that a person is likely to become a public charge. USCIS will consider and weigh each factor presented in an alien's case in the totality of the circumstances.[547] DHS notes that it has added an additional heavily weighted positive factor in section III.R. of this preamble.

Comment: Some commenters also indicated that it appeared more likely that applicants would be disqualified based on heavily weighted negative factors even though their application contains both positive and negative factors.

Response: DHS agrees that some applicants may be found in the totality of circumstances likely to become a

[540] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51197 (proposed Oct. 10, 2018).

[541] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[542] *See* 20 CFR part 656.

[543] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51211 (proposed Oct. 10, 2018).

[544] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51179 (proposed Oct. 10, 2018).

[545] *See Matter of Vindman,* 16 I&N Dec. 131 (Reg'l Comm's 1977) (consideration of past public benefits in determining the likelihood of becoming a public charge in the future); *Matter of Martinez-Lopez,* 10 I&N Dec. 409, 421–22 (BIA 1962; Att'y Gen. 1964) (in determining whether a person is likely to become a public charge, factors to consider include age, health, and physical condition, physical or mental defects which might affect earning capacity, vocation, past record of employment, current employment, offer of employment, number of dependents, existing conditions in the United States, sufficient funds or assurances of support by relatives or friends in the United States, bond or undertaking, or any specific circumstances reasonably tending to show that the burden of supporting he alien is likely to be case on the public.)

[546] *See* INA section 212(a)(4), 8 U.S.C. 1184(a)(4).

[547] *See* 8 CFR 212.22(a).

public charge even if they present positive factors. If negative factors in the alien's case (factors that increases an alien's likelihood of becoming a public charge) outweigh positive factors (factors that decrease the alien's likelihood of becoming a public charge), DHS would conclude, in the totality of the circumstances, that the applicant is inadmissible for likely becoming a public charge. Therefore, it may be that an alien is found inadmissible in light of a heavily weighted negative factor even if he or she may be able to present positive factors.

Comment: One commenter recommended that DHS provide guidance on how the ''totality of circumstances'' and likelihood determination should be reached using evidence-based methods, namely using a base rate as a prior probability which can be updated based on the evidence about a given alien. The commenter stated that starting from the ''inside view'' of the evidence about a given alien rather than the ''outside view'' of base rates about the reference class of all aliens would likely lead DHS to significantly more false positive determinations. The commenter stated that DHS should estimate a base rate—both before the rule takes effect and again after a sufficiently long interval to account for disenrollment—for the proportion of aliens non-exempt from public charge inadmissibility who would be considered public charges. This base rate should then be considered the prior probability that an alien is likely to become a public charge. The commenter also stated that DHS should also estimate average levels of receipt, duration, and other kinds of evidence in the totality of the circumstances so that officials may compare any given alien's evidence to average levels and make appropriate updates in the right direction. Another commenter suggested weighing factors using valid statistical methods, using administrative survey data to create a factor model to precisely calculate the probability of future use, and making the factor model available online for applicants to utilize before applying.

Response: The factors contained in this rule are based, in significant part, on data regarding the relationship between the minimum statutory factors and a person's likelihood of receiving public benefits. In the preamble to the proposed rule, for each positive and negative factor, DHS included supportive reasoning that related to either inferences regarding self-sufficiency or empirical data regarding the relationship between the factor and the likelihood that a person would receive public benefits. DHS relied on such data for all heavily weighted factors. For instance, in proposing the heavily weighted negative factor for lack of employability, DHS relied not only on the reasonable premise that ''[s]elf-sufficiency generally involves people being capable and willing to work and being able to maintain gainful employment,'' but also on Census Bureau data showing that individuals with full-time work were less likely to receive means-tested benefits during the year (ranging from 4.5 percent to 5.1 percent) than those with either part-time work (ranging from 12.6 percent to 14.2 percent) or those who were unemployed (ranging from 24.8 percent to 31.2 percent).[548]

That said, DHS cannot satisfy the commenter's request that DHS ''estimate . . . base rates—both before the rule takes effect and again after a sufficiently long interval to account for disenrollment—for the proportion of aliens non-exempt from public charge inadmissibility.'' This is because as DHS acknowledged in the proposed rule, DHS lacks access to data regarding the specific categories of aliens that are subject to the public charge ground of inadmissibility, let alone data regarding such aliens' public benefits use as it relates to the statutory factors. For instance, the proposed rule explained that much of the data that DHS relied upon came from the 2014 Panel of the SIPP. The SIPP Panel includes respondent-provided data on nativity, citizenship status, and initial immigration status, but does not provide data on current immigration classification. Additionally, the categories represented in the SIPP immigration status item do not align precisely with the populations covered by this rule—for instance, the results include refugees, asylees, and other populations that may access public benefits but are not subject to the public charge ground of inadmissibility. Finally, the SIPP data and DHS's analysis of this data do not examine whether the receipt of public benefits was authorized, and DHS did not examine program payment rate error information for this purpose. DHS sought comment on its use of the SIPP data, and whether alternative reliable data sources are available.[549] The commenter did not identify an alternative reliable data source that controls for whether an alien is subject to the public charge ground of inadmissibility.

Even if the commenter had identified such data, however, adjudicators would not have been able to rely heavily on such data, because the public charge assessment requires a prediction based on an assessment of the alien's particular circumstances within the framework of multiple statutory factors, and any other relevant considerations. A data set tailored to such particular individuals' circumstances may not be available, and in any event was not identified by the commenter.

DHS acknowledges that the predictive analysis it will be conducting based on an individual's particular circumstances leaves some room for error, however, so would any predictive algorithm or data-based ''outside view'' analysis, particularly given the data limitations DHS encountered and the likelihood that even if comprehensive data sets existed that could be utilized in the fashion the commenter suggests, they would not be detailed enough or sufficiently timely to account for changes in trends. For example, a dataset from the 2008–2010 timeframe may predict an appreciably higher rate of benefit receipt based on certain individual circumstances than a dataset from 2015–2017. Therefore, in the absence of adequate tools that would allow DHS to use a comprehensive quantitative framework for individual public charge inadmissibility determinations, USCIS officers will rely on their training and USCIS guidance to assess the relationship between factors and the likelihood to receive public benefits above the designated threshold at any time in the future. This analysis will include an assessment of all evidence provided by the alien in support of his or her application, including any credible and probative data that is relevant to the assessment. Furthermore, to the extent USCIS is able to identify credible and probative data sources that would provide context for

[548] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51198 (proposed Oct. 10, 2018) (citing Jeongsoo Kim, Shelley K. Irving, & Tracy A. Loveless, U.S. Census Bureau, *Dynamics of Economic Well-Being: Participation in Government Programs, 2004 to 2007 and 2009—Who Gets Assistance?* 12 (July 2012), available at *https://www2.census.gov/library/publications/2012/demo/p70–130.pdf* (last visited July 26, 2019); Shelley K. Irving & Tracy A. Loveless, U.S. Census Bureau, Dynamics of Economic Well-Being: Participation in Government Programs, 2009–2012: Who Gets Assistance? 10 (May 2015), available at *https://www.census.gov/content/dam/Census/library/publications/2015/demo/p70–141.pdf*) (last visited July 26, 2019).

[549] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51160–61 (proposed Oct. 10, 2018). The commenter also suggested that DHS generate such data. But, it does not seem possible to estimate the probability of becoming a public charge by following up with aliens who were subject to the determination. For instance, many of those who were denied a benefit may not reside in the United States at a later date.

adjudicators in evaluating one or more mandatory factors, USCIS may provide such data sources to adjudicators and ensure consistent application through guidance and training.

Comment: A few commenters provided feedback on the review process. One commenter stated that immigration officers will have a limited amount of time to properly review documents and employment letters, and will not undertake an effective, case-by-case appraisal of applications. Similarly, commenters indicated that supervising officers will not have enough time to review each denial thoroughly.

Response: DHS understands the concerns that the public charge determination could increase the adjudication time of immigration benefits and that individuals, including attorneys, may have additional questions. DHS and USCIS are committed to putting the necessary resources into place, including additional adjudicators, to minimize any impact on current immigration benefits adjudications and to provide for thorough consideration of each case and appropriate supervisory review.

Comment: Many commenters voiced concern about the disproportionate negative impact of the application of the mandatory factors on marginalized communities. This included negative effects on immigrants belonging to the LGBTQ community, HIV positive immigrants, immigrants with chronic health conditions and disabilities, immigrants of color, Latino immigrants, AAPI immigrants, immigrants from countries that are poor and largely people of color, senior citizens, women, and victims of domestic violence and sexual abuse.

Response: Regardless of whether this rule will impact the groups specified in these comments, DHS is not promulgating this rule for a discriminatory purpose. Rather, this rule will better ensure that aliens seeking to enter or remain in the United States either temporarily or permanently are self-sufficient, and rely on their own capabilities and the resources of their family, sponsors, and private organizations, rather than the government.[550] DHS will determine an individual's inadmissibility on public charge grounds of inadmissibility in the totality of the circumstances, based on the statutorily mandated factors.[551] Additionally, Congress did not make applicable the public charge ground of inadmissibility to certain classes of aliens, including certain victims of domestic violence, trafficking and other crimes. DHS therefore included these exemptions in this rulemaking.[552]

Comment: A few commenters cited the MPI study, which stated that of the over 2 million individuals granted lawful permanent residence status in the past five years (between 2012 and 2016), 69 percent of recent lawful permanent residents who are not refugees or other humanitarian admissions would have had at least one negative factor under the proposed new definition, 43 percent at least two negative factors, and 17 percent had at least three negative factors.[553] The same analysis reported that 39 percent of recent lawful permanent residents did not speak English well or not at all, 33 percent had household incomes below 125 percent of the FPG, 25 percent did not have a high school diploma, and 12 percent were under age 18 or over age 61. The analysis also estimated that 39 percent of recent lawful permanent residents had incomes at or above 250 percent of the FPG.

Response: DHS thanks commenters for citing the findings of the MPI study, which also highlighted that ''the rule does not specify how many negative versus positive factors someone must have for their application to be denied.'' [554] While an alien may have one, two, three, or more negative factors, the mere fact that the alien's negative factors outnumber the alien's positive factors is not a sufficient basis to find the alien inadmissible. DHS must find that the alien's negative factors outweigh the alien's positive factors based on the totality of circumstances analysis, such that the alien is more likely than not at any time in the future to receive one or more public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within any 36-month period.

Once effective, DHS is aware that this rule will likely result in more findings of public charge inadmissibility and may result in fewer overall admissions and approved adjustment of status applications to the United States, as DHS seeks to better enforce the public charge ground of inadmissibility and to ensure that aliens are self-sufficient when coming to the United States or seeking to adjust status. Notwithstanding, DHS will be bound by its own regulations in making public charge inadmissibility determinations based on the totality of the alien's circumstances, which includes considering and weighing all relevant factors that are favorable to the alien.

Comment: Commenters indicated that it is impossible to predict future self-sufficient behavior based on current resources of individuals who are, by definition, in transition (or trying to be) from living in another country to finding and creating opportunity in the United States.

Response: DHS disagrees that it is impossible to predict whether an individual is likely to become a public charge in the future based on the factors outlined in INA section 212(a)(4) of the Act, 8 U.S.C 1182(a)(4). The commenters' quarrel is with Congress, not DHS. While DHS acknowledges that the public charge determination is a complex assessment, DHS described at length in the NPRM how it would evaluate an alien's individual circumstances, including the minimum statutory factors, as part of the public charge determination. In Table 33 of the NPRM, DHS also outlined in detail the totality of the circumstances assessment and when the evidence in the totality of the circumstances may be indicative of the individual becoming a public charge. In this final rule, as explained below, DHS has further clarified and expanded on its approach.

Comment: Commenters pointed out that many who would be subject to the public charge rule are already barred from receiving public benefits for at least 5 years due to past welfare reform efforts.

Response: The commenters correctly pointed out that under PRWORA and other laws, most immigrants and nonimmigrants are not eligible for certain public benefits for a duration of at least five years. The public charge ground of inadmissibility, however, does not have any temporal limits in this regard and is prospective in nature; Congress directed the administering agencies to determine, for admissibility purposes, whether the alien is likely, ''at any time'' to become a public charge.

I. Age

1. Standard

Comment: A commenter expressed support for the proposed designation of the age range 18–61 as a positive factor and stated that there is a strong correlation between this prime working age range and a much lower rate of use

[550] 8 U.S.C. 1601(2)(A).

[551] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[552] *See* 8 CFR 212.23.

[553] MPI, Gauging the Impact of DHS' Proposed Public-Charge Rule on U.S. Immigration (Nov. 2018), *https://www.migrationpolicy.org/research/impact-dhs-public-charge-rule-immigration* (last visited July 25, 2019).

[554] *See* Capps, Randy et al, ''Gauging the Impact of DHS' Proposed Public-Charge Rule on U.S. Immigration,'' Migration Policy Institute. (November 2018). Available at: *https://www.migrationpolicy.org/research/impact-dhs-public-charge-rule-immigration* (last visited July 26, 2019).

of public benefits, compared to individuals outside that age range. The commenter also added that that both minors and elderly aliens, like their citizen counterparts, are more likely to be financially dependent on resources other than employment income. One commenter suggested that DHS conduct a more lenient ''Public Charge Check'' for aliens younger than 21 or older than 55 (if one is needed at all), and a more thorough check for aliens aged between 21 and 55. A commenter stated that since the 19th century, courts have recognized that it would be absurd to exclude every child from our shores, since no child, by his personal efforts alone, can take care of himself.'' [555]

Another commenter said the rule provides no justification for why a minor under 18 years old should be scrutinized when they are not expected to be self-sufficient, or why immigrants over the age of 61, many of whom work or provide support to the rest of their family, should be penalized merely because of their age. The commenter stated that the rule did not explain why these age thresholds are predictors of future public benefit use. One commenter stated that these age-range requirements are overly broad, ignore the possibility of a familial sponsor, and raise the income requirements in a cruel way that is detrimental to society. One commenter asserted that DHS's analysis for an age standard overlooks the substantial benefits that minor children bring to a family, including future potential working capacity. One commenter similarly stated that the rule does not factor in the potential children have to add value to society and also stated that seniors often play a critical caregiver role which allows others to work. Another commenter added that an alien's unemployment at age 16 or 17 provides no evidence of their future employability. One commenter gave an example that 16-year old high-school students are not likely to be employed for many years in the future, but once they complete their education they can reach their true potential. A commenter stated that, although those under the age of 18 are less likely to work since they will be in school, and therefore are more likely to become a public charge, those individuals typically learn English very quickly, integrate readily, and after completing their education (often including higher education), go on to work, contribute, and pay taxes in the United States for decades. A few commenters cited a report by the National Academies of Sciences, Engineering, and Medicine [556] for the proposition that second-generation child immigrants are the most fiscally positive of all immigrants to the United States.

Another commenter, in opposition to the age standard, said the question is not whether all children are likely to receive benefits, but rather whether children applying for lawful permanent resident status will. The commenter indicated that DHS cites no authority for its assertion that applicants who obtain lawful permanent resident status are more likely to become public charges simply due to their being under 18 years of age at the time of application. The commenter stated that because most aliens are not eligible for means-tested public benefits for at least the first five years after obtaining such status, the age range is too high. The commenter also stated that, for decades, DOS has used the age of 16 as the cut-off for when the child will be able to show employable job skills. The commenter sought justification for the change. One commenter stated that DHS bases this age standard on the minimum age at which one can start to claim retirement benefits under social security; however, this was never meant to be used to say that people are unable or even unlikely to work after that age. Some commenters stated that many over 61-year-olds are able to, willing to, and do work after immigrating.

Response: DHS agrees that the age range is appropriate due to the general correlation between the 18–61 age range and a lower rate of use of public benefits, and that people outside of this age range are, in general, more likely to be financially dependent on others.[557] DHS agrees that generally, most aliens are not eligible for means-tested public benefits for at least the first five years after obtaining such status; however, there are certain exceptions under PRWORA, including the availability of SNAP for children under 18.[558] DHS also acknowledges that certain individuals, depending on their status and circumstances, may not be eligible for public benefits in the near term and would take that fact into consideration in the public charge inadmissibility determination. DHS disagrees with the suggestion that USCIS provide a more lenient review of public charge for those below 21 and above 55. USCIS will apply the same public charge framework for all cases subject to public charge. DHS disagrees that there was no justification in the NPRM for the age range and will maintain the age ranges as identified in the NPRM. As established by Congress, an alien's age is a mandatory factor that must be considered when determining whether an alien is likely to become a public charge in the future.[559] As discussed in the NPRM, a person's age may impact his or her ability to legally or physically work and is therefore relevant to the likelihood of an alien becoming a public charge.[560]

In addition, regardless of an alien's age, DHS recognizes, consistent with longstanding case law, that the alien may have financial assets, resources, benefits through employment, education or skills, family, or other means of support that decrease his or her likelihood of becoming a public charge. Therefore, age is but one factor in the totality of the circumstances. As discussed in the NPRM,[561] the 18 through 61 age range is based on the ages at which people are generally able to work full-time before being able to retire with some social security retirement benefits under Federal law.[562] DHS notes that considering 18 years old as the earliest age in which one is expected to be able to work is consistent with current DOS guidance which directs consular officers to consider what skills individuals 18 years of age or older have to make a living.[563] DHS declines the request from the commenter to justify why this rule is contrary to past DOS guidance since that guidance is from another Department and never was binding on DHS. DHS understands that children may continue their education and obtain employment in the future. DHS would not make a determination of

[555] *See In re Day,* 27 F. 678 (S.D.N.Y. 1886).

[556] *See* National Academies of Sciences, Engineering, and Medicine, The Economic and Fiscal Consequences of Immigration (2017).

[557] The rate of receipt of cash and noncash benefits among noncitizen children age 0–17 decreased with the removal of Medicaid from consideration for that age group, changing from about 40 percent when the benefit was included to about 20 percent when it was not. The receipt rate of cash and noncash benefits among noncitizen children age 0–17 was no longer significantly different from that of noncitizens aged 18–61 when Medicaid was included only for the older age group, and both of these age groups had much lower receipt of benefits than noncitizens aged 62 and over. However, due to the restrictions on employment by minors and the fact that children are dependent on their parents or legal guardians, as discussed in the NPRM, DHS still consider the age range appropriate.

[558] *See, e.g.,* 8 U.S.C. 1612(a)(2)(J).

[559] *See* INA section 212(a)(4)(B), 8 U.S.C. 1182(a)(4)(B).

[560] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51179–81 (proposed Oct. 10, 2018).

[561] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 511179–81 (proposed Oct. 10, 2018).

[562] *See* 29 U.S.C. 213(c), 42 U.S.C. 416(*l*)(2) (''Early retirement age'' for social security purposes).

[563] *See* 9 FAM 302.8–2)(B)(2), paragraph d, available at *https://fam.state.gov/FAM/09FAM/09FAM030208.html* (last visited May 15, 2019).

inadmissibility based on public charge solely based on the age of a child. Instead, USCIS would also review the support provided by a parent or other source in the totality of the circumstances.

Comment: Commenters stated DHS based the proposed age standard on the minimum age at which one can start to claim retirement benefits under social security; however, this was never meant to be used to say that people are unable or even unlikely to work after that age. Several commenters explained that if DHS finalized the rule as proposed, many U.S. citizens would no longer be able to welcome their own parents into the country because it would be difficult for older adults to pass the ''public charge'' test under the new criteria. A commenter stated that applications for parents account for almost 30 percent of all family-based applications. Some commenters stated that many seniors immigrate to the United States in order to help care for children and other family members. Commenters stated this rule fails to recognize the value of intergenerational families who support each other and the proposed rule ''callously'' labels parents and grandparents as a burden because of their age or health needs and ignores the critical roles many grandparents play in caring for their grandchildren and other family members, often enabling others to work.

A few commenters stated that the proposed rule fails to accord appropriate dignity and respect to community elders seeking immigration relief by treating them as economically disposable, and would have the effect of straining and fracturing families who seek to maintain seniors within the familial unit.

A commenter said having older adults at home can eliminate the cost of childcare, which is one of the highest budget items for many families and can approach 20 percent of household income for low-income families. Citing studies, a commenter stated that limiting the age of workers has been shown to have a negative economic impact on society. Another commenter remarked that the proposed rule could prevent many American citizens from maintaining the dignity of their families due to ''exclusionary factors'' assigned to advanced age or receipt of life-saving medical savings under Medicare Part D. The commenter also stated that this illustrates a critical flaw in the proposed rule: it undervalues the important role a parent or grandparent contributes to a family. A few commenters stated that if U.S. citizens are unable to bring their parents to the United States, they would have to send money abroad for their care in their home country, which may require expensive residential care, financially hampering citizens and sending those dollars outside of the U.S. economy.

One commenter stated there is a priceless emotional benefit to U.S. citizens having their parents nearby for love, support, and for their families to be whole and enriched through the joyful and sorrowful life events of the birth of grandchildren and the passing of family elders. A commenter stated that some U.S. citizens bring their elderly parents to the United States because caring for them here will ease the burden of worrying about their care in countries that are many thousands of miles away. The commenter added that the ability to care for loved ones at the end stages of life is an important marker for all communities and nationalities, which would be nearly impossible if DHS finalized the rule as proposed.

Response: DHS disagrees that the age standard is arbitrary. As provided in the NPRM,[564] there is a correlation between the prime working age range and lower rates of public benefit use. As indicated in the NPRM,[565] the 18 through 61 age range is based on the ages at which people are generally able to work full-time before being able to retire with some social security retirement benefits under Federal law.[566] The age of 18 is based on the general age to be able to start working full-time; [567] the age of 61 is the year before the minimum ''early retirement age'' for social security purposes [568] (62 as of 2017). DHS will still consider the alien's age in relation to whether it makes the alien more or less likely to become a public charge, such as by impacting the alien's ability to work. DHS is not establishing the age range as a statement that people outside that range are unable to work. DHS acknowledges that people under the age of 18 and over the age of 61 may be working or have other adequate means of support, such as from family members. DHS would recognize such means as positive factors. In other words, a senior who establishes to DHS's satisfaction that she or he is not likely to become a public charge would not be deemed inadmissible on public charge grounds.

DHS recognizes the tangible and intangible value to individuals and communities of strong family bonds and support across generations. DHS notes that where an alien can establish that he or she is not likely to become a public charge in light of all the relevant factors—including, for example, the support of one or more family members—the alien would not be found inadmissible as a public charge. Accordingly, DHS does not believe that this rulemaking will necessarily render it impossible for individuals to care for family members. Rather, the rule seeks to ensure that aliens rely on themselves and on private sources, including their families, to meet their needs, rather than relying on public benefits. DHS does acknowledge that the rule could affect a family member's admissibility or eligibility to adjust status in some cases, but notes that such effect would be a consequence of the statutory scheme, under which the family member is subject to the public charge ground of inadmissibility.

Comment: A commenter asserted the statistics DHS used to establish the 18–61 age standard do not distinguish between those who are refugees and asylees and those who obtained legal status through a family or employment-based petition. The commenter added that lawful permanent residents who immigrate or adjust through other means are barred for their first five years from accessing SSI, and they are subject to sponsor-to-alien deeming of income thereafter. The commenter stated that it is inappropriate to lump this latter group of lawful permanent residents in with refugees and asylees, who are in fact encouraged to participate in Federal benefit programs, and it is disingenuous to use it as a basis to make age above 61 years a negative factor.

Response: As discussed in the NPRM, DHS recognizes that the statistics provided do not distinguish the immigrant status of the alien, and ''the results include refugees, asylees, and other populations that may access public benefits but are not subject to the public charge ground of inadmissibility.'' [569] The SIPP data and DHS's analysis of this data do not examine whether the receipt of public benefits was authorized, and DHS did not examine program payment rate error information for this purpose. Notwithstanding these limitations, DHS believes the SIPP data on noncitizen participation is instructive with respect

[564] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51180 (proposed Oct. 10, 2018).

[565] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51180 (proposed Oct. 10, 2018).

[566] *See* 29 U.S.C. 213(c), 42 U.S.C. 416(*l*)(2).

[567] *See* 29 U.S.C. 213(c); 29 CFR part 570; *see also* Dep't of Labor, *Table of Employment/Age Certification Issuance Practice Under State Child Labor Laws, available at https://www.dol.gov/whd/state/certification.htm* (last visited July 26, 2019).

[568] *See* 42 U.S.C. 416(*l*)(2).

[569] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51160 (proposed Oct. 10, 2018).

to the receipt of non-cash benefits by the noncitizen population overall.

Comment: A few commenters stated this proposal could undermine access to healthcare, nutrition, and housing programs for children of immigrants and their aging family members. One commenter said the proposed consideration of age could contribute to family separations. The commenter added that by weighing age negatively in the totality of circumstances, immigrant children younger than 18 years of age are likely to see their green card or visa applications denied, which could lead to members of the same family obtaining differing immigration statuses, with some members unable to remain in the United States. A few commenters said the rule could increase family separation, which can cause emotional stress and trauma in children that leads to negative health outcomes. Another commenter cited an MPI analysis, which found that 45 percent of children who recently received green cards had two or more negative factors. The commenter added that depriving children, including U.S. citizens, of access to public benefits that would otherwise increase their families' ability to thrive will lead to deep stress, which studies show then in turn leads to reduced outcomes throughout life. A commenter indicated that being a child should not weigh against an individual in a public charge determination. The commenter stated that because children generally are not allowed to work, it is unlikely they could have an income or assets on their own equal to 125% or more of the FPG.

Response: DHS understands that individuals, including children, will be impacted by this rulemaking, once effective. When codifying section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), Congress did not generally exempt children from the public charge inadmissibility ground and an alien's age is a mandatory, statutory factor that DHS must be considered when determining whether an alien is likely at any time in the future to become a public charge.[570] Accordingly, DHS will consider whether the alien's age makes the alien more likely than not to become a public charge, such as if the alien's age affects an alien's ability to work. DHS understands that children are in a unique position in some respects, especially as it relates to employability. The commenter referred to the MPI's study, which attempted to measure the general impact of the proposed rule by examining the situations of recent green card recipients. The MPI study estimated that among recent green card recipients, about 45 percent of the children would have had two or more negative factors if the proposed rule had been applied to them.[571] DHS appreciates the input on the potential impact. As indicated in the NPRM, however, DHS is not able to quantify the number of aliens, including children, who would possibly be denied admission based on a public charge determination under this rule. Again, DHS is qualitatively acknowledging this potential impact.

DHS would like to clarify, however, the following aspects of the inadmissibility determination in relation to children under the age of 18: DHS understands that children may continue their education and obtain employment in the future. As indicated throughout this preamble, DHS would not make a public charge inadmissibility determination solely based on the age of a child. Instead, USCIS will review the support provided by a parent or the parents, and any other evidence addressing the resources and assets available to the child in the totality of the circumstances when determining whether the child is more likely than not at any time in the future to become a public charge. DHS has also made a number of changes and clarifications in this final rule that are relevant to the rule's effects on children, including (1) excluding receipt of Medicaid by children under age 21, and (2) clarifying that receipt of benefits by another beneficiary's behalf is not attributed to the person who received it (such as a parent or legal guardian, for example). DHS does not anticipate outcomes that would require family members to live in different countries, so long as any family members who have applied for an immigration benefit for which admissibility is required can demonstrate that they are not inadmissible.

Overall, DHS notes that the public charge inadmissibility determination requires DHS to evaluate the alien child's particular circumstances. DHS's totality of the circumstances standard involves weighing all the positive and negative considerations related to an alien's age; health; family status; assets, resources, and financial status; education and skills; required affidavit of support; and any other factor or circumstance that may warrant consideration in the public charge inadmissibility determination.[572] If the negative factors outweigh the positive factors, then the alien would be found inadmissible as likely to become a public charge; if the positive factors outweigh the negative factors, then the alien would not be found inadmissible as likely to become a public charge.

2. Age Discrimination

Comment: Some commenters stated that rule discriminates against people of certain ages. Commenters stated that the age standard is not only discriminatory towards children, but is also logically inconsistent as children have a lifetime of productive years ahead of them. Commenters stated that adding age and disability discrimination into our immigration regulations would unjustly deny U.S. citizens the ability to reunite with, receive support from, and if necessary, provide support to their family members.

Response: DHS does not agree that this rule adds discrimination based on age or disability. An alien's age is a mandatory factor that must be considered when determining whether an alien is likely to become a public charge in the future.[573] Therefore, the rule includes this factor. As DHS noted in the NPRM, a person's age may impact his or her ability to legally or physically work and is therefore relevant to being self-sufficient, and the likelihood of becoming a public charge. An alien's likelihood of becoming a public charge is prospective and based on the totality of the alien's circumstances. If an alien's positive factors outweigh the negative factors, then the alien would not be found inadmissible as likely to become a public charge. No one factor, apart from the failure to submit a sufficient affidavit of support where required, is outcome determinative.

Additionally, to the extent that this rule may result in the denial of some applications filed by relatives of U.S. citizens, DHS disagrees that this rule would deny U.S. citizens the ability to reunite with, and support, their families. DHS acknowledges that the rule could affect a family member's admissibility or eligibility for adjustment of status, but such effect would be a consequence of the statutory scheme, under which the family member is subject to the public charge ground of inadmissibility. This rule does not change the criteria applicable to a U.S. citizen filing Petition for Alien

[570] *See* section INA section 212(a)(4)(B), 8 U.S.C. 1182(a)(4)(B).

[571] *See* Capps, Randy et al, ''Gauging the Impact of DHS' Proposed Public-Charge Rule on U.S. Immigration,'' Migration Policy Institute. (November 2018). Available at: *https://www.migrationpolicy.org/research/impact-dhs-public-charge-rule-immigration* (last visited July 26, 2019).

[572] *See* 8 CFR 212.22.

[573] *See* INA section 212(a)(4)(B), 8 U.S.C. 1182(a)(4)(B).

Relative (Form I–130), which does not require the beneficiary's admissibility. This rule addresses the criteria for establishing eligibility for admission or adjustment of status and for demonstrating that the applicant is not inadmissible as likely to become a public charge. In other words, even if an alien may be eligible statutorily to be granted adjustment of status based upon the approval of a Form I–130 filed by a U.S. citizen relative, the alien is not entitled to be admitted to the United States or granted adjustment,[574] and the U.S. citizen is not entitled to be reunified with the applicant.

J. Health

1. Standard

Comment: Several commenters stated that the rule perpetuates the ''false assumption'' that a medical diagnosis is solely determinative of an individual's current abilities and future prospects, with some asserting that chronic illness is not an accurate indicator of future self-sufficiency and full-time employment capabilities. One commenter stated that this policy assumes that the presence of a physical or mental condition is a financial risk to the state and fails to recognize the significant contributions that people with chronic health and other conditions can and do make as professionals and community members. One commenter stated the that consideration of disability in the health factor was a per se rule that is inconsistent with the fact that ''health status is far from necessarily predictive of a person's ability to engage productively in work and other aspects of community life.'' Another commenter stated that DHS failed to consider that with access to health insurance (*e.g.,* Medicaid), preventive medical treatment, and health care professionals, individuals with chronic medical conditions can exhibit drastic improvements in their health and productivity. A different commenter stated that counting conditions that require extensive medical treatment and/or hospitalization as negative factors ignores the reality that a Class A or B medical condition, especially a curable one, is not an accurate indicator of future self-sufficiency and full-time employment capabilities. Commenters noted that advances in medical technology could make certain conditions, such as HIV/AIDS more manageable in the future, with one noting that Type 1 Diabetes was a disabling condition in the 1950s but now adults and children with Type 1 Diabetes lead full, productive, and independent lives.

Conversely, one commenter agreed that the proposed health factor approach is appropriate for public charge purposes, so long as the inquiry is limited to whether aliens are likely to be able to pay for health-related expenses for themselves and any household dependents without the use of public resources.

Response: DHS recognizes that an individual with medical conditions may provide significant contributions to society. As established by Congress, an alien's health is a factor that must be considered when determining whether an alien is likely to become a public charge at any time in the future.[575] As indicated in the NPRM, the mere presence of a medical condition would not render an alien inadmissible.[576] Instead, DHS would consider the existence of a medical condition in light of the effect that such medical condition is likely to have on the alien's ability to provide and care for himself or herself; DHS will weigh such evidence in the totality of the circumstances. DHS officers will not be making medical determinations or determining the effects of the conditions. Instead, officers will review any required Form I–693 or applicable DOS medical examination form [577] submitted in support of the application for the diagnosis of medical conditions according to the procedures established by HHS; [578] or any other evidence of a medical condition that is likely to require extensive medical treatment or institutionalization after arrival, or that will interfere with the alien's ability to care for himself or herself, to attend school, or to work. The HHS regulations direct physicians conducting the immigration medical examinations for either Class A or Class B conditions to explain on the medical report ''the nature and extent of the abnormality; the degree to which the alien is incapable of normal physical activity; and the extent to which the condition is remediable . . . [as well as] the likelihood, that because of the condition, the applicant will require extensive medical care or institutionalization.'' [579] In addition, the CDC Technical Instructions for Medical Examinations of Aliens, directs physicians to provide information about Class B conditions, which, although do not ''constitute a specific excludable condition, represents a departure from normal health or well-being that is significant enough to possibly interfere with the person's ability to care for himself or herself, to attend school or work, or that may require extensive medical treatment or institutionalization in the future.'' [580] Such an assessment would necessarily account for any recent advancements in treating the medical condition, and goes directly to the prospect of the alien being able to care for himself or herself and being able to attend school or go to work. And, of course, the alien could provide further information with the application.

Comment: One commenter stated that, while health has always been a factor in the public charge test, the proposed rule codifies and unduly weighs the specific standard for evaluating an individual's health. Similarly, another commenter stated that the proposed rule essentially counts the same health status as two negative factors and also as a heavily weighted negative factor: Once as a negative health factor; again as a negative assets, resources and financial status factor; and then again as a heavily weighted negative factor if the non-citizen is uninsured. A different commenter said the combination of penalizing someone's medical condition

[574] *See Mudric* v. *Att'y Gen. of U.S.,* 469 F.3d 94, 98 (3d Cir. 2006) (''While an alien may be eligible for a grant of . . . adjustment of status under the immigration laws, he is not entitled to such benefits as a constitutional matter.''); *see also,* Matter of Ho, 19 I&N Dec. 582, 589 (BIA 1988) (holding that ''[a]pproval of a visa petition is but a preliminary step in the visa or adjustment of status application process, and the beneficiary is not, by mere approval of the petition, entitled to an immigrant visa or to adjustment of status.'')

[575] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[576] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51181–84 (proposed Oct. 10, 2018).

[577] This is currently the Immigrant or Refugee Application (Form DS–2054).

[578] The medical examination documentation indicates whether the applicant has either a Class A or a Class B medical condition. In addition, the alien must provide a vaccination record as part of the medical examination. Class A and Class B medical conditions are defined in the HHS regulations. *See* 42 CFR 34.2.

[579] 42 CFR 34.4(b)(2) (Class A); 42 CFR 34.4(c)(2) (Class B).

[580] *See* Ctrs. for Disease Control & Prevention, *Required Evaluations—Other Physical or Mental Abnormality, Disease, or Disability, Technical Instructions For Medical Examination Of Aliens, available at https://www.cdc.gov/immigrant refugeehealth/exams/ti/panel/technical-instructions/panel-physicians/other-physical-mental.html* (last updated Nov. 23, 2016) (last visited July 26, 2019); Ctrs. for Disease Control & Prevention, *Required Evaluation Components Other Physical or Mental Abnormality, Disease or Disability, Technical Instructions for the Medical Examination of Aliens in the United States, available at https://www.cdc.gov/immigrant refugeehealth/exams/ti/civil/technical-instructions/civil-surgeons/required-evaluation-components/other-disease-disability.html* (last updated Aug. 3, 2010) (last visited July 26, 2019). The HHS regulations require physicians conducting medical examinations for an alien to comply with the CDC's Technical Instructions for Medical Examinations of Aliens. 42 CFR 34.3(i).

and negatively weighting use of benefits and services that help to treat that medical condition will create an insurmountable bar for many older adults and people living with chronic illnesses or disabilities. Another commenter said health and disability are factors that are improperly considered twice under the rubric of the proposed rule.

Response: DHS disagrees that the review of the health factor in the public charge inadmissibility determination is an insurmountable bar for people with chronic illness or disabilities. The mere presence of a medical condition would not render an alien inadmissible. Instead, DHS would consider the existence of a medical condition in light of the effect that such medical condition is likely to have on the alien's ability to attend school or work, and weigh such evidence in the totality of the circumstances. As part of the assets, resources and financial status factor, DHS would also consider whether the alien has the resources to pay for associated medical costs.

As stated in the NPRM, an alien is at high risk of becoming a public charge if he or she does not have the resources to pay for reasonably foreseeable medical costs, including costs related to a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide care for himself or herself, to attend school, or to work.[581]

The mere presence, however, of any one enumerated circumstance, would not alone be determinative. A heavily weighted factor could be outweighed by countervailing evidence in the totality of the circumstances. DHS also disagrees that it is impermissibly counting factors twice. DHS acknowledges that multiple factors may coincide or relate to each other and emphasizes that the public charge determination reviews all factors in the totality of the circumstances. Therefore, the fact that a person has a medical condition that prevents him or her from working or going to school and lacks private health insurance is considered in the totality of the circumstances without assigning a point system or value to various factors. Finally, as discussed in section III. R. of this preamble, DHS has added a heavily weighted positive factor for private health insurance appropriate to intended the duration of the alien's stay.

Comment: Some commenters expressed concern that this aspect of the rule contained vague wording. One commenter stated that considering ''any physical or mental condition'' as part of the individual's health is overly broad and open to interpretation. Another commenter stated that the rule would stretch the INA's public charge language beyond recognition by adding vague references to ''extensive medical treatment'' and ''interference'' with an individual's ability to work, attend school, or otherwise be self-sufficient. The commenter stated that the manner in which DHS proposed to consider the health of an immigrant in making a forward-looking public charge determination leaves so much room for discretion that it renders the health factor consideration meaningless. A different commenter objected to using the standard of whether a health condition ''interferes with work or school'' as too broad, vague, and biased against people of color who will be prejudiced by this generic standard. The commenter stated that social determinants of health are one of the main inequalities between whites and persons of color. A commenter said that the proposed rule's consideration of medical conditions ''likely'' to require extensive medical treatment in the future was highly speculative, and that medical predictions about the future are notoriously inaccurate.

One commenter stated that, although the rule claims to use a physician's medical examination/report with two classes of medical conditions, it is vague, provides the physician with great latitude, and does not provide a clear definition of which medical conditions would be considered as a negative factor. This commenter stated that this suggests that any pre-existing condition may be counted against a green card applicant regardless of whether it will seriously undermine an individual's self-sufficiency.

Some commenters provided input on the role of DHS adjudicators as it relates to the health factor. Several commenters questioned the ability of an adjudicator to determine if someone living with a chronic condition will be a public charge in the future. One commenter said authorizing DHS personnel to make projections about whether a person's health condition could, in the future, affect their ability to work, study or care for themselves or require expensive treatment invites unbridled speculation and discrimination against persons with disabilities or other observable physical conditions. Another commenter stated that USCIS lays out no standards for determining whether a disability or other serious health condition will lead the agency to decide whether an applicant has a ''reasonable prospect of future employment.'' A different commenter said the rule would authorize non-medically trained personnel to overrule a medical professional's determination about whether a person's health should be a barrier to admission. Another commenter said immigration officials lacking any specialized medical knowledge would rely on hastily composed medical reports (frequently from medical providers who would have no established medical relationship with an individual) to exclude a noncitizen from the immigration benefit solely because of the presence of a particular illness or disability that may appear ''grave'' or ''costly'' based on preconceived and often erroneous assumptions. Some commenters said the proposed rule discounts future advancements in medical science and social norms by allowing DHS officials to make present-day judgements about an individual's future capabilities. A couple of commenters stated that the rule does not provide meaningful guidance on permissible and impermissible considerations when factoring in a person's disability during a public charge inadmissibility finding, which leaves immigration officials with seemingly open-ended interpretation.

Response: DHS disagrees that the wording regarding the health factor is vague and does not provide guidance on the consideration of disability. DHS's language mirrors the language as provided by HHS regulations and CDC guidance. In identifying a Class A medical condition, the HHS regulations direct physicians conducting the immigration medical examinations to explain on the medical report ''the nature and extent of the abnormality; the degree to which the alien is incapable of normal physical activity; and the extent to which the condition is remediable . . . [as well as] the likelihood, that because of the condition, the applicant will require extensive medical care or institutionalization.'' [582]

A Class B medical condition is defined as a physical or mental condition, disease, or disability serious in degree or permanent in nature.[583] Currently, the CDC Technical Instructions for Medical Examinations of Aliens, which direct physicians to provide information about Class B conditions, describe a Class B condition as one that, although it does not ''constitute a specific excludable

[581] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51182 (proposed Oct. 10, 2018).

[582] 42 CFR 34.4(b)(2).

[583] *See* 42 CFR 34.2(b)(2).

condition, represents a departure from normal health or well-being that is significant enough to possibly interfere with the person's ability to care for himself or herself, to attend school or work, or that may require extensive medical treatment or institutionalization in the future.'' [584]

As discussed in the NPRM,[585] as part of the immigration medical examination, when identifying a Class B medical condition, civil surgeons and panel physicians are required to report on certain disabilities, including the nature and severity of the disability, its impact on the alien's ability to work, attend school, or otherwise support himself or herself, and whether the disability will require hospitalization or institutionalization. DHS would only consider disability as part of the health factor to the extent that such disability, in the context of the alien's individual circumstances, impacts the likelihood of the alien becoming a public charge; *i.e.,* the rule calls for a consideration of the potential effects on the alien's ability to work, attend school or otherwise support himself or herself. Further, if an immigration medical examination by a civil surgeon or panel physician is required, officers will generally defer to the report when assessing whether an individual's medical condition will affect a person's ability to care for himself or herself, work, or go to school. DHS would generally defer to such report, unless there is evidence that the report is incomplete. DHS has amended the regulatory text consistent with this approach. Consistent with the NPRM, however, DHS will also permit the alien to submit other documentation regarding the alien's medical conditions to assess whether the alien's health makes the alien more likely than not to become a public charge at any time in the future. This should provide ample opportunity for the alien to provide the full context surrounding his or her health.

Comment: Another commenter stated that the Form I–693 medical exam could not be expected to detect ailments or conditions not indicated on Form I–693, and therefore, DHS may never be made aware of many health conditions among future applicants and petitioners. The commenter further indicated that an individual could delay seeking treatment for a condition, and could delay application for Medicaid or Medicare until after naturalizing. Another commenter expressed concern that the list of medical conditions included in the Form I–693 medical exam may be subject to additions after finalization of the proposed rule threatening the hard-won progress towards ending many epidemics in the United States.

Response: DHS's general reference for review of the health factor is the Form I–693. Civil surgeons test for Class A and Class B conditions and report the findings on the Form I–693, as directed by the CDC Technical Instructions; an officer would review the civil surgeon's findings in the totality of the circumstances. However, DHS would also take into consideration any additional medical records or related information provided by the alien to clarify any medical condition included on the medical form or other information that may outweigh any negative factors. Such documentation may include, for instance, a licensed doctor's attestation of prognosis and treatment of a medical condition. DHS would consider the evidence in the totality of the circumstances. DHS acknowledges that this approach is imperfect, but believes that it appropriately implements the statute in the context of adjudicators' limited expertise.

Comment: A commenter said the rule's inclusion of Class B medical conditions as impacting admissibility is an impermissible use of regulatory power. Specifically, the commenter said the proposed rule seeks to create a new ground of inadmissibility by finding those who are not inadmissible under section 212(a)(1) of the Act, inadmissible under section 212(a)(4) of the Act and is attempting to substitute medical determinations by congressionally enabled civil surgeons and panel physicians with its own determination about medical inadmissibility.

Response: DHS disagrees with the commenter that considering Class B medical conditions as part of the public charge determination is an impermissible use of regulatory authority. As part of the public charge determination, Congress directed agencies to consider, among other factors, the health of the alien.[586] As explained in the NPRM,[587] prior to Congress establishing health as a factor for the public charge determination, the courts, the BIA and INS had also held that a person's physical and mental condition was of major significance to the public charge determination, generally in relation to the ability to earn a living.[588] Accordingly, DHS proposed that when considering an alien's health, DHS will consider whether the alien has any physical or mental condition that, although not considered a condition or disorder that would render the alien inadmissible under the health-related ground of inadmissibility,[589] is significant enough to interfere with the person's ability to care for himself or herself or to attend school or work, or that is likely to require extensive medical treatment or institutionalization in the future. USCIS-designated civil surgeons and DOS-designated panel physicians examine whether an alien has a condition that renders the alien inadmissible on medical grounds (a Class A medical condition according HHS regulation) [590] or whether the alien has a medical condition that is significant enough to interfere with the person's ability to take care of himself or herself, to attend school or to work and would likely receive extensive medical treatment (a Class B condition).[591] If the alien is required to

[584] *See* Ctrs. for Disease Control & Prevention, *Required Evaluations—Other Physical or Mental Abnormality, Disease, or Disability, Technical Instructions For Medical Examination Of Aliens, available at https://www.cdc.gov/immigrant refugeehealth/exams/ti/panel/technical-instructions/panel-physicians/other-physical-mental.html* (last updated Nov. 23, 2016) (last visited July 26, 2019); Ctrs. for Disease Control & Prevention, *Required Evaluation Components Other Physical or Mental Abnormality, Disease or Disability, Technical Instructions for the Medical Examination of Aliens in the United States, available at https://www.cdc.gov/immigrant refugeehealth/exams/ti/civil/technical-instructions/civil-surgeons/required-evaluation-components/other-disease-disability.html* (last updated Aug. 3, 2010) (last visited July 26, 2019). The HHS regulations require physicians conducting medical examinations for an alien to comply with the CDC's Technical Instructions for Medical Examinations of Aliens. *See* 42 CFR 34.3(i).

[585] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51181–84 (proposed Oct. 10, 2018).

[586] *See* INA section 212(a)(4), 8 U.S.C. 1182.

[587] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51181–84 (proposed Oct. 10, 2018).

[588] *See, e.g., Matter of Martinez-Lopez,* 10 I&N Dec. 409, 421–23 (Att'y Gen. 1964); *see also Matter of A-,* 19 I&N Dec. 867, 869 (Comm'r 1988) (*citing Matter of Harutunian,* 14 I&N Dec. 583 (Reg'l Comm'r 1974); *Matter of Vindman,* 16 I&N Dec. 131 (Reg'l Comm'r 1977)).

[589] *See* INA section 212(a)(1), 8 U.S.C. 1182(a)(1).

[590] *See* INA section 212(a)(1), 8 U.S.C. 1182(a)(1).

[591] A Class B condition is defined as a physical or mental condition disease or disability serious in degree or permanent in nature. *See* 42 CFR 34.2(b)(2). The Technical Instructions for the Medical Examination of Aliens directs physicians to provide information about Class B conditions in the medical forms submitted as part of the immigration benefits application. *See* Ctrs. for Disease Control & Prevention, *Required Evaluations—Other Physical or Mental Abnormality, Disease, or Disability, Technical Instructions For Medical Examination Of Aliens, available at https://www.cdc.gov/immigrant refugeehealth/exams/ti/panel/technical-instructions/panel-physicians/other-physical-mental.html* (last updated Nov. 23, 2016) (last visited July 26, 2019); Ctrs. for Disease Control & Prevention, *Required Evaluation Components Other Physical or Mental Abnormality, Disease or Disability, Technical Instructions for the Medical*

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undergo an immigration medical examination, USCIS will generally defer to the findings from the civil surgeon or panel physician made in the immigration medical examination report (unless the report appears incomplete) in regard to the determination of the medical condition and its impact on the person's ability to take care of himself or herself, to attend school or to work, or whether the condition requires medical treatment. USCIS may also use other evidence of medical conditions in the alien's file.[592]

2. Health and Disability Discrimination

Comment: A commenter said the inclusion of ''interfere[nce] with the alien's ability to provide and care for him- or herself'' at 8 CFR 212.22(b)(2)(i) in the NPRM also raises concerns under *Olmstead* v. *L.C.,* 527 U.S. 581 (1999), which recognized that the Americans with Disabilities Act (ADA) mandate provides people with disabilities a life in the most integrated setting appropriate to their needs. Relatedly, a commenter stated that the proposed rule codifies discriminatory standards for evaluating a noncitizen's health and may be in violation of the ADA. The commenter also indicated that individuals with disabilities who would have been institutionalized before *Olmstead* live at home with their families, go to school, and hold jobs even though they cannot solely care for themselves. Therefore, the commenter indicated that the ''ability to care for oneself'' factor excludes many people who are not public charges and is likely to generate the kind of discrimination that *Olmstead* seeks to prevent.

Response: DHS disagrees with the commenter's assertion that the rule, as proposed, would generate the kind of discrimination that *Olmstead* sought to prevent. In *Olmstead,* the Court held that, in accordance with Title II of the ADA, and under the implementing regulations, states are required to provide community-based treatment for persons with mental disabilities when the State's treatment professionals determine that such placement is appropriate, the affected persons do not oppose such treatment, and the placement can be reasonably accommodated, taking into account the resources available to the State and the needs of others with mental disabilities.[593] At issue was whether the state interpreted the reasonable accommodation provision properly or incorrectly continued to institutionalize the plaintiff because community placement would have been costly.[594]

Title II of the ADA does not govern DHS's actions in this context. In addition, unlike in the ADA provision and the regulatory provision discussed in *Olmstead,* Congress did not single out disability in section 212(a)(4) of the Act. As explained in the NPRM,[595] DHS has carefully considered the interaction between various federal laws and regulations with respect to discrimination and determined that considering, as part of the health factor, an applicant's disability diagnosis, in the context of the alien's individual circumstances and how it affects his or her ability to work, attend school, or otherwise care for himself or herself, is not inconsistent with these laws. The alien's disability is treated just like any other medical condition that affects an alien's likelihood, in the totality of the circumstances, of becoming a public charge—it is neither singled out nor treated differently and, within the totality of the circumstances, is also not the sole basis for an inadmissibility finding.[596] Similarly, DHS does not single out or treat differently any one health-related or medical condition over another but has continuously emphasized that all factors will have to be considered in the totality of the alien's circumstances and that no one factor is determinative.

Comment: Several commenters expressed concern that the proposed changes would be discriminatory against or penalize immigrants based on their health status, particularly those with chronic health conditions and disabilities and the elderly. One commenter noted that ''[w]hile it is illegal to discriminate against someone on the basis of disability, the proposed rule encourages this form of discrimination, and furthers the idea that some people are more worthy than others.'' A commenter expressed that individuals with the misfortune of suffering serious health issues or living with a disability will be at risk of a high rate of application denials under this proposed rule. One commenter stated this rule would discriminate against individuals with chronic health conditions such as heart disease, which tend to disproportionally impact communities of color. One commenter noted that the very definition of disability, a condition that '' 'interferes' with a person's ability to do such things as go to school or work,'' means that ''virtually every person with a health condition affecting her or his life could be deemed a public charge, no matter how well the person has coped with the condition.'' A couple of commenters warned that the discrimination against individuals with disabilities would have the unintended consequence of splitting up families, even in an asylum seeking application, or penalizing family members providing support for individuals with disabilities.

Several commenters stated that the rule penalizes and discriminates against individuals with serious medical conditions, such as cancer, cystic fibrosis, multiple sclerosis, heart, lung disease. Commenters also stated that, under this proposed policy, an individual cancer survivor would be penalized, regardless of the individual's type of cancer, period of survivorship, or long-term health outcome, which is discriminatory. An individual commenter said the classification of arthritis and heart disease as serious health conditions seems overly exaggerated and extreme, since almost 50 percent of individuals over 65 have doctor reported arthritis and healthy lifestyle can help reduce the negative consequences of heart disease.

Multiple commenters said the proposal would equate any person with a serious health condition as effectively having a ''pre-existing condition'' that disqualifies them for immigration, asserting that this would have a profound impact on racial and ethnic minorities who, because of many social determinants of health, disproportionately experience a number of chronic conditions (with many citing studies as support). One commenter pointed to studies indicating that social determinants of health are one of the main inequalities between whites and persons of color.

Numerous commenters expressed general concern about the rule's negative effects on aliens with disabilities and their families. Many commenters also expressed concern over the negative assessments that individuals with intellectual and developmental disabilities, psychiatric disabilities, or physical disabilities would receive under the ''health'' factor in public charge determination. The commenters indicated that the rule

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Examination of Aliens in the United States, available at https://www.cdc.gov/immigrant refugeehealth/exams/ti/civil/technical-instructions/civil-surgeons/required-evaluation-components/other-disease-disability.html (last updated Aug. 3, 2010) (last visited July 26, 2019). The HHS regulations require physicians conducting medical examinations for an alien to comply with the CDC's Technical Instructions for Medical Examinations of Aliens. 42 CFR 34.3(i).

[592] *See* 8 CFR 212.22(b)(2)(ii).

[593] *Olmstead* v. *L.C. ex rel. Zimring,* 527 U.S. 581, 607 (1999).

[594] *See Olmstead* v. *L.C. ex rel. Zimring,* 527 U.S. 581, 598 (1999).

[595] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184 (proposed Oct. 10, 2018).

[596] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184 (proposed Oct. 10, 2018).

discriminates against immigrants with disabilities because a range of medical conditions that constitute disabilities, as well as the existence of a disability, would be unduly weighted in the determination of whether an immigrant is likely to become a public charge. Multiple commenters remarked that individuals with disabilities often lack private health insurance and are currently using or recently used Medicaid, which are two heavily weighted negative factors. Other commenters expressed concern that the rule's health standard is overbroad, specifically in its inclusion of individuals with chronic health conditions, like heart disease, cancer, trauma, mental disorders, and pulmonary conditions, and potentially individuals who may need Individualized Education Plans to study or reasonable accommodations to work. Some commenters stated that the rule would perpetuate the false notion that a medical diagnosis is solely determinative of an individual's current abilities and future capabilities.

Response: DHS neither proposed to exclude from the United States individuals who have specific health conditions, nor sought to disproportionally impact communities of color or people with disabilities. DHS is required by statute to consider in the totality of the circumstances whether *any* health condition an alien may have would make the alien likely to become a public charge. This determination takes into account any health condition in the context of the alien's ability to support himself or herself and like all of the mandatory factors, is highly fact-specific; *i.e.,* dependent on the alien's precise circumstances. For example, an alien may have a health condition that does not impact the alien's ability to work or secure employment or constitute a drain on the alien's financial resources, and therefore such health condition would not make the alien likely to become a public charge. Similarly, an alien may have a health condition that if unmanaged would affect the alien's ability to work but if successfully managed would not impact the alien's ability to work or find employment or constitute a drain on the alien's financial resources. In those cases, USCIS would look at whether the alien has or is likely to obtain private health insurance or any other means to pay for medical treatment. Finally, even if an alien has a health condition that precludes employment, if the alien has the financial means to pay for medical treatment and is able to be self-sufficient without working, then the alien may not be likely to become a public charge.

Comment: A commenter stated the rule should require immigration officials to take the letter and spirit of federal anti-discrimination laws into account when determining public charge. Multiple commenters stated that the rule ''disfavor[s] people with disabilities in the public charge analysis,'' and will deem, inappropriately, people with disabilities, who contribute to the economy, public charges.

Several commenters stated that the rule is contrary to decades of bipartisan congressional lawmaking regarding disability inclusion, including the ADA, Section 1551 of the ACA, Fair Housing Act, and the Rehabilitation Act of 1973 (Rehab Act). A few commenters, in particular, warned that the rule would echo the types of bias and archaic attitudes about disability that the Rehab Act was meant to overcome. One commenter stated that, while the proposed changes to the totality of circumstances would especially affect people with disabilities, excluding them from the United States by claiming they are more likely to need government assistance, the Rehab Act makes it unlawful to discriminate against anyone on the basis of disability, whether or not they are a citizen. Some commenters stated that the proposed rule's broad reading of the statutory health and resources factors for public charge determinations are inconsistent with Section 504's prohibition on disability-based discrimination.

One commenter stated that the rule is inconsistent with the intent of the 1990 amendments to the INA, which ensured that individuals were not deemed inadmissible based on their disability status by deleting the prior grounds of exclusion for, among others, paupers and those with a physical disability. The same commenter stated that the rule is also contradictory to Section 504's bar on disability-based discrimination in DHS's programs and activities.

A couple of commenters stated that the rule would violate the Developmental Disabilities Assistance and Bill of Rights Act. One commenter noted that ''that further clarification is needed explaining precisely how DHS will consider certain factors like a disability ''to the extent that such disability . . . would entail consideration of the potential effects on the alien's ability to work, attend school or otherwise support himself or herself.'' Other commenters stated that the rule needs to make accommodations for individuals with disabilities and that the proposed rule ''reflects the types of bias and ''archaic attitudes'' about disabilities that the Rehab Act was meant to overcome.'' Other commenters stated that the proposed rule discriminates against individuals with disabilities. An individual commenter stated that, while DHS states that the impact of using health as a factor in determining if they will become a public charge would not violate IDEA or the ADA, it is hard to see how DHS actually thinks that will happen given that a disability is concretely being deemed a negative factor which needs to be ''rectified'' by ability to work. This and other commenters said DHS's interpretation seems to violate 6 CFR 15.30(b)(1)(i) by denying a benefit on the basis of disability.

Response: DHS disagrees with the comments stating that the rule discriminates against individuals with disabilities or those with specific medical conditions. As noted in the NPRM, in enacting section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), Congress required DHS to consider, as part of the public charge inadmissibility determination, an alien's health. Although Congress has, over time, significantly reduced the prohibitions on immigration for persons with mental and physical disabilities and also amended PRWORA to restore the ability of certain aliens with disabilities to receive certain public assistance, such as SSI,[597] Congress has never correspondingly prohibited the application of the public charge inadmissibility ground to aliens with disabilities who receive, or are likely to receive, disability benefits for which they are eligible.[598]

As noted in the NPRM, this rule is not inconsistent with federal statutes and regulations with respect to discrimination against aliens with disabilities, as an alien's disability is

[597] *See generally* Mark C. Weber, *Opening the Golden Door: Disability and the Law of Immigration,* by 8 Journal of Gender, Race, and Justice at pp. 4–5, 8 (Spring 2004) (discussing historical changes in 1986 and 1990 immigration laws that removed various prohibitions on aliens with mental and physical disabilities, unless they represented a threat to themselves or others; describing restoration of SSI disability benefits to aliens who had been receiving them before Aug. 22, 1996). *See also* John F. Stanton, *The Immigration Laws from a Disability Perspective: Where We Were, Where We Are, Where We Should Be,* 10 Geo. Immigr. L. J. 441 (Spring, 1996) (pre-PRWORA analysis).

[598] Congress did permit a waiver of INA section 212(a)(4), 8 U.S.C. 1182(a)(4), for aliens seeking lawful permanent resident status under the legalization provision of the Immigration Reform and Control Act of 1986 (IRCA) if they met the age, blindness, or disability standards for SSI. *See* INA section 245A(d)(2)(B)(ii)(IV), 8 U.S.C. 1255a(d)(2)(B)(ii)(IV).

treated just as any other medical condition that affects an alien's likelihood, in the totality of the circumstances, of becoming a public charge. A diagnosis of a disability is related to an alien's health, and therefore is properly considered as part of the public charge analysis.

An alien's health is not outcome determinative—that is, an alien's health cannot be the sole basis for a finding that an alien is inadmissible as likely to become a public charge. As such, a diagnosis that an alien has a disability, alone, will never result in a public charge inadmissibility finding. As with any other medical condition identified in the alien's application and supporting documentation, the alien's disability will be considered in the totality of the circumstances framework. An alien with a disability will neither be treated differently nor singled out, and the disability itself would not be the sole basis for an inadmissibility finding. In other words, as with any other mandated factor and consideration in the public charge inadmissibility determination, DHS would look at each of the mandatory factors, and the affidavit of support, if required, as well as all other relevant factors in the totality of the circumstances. Therefore, consideration of a disability in the context of the totality of circumstances does not violate the Rehabilitation Act's prohibition on denying a benefit ''solely by reason of [an applicant's] disability.'' [599]

Likewise, DHS does not believe the rule is in violation of or inconsistent with the other cited authorities. For example, the rule is not inconsistent with the regulation that prohibits DHS from denying benefits to a ''qualified individual with a disability . . . by reason of his or her disability.'' [600] Public charge determinations will be made based on the totality of circumstances and not on the basis of a disability, and the regulatory definition of a ''qualified individual with a disability'' requires a person to ''meet the essential eligibility requirements.'' [601] The essential requirements in the context of admission and adjustment of status require that an applicant not be likely at any time in the future to become a public charge.

DHS does not believe the rule is inconsistent with the 1990 amendments to the INA and its revision of the prior grounds of exclusion with the grounds of inadmissibility. The rule is not recreating the prior grounds of excludability that, prior to 1990, included persons certified to have a ''physical defect, disease, or disability'' who is required to work.[602] Rather, the rule is providing guidance to the public charge inadmissibility ground as it has existed since the 1990 amendments to the INA.[603]

As to the comment that the public charge inadmissibility rule violates the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act) (42 U.S.C. 15001 *et seq.*),[604] the statute was enacted to ensure that individuals with developmental disabilities and their families ''participate in the design of and have access to needed community services, individualized supports, and other forms of assistance that promote self-determination, independence, productivity, and integration and inclusion in all facets of community life, through culturally competent programs. . . .'' [605] The programs within the DD Act are funded through congressional appropriations for the Administration for Community Living, which are not related to Medicaid or TANF appropriations or other federal benefit programs covered by the proposed public charge rule. The State Councils on Developmental Disabilities, Protection and Advocacy Systems, University Centers of Excellence in Developmental Disabilities, and Projects of National Significance participate in capacity building, systems change, advocacy, protect legal and human rights of people with developmental disabilities, conduct research, provide inter-disciplinary training for students and fellows, leadership training, direct support services training, community based training, and clinical or other training to strengthen the workforce that serves individuals with developmental disabilities.

The DD Act is intended for all individuals with developmental disabilities and their families regardless of immigration status.[606] The DD Act states that: ''there is a need to ensure that services, supports, and other assistance are provided in a culturally competent manner that ensures that individuals from racial and ethnic minority backgrounds are fully included in all activities provided under this title.''

Based on the language in the DD Act, DHS believes that services under the DD Act are not public benefits as defined in the rule, because all individuals with developmental disabilities, without regard to income, are eligible for services that the DD Act allows.

DHS further does not believe that the rule violates the DD Act. While the policy of the DD Act is to offer protections and advocacy to individuals with developmental disabilities, and while the services provided pursuant to the DD Act would not make an individual a public charge, DHS does not believe the DD Act would govern DHS's public charge determination regarding other benefits. The DD Act is silent regarding the issue of whether an individual can be considered a public charge based upon receipt of services that do not fall under the DD Act. Other HHS disability and aging statutes and programs such as the Traumatic Brain Injury Act, Limb Loss Act, Older Americans Act, and the Christopher and Dana Reeves Paralysis Act do not receive Medicaid or Medicare funds and do not have restrictions on immigration or citizenship status.

Comment: Some commenters suggested that the USCIS should estimate the extent to which any regulatory changes will impact the number of otherwise eligible applicants with disabilities when compared to the current and historical baselines, and then reconsider other less harmful alternatives.

Response: As indicated in the NPRM, DHS would only consider disability as part of the health factor to the extent that such disability, in the context of the alien's individual circumstances, impacts the likelihood of the alien becoming a public charge.[607] Although a study of the correlations between different disabilities and the array of positive and negative factors were not included in the text of the rule, DHS understands that those correlations may exist and may also be affected by the type and severity of the disability. However, DHS would not distinguish between Medicaid recipients who are disabled from those who are not disabled. Instead, DHS would look to the information provided in the medical certification as to whether it would affect the person's ability to work or attend school. DHS provided estimates of benefit use by an array of characteristics in the NPRM, and does

[599] 29 U.S.C. 794(a).

[600] 6 CFR 15.30(a). *See also* 6 CFR 15.30(b)(1)(i) (prohibiting denying a benefit ''on the basis of a disability'').

[601] 6 CFR 15.3(e)(2).

[602] *See* section 212(a)(7) of the Act, 8 U.S.C. 1182(a)(7) (1988).

[603] *See* Immigration Act of 1990, Public Law 101–649, section 601, 110 Stat. 4978, 5072 (Nov. 29, 1990).

[604] Public Law 106–402, 114 Stat. 1677 (Oct. 30, 2000).

[605] Id.

[606] *See* INA section 101(b) and 101(c).

[607] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51183 (proposed Oct. 10, 2018).

not believe additional tables for disability are needed in the justification for the rule.

Comment: Numerous commenters cited to the impact on individuals with disabilities and children with disabilities. Many commenters cited the statistic that roughly 2.6 million children in immigrant families have a disability or special healthcare need. Numerous commenters asserted that children with special health and developmental needs require medical, behavioral, and educational services above and beyond typical children, which makes immigrant families vulnerable to economic hardship. Many commenters cited the fact that children with disabilities are more likely to live in low-income households experiencing food insecurity and housing instability. Multiple commenters concluded that access to Medicaid is uniquely critical, as children with disabilities rely on the public health coverage for occupational, physical, or speech therapies and prescription drugs. One commenter stated that, although there is a Medicaid exception for foreign-born children adopted by U.S. citizens, there is not one for special needs children that are foreign-born with immigrant parents. One commenter stated that individuals with disabilities will be uniquely affected by the rule because of the inclusion of Medicaid-funded services, including services in the home and in communities, and will be disproportionately impacted by the inclusion of housing and food assistance programs.

Response: DHS appreciates the numerous programs that provide services to individuals with disabilities. As discussed in the NPRM,[608] as part of the immigration medical examination, when identifying a Class B medical condition, civil surgeons and panel physicians are required to report on certain disabilities, including the nature and severity of the disability, its impact on the alien's ability to work, attend school, or otherwise support himself or herself, and whether the disability will require hospitalization or institutionalization. DHS would only consider disability as part of the health factor to the extent that such disability, in the context of the alien's individual circumstances, impacts the likelihood of the alien becoming a public charge; *i.e.,* a consideration of the potential effects on the alien's ability to work, attend school, or otherwise support himself or herself.

As discussed in the NPRM,[609] DHS has determined that considering, as part of the health factor, an applicant's disability diagnosis that, in the context of the alien's individual circumstances, affects his or her ability to work, attend school, or otherwise care for himself or herself, is not inconsistent with federal statutes and regulations with respect to discrimination, as the alien's disability is treated just as any other medical condition that affects an alien's likelihood, in the totality of the circumstances, of becoming a public charge. Under the totality of the circumstances framework, an alien with a disability is not being treated differently, or singled out, and the disability itself would not be the sole basis for an inadmissibility finding. DHS would look at each of the mandatory factors, and the affidavit of support, if required, as well as all other factors in the totality of the circumstances.

Therefore, an applicant's disability could not be the sole basis for a public charge inadmissibility finding. In addition, DHS recognizes that the ADA, the Rehabilitation Act, IDEA, and other laws provide important protections for individuals with disabilities, including with respect to employment opportunities. Furthermore, as it relates to a determination of inadmissibility under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), when the alien is applying for the immigration benefit, DHS does not stand in the position of an employer or school where additional provisions of the ADA and Rehab Act or IDEA would apply.

Comment: Numerous commenters expressed concern about the impact this rule would have on individuals living with HIV/AIDS. A commenter said most applicants with HIV will automatically have two heavily weighted negative factors: Having a health condition without private insurance to cover the cost of treatment and receiving a public benefit in the form of Medicaid. Some commenters expressed concern that, because treatment is prohibitively expensive unless subsidized by government programs, these individuals would be subjected to additional constraints regarding the enrollment of health insurance (*i.e.,* they would be forced into buying non-subsidized medical coverage, which does not typically cover anti-retroviral therapy, or buying additional coverage due to lack of adequate coverage from their government-subsidized plan). Multiple commenters said immigrants with HIV will potentially forego subsidized healthcare treatment due to this rule, resulting in substantial negative health outcomes, not only to affected individuals but also the community at large. Multiple commenters stated that reports are already emerging of individuals who are considering waiting to begin life-saving treatment in the belief that this will ensure their eligibility.

Several commenters stated that the rule sends the signal that individuals with HIV/AIDS and other chronic health conditions are ''undesirable.'' A couple of commenters said the proposal will create a ''backdoor means'' of excluding those with HIV from the United States by classifying HIV/AIDS as a Class B medical condition that can be used as a negative factor in determining public charge. Some commenters said the inclusion of HIV as a negatively weighted factor undoes congressional intent in removing HIV as a ground of inadmissibility and draws disturbing parallels to the 1987 HIV travel and immigration ban overturned in 2010.[610] A commenter said the rule could operate as a de facto ban on admission of HIV positive immigrants because it would be difficult for an HIV positive noncitizen to withstand the revised public charge analysis. This commenter also said the de facto ban on HIV positive noncitizens runs against the stated goal of the Trump Administration to lead a global effort against HIV/AIDS and undermines U.S. leadership in this area.

Many commenters said the rule ignores the reality that suffering from a chronic illness such as HIV/AIDS is not an accurate indicator of future self-sufficiency and full-time employment capabilities. One commenter stated that a large portion of people living with HIV/AIDS have incomes below the poverty line, which is not due to their inability to work due to health conditions, but rather due to the continued stigma of HIV/AIDS on people's ability to get work.

Another commenter stated that the disproportionate negative impact on people living with HIV/AIDS will also cause a disproportionate negative impact on LGBT immigrants who apply for admission to the United States because they account for a large portion of the HIV diagnoses.

For similar reasons expressed above relating to HIV, some commenters expressed concerns about the rule's impact on individuals with Hepatitis B

[608] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51182–84 (proposed Oct. 10, 2018).

[609] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51182–84 (proposed Oct. 10, 2018).

[610] 74 FR 56547 (Nov. 2, 2009) (removing HIV from the list of communicable diseases of public health significance at 42 CFR 34.2).

and Hepatitis C. One commenter said the proposed rule would undermine its approach, as a State agency, to combating HIV/AIDS and Hepatitis C.

Response: As indicated in the NPRM,[611] DHS will consider any medical condition diagnosed in the totality of the circumstances. The fact that an alien has been diagnosed with a medical condition would not serve as the sole factor considered when determining whether an alien is likely at any time in the future to become a public charge.[612] The consideration entails whether, in light of the alien's health, the alien will be able to care for himself or herself, to attend school, or to work.[613] Relatedly, as part of the assets, resources and financial status factor, DHS would consider whether the alien either has sufficient household assets and resources, including but not limited to private health insurance, to cover any reasonably foreseeable medical costs.[614] The rule does not focus on any specific medical condition and people living with certain conditions may still be able to care for themselves, attend school, or go to work,[615] which the medical professional would be able to affirm in the medical certification.

K. Family Status

Comment: Several commenters requested family size be removed from consideration as a public charge. One commenter indicated that the proposal would be harmful to families, including all members of the nuclear family, and may prohibit nuclear families from immigrating.

A few commenters voiced concerns about the statement that the applicant's household size would be counted in both the family status factor and the assets, resources, and financial status factor, claiming the rule has the potential to double-count negative factors. Another commenter stated that family status should not count as a negative factor if an immigrant has sufficient income and resources.

Conversely, a commenter expressed support for considering the size of an alien's household as the primary element of the family status factor, adding that this factor appropriately involves the assessment of whether an alien has a household to support, or is being supported by another household, when calculating the alien's household size. The commenter also stated that the NPRM correctly notes research showing that receipt of non-cash benefits increases as family size increases.

Response: DHS is required by statute to consider an applicant's family status when determining whether the alien is likely at any time in the future to become a public charge.[616] As discussed in the NPRM, DHS will consider whether the alien has a household to support or whether the alien is being supported by another household and whether the alien's household size makes the alien more or less likely to become a public charge.[617] The receipt of non-cash benefits generally increases as family size increases [618] and is relevant to assessing self-sufficiency. Therefore, DHS will retain the household size as a consideration in the public charge inadmissibility determination.

Comment: A commenter stated that DHS does not provide sufficient data or explanation for stakeholders to meaningfully comment on the way it will evaluate family status in a public charge determination, so the requirement to provide sufficient notice under the APA has not been met. A few commenters stated that the rule fails to provide any evidence that larger household sizes results in lack of self-sufficiency, pointing to research showing that household size, by itself, is not an indicator of future public benefit use or self-sufficiency. Another commenter said an extended family structure offers many advantages, including stability, coherence, and physical and psychological support, particularly in times of need and should not be counted as a negative factor.

Response: DHS disagrees that the NPRM does not provide data or an explanation about family status. The NPRM states that ''Table 16 and Table 17 show that among both U.S. citizens and noncitizens, the receipt of non-cash benefits generally increased as family size increased.'' [619] Based on that data, DHS would consider the number of people in a household as defined in the proposed 8 CFR 212.21(d). As with the other factors, household size, on its own, would never dictate the outcome of a public charge inadmissibility determination. Household size is also not an inherently negative factor under DHS's regulations, as certain commenters indicate. If an alien demonstrates that the alien's household structure and members offer advantages that decrease the alien's likelihood of receiving one or more public benefits at any time in the future above the 12 aggregate months in a 36-month period threshold, then DHS will consider household size a positive factor.

The rule also permits consideration of the alien's family status within the context of assessing the alien's household income, assets, and resources instead of simply the alien's own income, assets, and resources. Therefore, an alien may present evidence of how the alien's household provides advantages relevant to consideration under income, assets, and resources and makes the alien less likely at any time to become a public charge. For instance, an alien who is part of a large family may have more household assets and resources available to use or may have his or her own income or access to additional assets and resources that would assist in supporting the household. DHS would take these family status-related considerations into account when examining the totality of the alien's circumstances.

Comment: A commenter expressed concern for how family status could impact families that have a member with chronic conditions because family members would be spending a significantly higher proportion of their income and resources on the family member with that condition, which under the proposed rule would be weighted as a negative factor against those families.

Response: DHS recognizes that chronic conditions may impact a person's income availability. However, an applicant's family status is a factor that must be considered when determining whether the alien is likely to become a public charge in the future.[620] As explained in the NPRM, DHS's proposed totality of the circumstances standard would involve weighing all the positive and negative considerations related to an alien's age; health; family status; assets, resources, and financial status; education and skills; required affidavit of support; and any other factor or circumstance that may warrant consideration in the public charge inadmissibility determination.

[611] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51183 (proposed Oct. 10, 2018).

[612] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51183 (proposed Oct. 10, 2018).

[613] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51183 (proposed Oct. 10, 2018).

[614] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51183 (proposed Oct. 10, 2018).

[615] *See* HIV.gov, Aging with HIV available at *https://www.hiv.gov/hiv-basics/living-well-with-hiv/taking-care-of-yourself/aging-with-hiv* (last visited January 17, 2019); and HIV.gov, Working with HIV, available at *https://www.hiv.gov/hiv-basics/living-well-with-hiv/taking-care-of-yourself/employment-and-health* (last visited January 17, 2019).

[616] *See* 8 CFR 212.2; *see also* INA section 212(a)(4)(B)(i)(III), 8 U.S.C. 1182(a)(4)(B)(i)(III).

[617] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184 (proposed Oct. 10, 2018).

[618] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184–85 (proposed Oct. 10, 2018).

[619] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184 (proposed Oct. 10, 2018).

[620] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

However, DHS would not consider the medical conditions of a member of the alien's household. DHS would only consider the household size in relationship to the FPG level for the assets, resources and financial status factor.

Regardless of household size, an alien may present other factors (*e.g.,* assets, resources, financial status, education, and skills) that weigh for or against a finding that the alien is likely to become a public charge. For instance, an alien who is part of a large household may have his or her own income or access to additional assets and resources that would assist in supporting the household which would also be considered in the totality of the circumstances.

Comment: One commenter said this rule would punish applicants who have larger families, thus creating another disincentive to have children. Another commenter stated the rule would discriminate against immigrants from countries whose cultural or religious traditions encourage larger and multi-generational families, disregarding whether such interdependence was required or recognized by law. Similarly, a commenter suggested that Asian Americans would be most affected by this rule because they are the most likely to live in multigenerational homes. Another commenter said this aspect of the proposed rule would have the greatest impact on applicants from Mexico and Central America (71 percent), Africa (69 percent), and Asia (52 percent)—regions that typically account for substantial numbers of Muslim immigrants. The commenter stated this aspect would have substantially lower impacts on European or Canadian applicants. One commenter stated that DHS has not adequately analyzed the adverse impact this proposal would have on families seeking lawful permanent residence for a spouse or a child. One commenter asked if DHS would consider it more beneficial to be single and unmarried than to be in a committed relationship with children and/or parents living with the family.

Response: DHS appreciates the comments but disagrees that the rule punishes people with larger families. As discussed in the NPRM, DHS will consider whether the alien has a household to support, or whether the alien is being supported by another household and whether the alien's household size makes the alien more or less likely to become a public charge.[621] As previously indicated Congress established that family status would be a factor in the public charge inadmissibility determination.[622] Having a larger family does not necessarily lead to a conclusion that the person is likely to be a public charge. The household may have multiple sources of income that increase the income, assets, and resources of the household allowing the person and household to be self-sufficient. Alternatively, a single person may or may not have additional income, assets, or resources to be self-sufficient. While the receipt of non-cash benefits generally increases as family size increases as discussed in the NPRM,[623] DHS will never determine that a person is likely to become a public charge based on family size alone. DHS recognizes that family status can also have positive benefits and would take all relevant factors into account when assessing the totality of the circumstances regarding the alien's likelihood to become a public charge.

L. Assets, Resources, and Financial Status

1. Income Standard

Comment: Multiple commenters expressed general concern that the income assessment would penalize low-income immigrants. One commenter said that the income threshold is arbitrary. Using hypotheticals to illustrate that someone seeking to adjust status might still be found to be likely to become a public charge despite minimal use of benefits and adequate family support, a commenter stated that having a low income and multiple negative or heavily weighted negative factors had no clear correlation to self-sufficiency, and that the rule slanted toward denials. One commenter stated that the assets, resources, and financial status factors are not realistic given the realities of low-wage work. Another commenter said that the proposed assets, resources, and financial status factor ignores the cultural and economic value of immigrants. Several commenters stated that having an income threshold is in conflict with the American ideal of upward mobility. Other commenters stated that the proposed income threshold of 125 percent of the FPG lacked rational basis in that the affidavit of support standard is unconnected with the likelihood of an applicant becoming a public charge and relates to whether the sponsor can support someone else rather than themselves. An individual commenter said the proposed rule would affect spouses of individuals seeking a ''green card'' because the proposed rule requires the couple's income to be at $41,000. Therefore, the commenter said that this rule would result in making decisions on whom to marry based on a potential spouse's income, which could increase fraudulent marriages.

In contrast, one commenter voiced general support for the proposed threshold of 125 percent of the FPG, and another commenter suggested that the rule include a provision that requires applicants to show that they make an income high enough that neither they nor their dependents qualify for public benefits.

Response: Even though this rule considers an applicant's income in the totality of the circumstances, which may negatively impact low-income aliens, DHS disagrees with comments that this rule is aimed at denying the admission or adjustment of status of low income aliens. Instead, this rule is aimed at better ensuring the self-sufficiency of aliens seeking to reside in the United States.

As noted elsewhere in this final rule, an alien's income is one of many pieces of evidence that DHS will consider in the totality of the circumstances. As provided in the NPRM, DHS will generally consider whether the alien has a gross household income of at least 125 percent of the FPG based on the alien's household size. If the alien's household income is less than 125 percent of the FPG, DHS will generally consider whether the alien has assets and resources is at least five times the difference between the household income and 125 percent of the FPG based on the household size.[624] DHS also disagrees that the standard is unconnected to becoming a public charge or should be raised to other levels. DHS is adopting the standard established by Congress with the affidavit of support, which has long served as a touchpoint for public charge inadmissibility determinations.[625] An alien subject to section 213A of the Act,

[621] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184 (proposed Oct. 10, 2018).

[622] *See* INA section 212(a)(4)(B)(i)(III), 8 U.S.C. 1182(a)(4)(B)(i)(III).

[623] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184–85 (proposed Oct. 10, 2018).

[624] This is consistent with the provisions for assets under the affidavit of support in 8 CFR 213a.2(c)(2)(iii)(B)(3). As explained below, in certain cases, the standard applied may be less than five times under 8 CFR 213a.2(c)(2)(iii)(B)(*1*) and (*2*). To be fully consistent with the affidavit of support provisions, DHS also applies the other standards for purposes of the public charge determination and amended the provision accordingly.

[625] *See* INA section 213A(f)(1)(E), 8 U.S.C. 1183a(f)(1)(E); *see* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51187 (proposed Oct. 10, 2018).

8 U.S.C. 1183a, who does not have a sponsor capable of supporting himself or herself, the household, and the alien would currently be found inadmissible based on public charge grounds.

DHS also notes that to the extent that aliens will make marriage decisions based how much income a potential spouse earns in order to avoid any negative consequences that might stem from having household income under 125 percent of the FPG, aliens who enter into marriage for the sole purpose of circumventing the immigration laws have not entered into a valid marriage for immigration purposes and would not be eligible for adjustment of status.[626]

Comment: One commenter opposed DHS's proposal that an alien who fails to demonstrate income greater than 125 percent of the FPG may overcome the deficiency by providing evidence of assets totaling at least five times the difference between the household income and 125 percent of the FPG for the household size. This commenter indicated that DHS failed to provide any arguments or evidence as to why this threshold is appropriate or relevant to the public charge determination. A commenter suggested that if the rule must include a ratio of assets to the difference between household income and 125 percent of the FPG, it should be a ratio of two times. The commenter stated that this would enable the individual or household to have a two-year period of financial security during which they may be able to increase their income.

Response: DHS disagrees that it failed to outline the appropriateness of the standard and that the standard is arbitrary and capricious. DHS will also not incorporate the commenter's suggestion to change the standard to a ratio of two times. DHS disagrees that two times the FPG is more appropriate because the commenter's reasoning relies on increasing income in the future and as discussed in the NPRM, whether a person may be qualified for public benefits frequently depends on where the person's household income falls with respect to the FPG.[627]

As explained in the NPRM,[628] DHS will consider whether the applicant has a gross household income[629] of at least 125 percent of the FPG for the household size, and alternatively, whether the applicant has substantial assets as described in the rule and the FPG for the household size, because it has long served as a touchpoint for public charge inadmissibility determination and the enforceable affidavit of support.[630] The suggestion to reduce the standard to a ratio of two times was also a comment in response to the Affidavit of Support Rule promulgated in 2006 and was not incorporated because the purpose of the requirement was ''to ensure that a sponsor whose income is not sufficient will nevertheless be able to provide the needed support until the sponsorship obligation ends.'' [631] Similarly, the significant assets provision in this rule allows an alien whose income is below the applicable income threshold to demonstrate sufficient assets to support himself or herself, thereby reducing the likelihood of becoming a public charge.

The five times the FPG was chosen for the Affidavit of Support because ''[i]n most cases, an alien is not eligible for naturalization until he or she has been a permanent resident alien for at least 5 years,'' [632] to show that the sponsor has the assets to support the beneficiary until they generally qualified for naturalization. In addition to being similar to the support obligation, five times would also be consistent with the reasoning behind the bond cancellation authority under 8 CFR 103.6(c)(1) in 1984. As explained in the NPRM, INS reasoned that if an alien is self-sustaining for a five-year period, it would not be probable that the alien would become deportable as a public charge after five years because an alien is deportable as a public charge only if the reason for the becoming a public charge is based on factors in existence prior to admission as an immigrant.[633]

After further consideration and consistent with the explanation in the proposed rule, however, DHS has decided to adjust the amount to match the affidavit of support provision in regards to income level used and amended the provision to reflect that those aliens on active duty, other than in training, in the U.S. Armed Forces have to establish household income reflecting 100 percent of the most recent FPG for the alien's household size.

Additionally, to be more consistent with the affidavit of support regulations, DHS also decided to define significant assets for purposes of the assets and resources factor in the public charge inadmissibility determination, using a similar standard, as that outlined in 8 CFR 213a.2(c)(2)(iii)(B), but applying it to the public charge rule and the alien's household. According to 8 CFR 213a.2(c)(2)(iii), if the sponsor is unable to meet the 125 percent of the FPG (100 percent for those on active duty, other than training, in the U.S. Armed Forces) income requirement, he or she can use significant assets to make up the difference between the sponsor's income and the required FPG standard according to a particular formula similarly in 8 CFR 213a.2(c)(iii)(B)(*1*), (*2*), and (*3*), as applicable to the sponsor's household.

In applying this provision for purposes of the public charge determination, the rule provides that an alien may establish ownership of significant assets, such as savings accounts, stocks, bonds, certificates of deposit, real estate or other assets, in which the combined cash value of all the assets (the total value of the assets less any offsetting liabilities) exceeds:

(1) If the intending immigrant is the spouse or child of a United States citizen (and the child has reached his or her 18th birthday), three times the difference between the alien's household income and 125 percent of the FPG (100 percent for those on active duty, other than training, in the U.S. Armed Forces) for the alien's household size;

(2) If the intending immigrant is an orphan who will be adopted in the United States after the alien orphan acquires permanent residence (or in whose case the parents will need to seek a formal recognition of a foreign adoption under the law of the State of the intending immigrant's proposed residence because at least one of the parents did not see the child before or during the adoption), and who will, as a result of the adoption or formal recognition of the foreign adoption, acquire citizenship under section 320 of the Act, 8 U.S.C. 1431, the difference between the alien's household income and 125 percent of the FPG (100 percent for those on active duty, other than training, in the U.S. Armed Forces) for the alien's household size; or

[626] *See Matter of Patel,* 19 I&N Dec 774 (BIA 1988).

[627] The poverty guidelines are updated periodically in the **Federal Register** by HHS. The U.S. Census Bureau definition of family and family household can be found in U.S. Census Bureau, *Current Population Survey 2017 Annual Social and Economic Supplement (ASEC*) 9–1 to 9–2, *available at https://www2.census.gov/programs-surveys/cps/techdocs/cpsmar17.pdf* (last visited July 26, 2019).

[628] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51187 (proposed Oct. 10, 2018).

[629] Gross income includes ''all income you receive in the form of money, goods, property, and services that isn't exempt from tax. It also includes income from sources outside the United States or from the sale of your main home (even if you can exclude all or part of it).'' *See* IRS Publication 17, Your Federal Income Tax, page 5 (2018), available at *https://www.irs.gov/pub/irs-pdf/p17.pdf* (last visited July 26, 2019).

[630] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51187 (proposed Oct. 10, 2018); *see also* INA sections 213A(f)(1)(E) and 213A(f)(6)(A)(ii), 8 U.S.C. 1183a(f)(1)(E) and 1183a(f)(1)(E) and 8 CFR 213a.2.

[631] *See* 71 FR 35731, 35739.

[632] *See* 71 FR 35731, 35739.

[633] *See* 49 FR 24010, 24011.

(3) In all other cases, five times the difference between the alien's household income and 125 percent of the FPG (100 percent for those on active duty, other than training, in the U.S. Armed Forces) for the alien's household size.

Comment: Many commenters expressed general concern that the income assessment would penalize low-income immigrants, low-wage workers, members of ''marginalized groups,'' and families and farmworkers. A commenter stated that counting wealth and income as indicators of a person's future contribution amounts to a sea change in U.S. immigration policy. Other commenters stated that the proposed income thresholds are biased against low and middle-income immigrants while unfairly favoring wealthy immigrants; disregard and devalue low wage-workers and their contributions to society; and ignore the ability of immigrants to raise their wages over time. A few commenters said the 125 percent income threshold is too high. Others provided data on starting salaries and on some of the fastest growing occupations that are in fields with low wages. A commenter stated that six of the 20 largest occupational fields in the country have median wages close to or below the poverty threshold for a family of three. According to the commenter, this means that lawfully present non-citizens who have jobs in these sectors through an employment visa may not be able to renew that visa. Another commenter indicated that immigrants increasingly are needed to fill middle-skill level jobs, referring to those jobs that require more than a high school diploma but less than a four-year degree. Therefore, the commenter asserted, businesses that largely employ individuals at low wages would suffer, as legally present non-citizens could become too encumbered to continue their employment, and those who have low wages would be penalized because they use benefits to supplement their wages, which allows them to thrive.

One commenter indicated that the threshold for household income would have a large impact on the eligibility for admission of intending immigrants and make it very difficult for entry level workers and other individuals to seek admission to the United States; this would harm the U.S. economy, educational institutions and businesses, and sends a message that only those with financial resources are welcome although study after study has shown that immigrants are job creators and provide a net benefit to the United States. Another commenter indicated that U.S. employers will find it more difficult and less predictable to extend the status of highly skilled workers on H–1B nonimmigrant (skilled worker) visas or recruit students, unless the employer offers a salary of more than the newly created 250 percent threshold, or risk that the worker is not able to renew the work visa given the complex and subjective considerations from USCIS adjudicators.

Additionally, some commenters stated that if the proposed income tests are applied to U.S. citizens, many would fail the test and therefore the tests should not be applied. Another commenter further stated that if the proposed public charge test is applied to U.S. born citizens, only five percent would meet the criteria, as compared to 29 percent under current guidance. Another commenter indicated that currently, 21 percent of immigrants nationally fall below the 125 percent threshold and 17 percent of citizens do as well. The commenter asserted that if the current public charge rule was applied to all Kentuckians, just 8 percent would fall into the ''public charge'' category, but under the proposed rule 33 percent of all Kentuckians would.

Some commenters provided data on the number of people in the United States living below 125 percent of the FPL and facts about the affected low-income population. Other commenters stated that the 125 percent income threshold would be incredibly difficult for young adults working in entry-level jobs to overcome. A commenter noted that the 125 percent of FPG standard has been the income threshold to be met by sponsors who are required to submit an affidavit of support, not by the immigrant subject to the public charge inadmissibility determination. The commenter questioned why, if a sponsor is expected to care for his or her own needs and the person he or she is sponsoring based on an income of 125 percent of the FPG, the same standard would apply individually to the intending immigrant.

Several commenters indicated that those working for minimum wage would not be able to meet the proposed threshold even if working full time, and that the minimum wage has not kept pace with changes in the cost of living in the United States. A commenter stated that basing entry into this country and adjustment of status solely on the basis of wealth is not only anathema to longstanding American values of upward mobility, but it also destabilizes financial security of immigrant families already in the United States, particularly in instances of family-based green card petitions.

Some commenters warned that the proposed income threshold would be nearly impossible for immigrants from very poor countries to achieve, and would therefore disproportionately and negatively affect immigrants from poorer regions of the world compared to immigrants from wealthier regions, such as Europe and Canada. A commenter stated that the proposed income thresholds are arbitrary and unreasonable and will be compounded by income inequality and variations in cost of living in the United States.

Some commenters stated that the rule will have a disproportionate effect on low income workers, leading to shortages in industries in which immigrants make up a substantial portion of the workforce.

Response: DHS understands that the rule changes the public charge inadmissibility determination as set forth in the 1999 Interim Field Guidance. However, Congress mandates that, as part of the public charge inadmissibility assessment, officers consider the applicant's assets, resources, and financial status, which, as explained in the NPRM, includes consideration of whether the applicant's household income is at or above 125 percent of the FPG income. DHS chose the 125 percent of FPG threshold (100 percent for an alien on active duty, other than training, in the U.S. Armed Forces) standard because Congress imposed it as part of the affidavit of support, which has long been a touchpoint for the public charge ground of inadmissibility.[634] Therefore, DHS disagrees that the threshold is arbitrary.

DHS also disagrees that if a sponsor is expected to demonstrate an income of 125 percent of the FPG, the alien should not be subject to the same standard. As noted elsewhere in this rule, Congress did not add the affidavit of support requirements as a substitute for a public charge inadmissibility determination or to supplant the mandatory factors set forth in section 212(a)(4)(B), 8 U.S.C. 1182(a)(4)(B). Instead, Congress added the affidavit of support as an additional assurance that the alien will not become a public charge at any time in the future. As Congress believed that 125 percent was an appropriate minimum threshold in the affidavit of support context, DHS does not believe the threshold should be lowered. Although Congress believed that 125 percent of the FPG based on the sponsor's household income was a reasonable minimum threshold in the affidavit of support context to support the sponsored alien and the sponsor's household, it does not necessarily

[634] Under INA section 213A, 8 U.S.C. 1183a.

follow that Congress believed that half that amount (assuming the sponsor used half the amount to support himself or herself), or any amount lower than 125 percent of the FPG, would be sufficient to demonstrate that the alien is not more likely than not to become a public charge. Rather, Congress' retention of the public charge inadmissibility determination indicates that Congress believed it was necessary to consider the alien's assets, resources, financial status (including, of course, income), and other relevant factors in addition to requiring the affidavit of support. Further, household income below 125 percent of the FPG would be reviewed along with the other factors in the totality of the circumstances such that on its own, such income would not be a basis for a public charge inadmissibility determination.

DHS disagrees that the rule bases entry into this country and adjustment of status solely on wealth. DHS notes that it must consider an applicant's assets, resources, and financial status in making a public charge inadmissibility determination, which includes consideration of the applicant's household income.[635] However, DHS does not intend the rule to penalize or negatively affect any particular group, and being a low-income worker would not necessarily in itself render an applicant inadmissible on public charge grounds. The rule abides by the statutory requirement as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and is consistent with congressional statements relating to self-sufficiency in 8 U.S.C. 1601, when Congress declared it to be the United States' continued immigration policy that ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' Further, the data in the NPRM shows that the percentage of people receiving these public benefits generally goes down as the income percentage increases. Therefore, DHS will maintain the 125 percent of the FPG (100 percent for an alien on active duty, other than training, in the U.S. Armed Forces) standard. After consideration of the comments, DHS also believes it necessary to clarify that when assessing the alien's annual gross household income, DHS will consider as evidence the most recent tax-year transcripts from the IRS, U.S. Individual Tax Return (Form 1040) from each household member whose income will be considered.[636] If such a Federal income tax return transcript is unavailable, DHS will consider other credible and probative evidence of the household member's income, including an explanation why the evidence is not available,[637] which may include Form W–2, Wages and Tax Statement, Social Security Statements, or Form SSA–1099, Social Security Benefit Statement.

Concerning nonimmigrants seeking extension of stay or change of status, DHS notes that the rule does not require them to demonstrate that they have income over 125 or 250 percent of the FPG. That threshold is a heavily weighted negative factor in the public charge inadmissibility determination, which is not applied to extension of stay and change of status. Further, as previously indicated, DHS is no longer reviewing whether the alien is likely to receive public benefits in the future in extension of stay and change of status determinations, and therefore, none of the factors in the public charge inadmissibility determination will be considered for nonimmigrants.

Comment: A few commenters stated that the heavy positive weight assigned to household income 250 percent above the poverty level discriminates against persons with disabilities because individuals with disabilities and their families are more likely to live in poverty than those without disabilities, and that such individuals will consequently not have the benefit of the heavily-weighted positive factor to offset any negative factors. In the same vein, commenters stated that individuals with disabilities will be disproportionately affected by the negative weight associated with incomes that fall below 125 percent of the poverty level.

Response: DHS disagrees that considering household income at or above 250 percent of the FPG a heavily weighted positive factor in the totality of the circumstances discriminates against persons with disabilities. DHS recognizes that any income threshold may affect aliens with low-income. However, DHS did not intend, in adding this income threshold as a heavily weighted positive factor, to discriminate against applicants on the basis of their applicant's race, nationality, medical condition, disability, or membership in any protected class. Even if applicants who have low income are unable to get the benefit of this heavily-weighted positive factor to offset any negative factors, the presence of any other positive factors could, in the totality of the circumstances, render the alien admissible.

Comment: A few commenters stated the proposed threshold could lead to greater family separation and undermine family unity. Another commenter stated that the rule will have an immediate and direct effect on families and their ability to stay united, and could lead to the separation of U.S. citizen children from their immigrant parents. The commenter stated that U.S. citizens will also be directly harmed by the rule, as they will be unable to petition for and sponsor family members. The commenter provided an example of a U.S. citizen mother and wife, who relies on the income of her non-U.S. citizen husband who entered the U.S. on a visa and who would be unable to sponsor her husband under the NPRM because she has no income. The commenter stated that if the U.S. citizen's husband cannot demonstrate sufficient assets or earnings, she would need to find another sponsor for her husband.

Other commenters stated that the proposed income threshold would negatively affect U.S. citizen children, as having children would make meeting the standard more difficult, which is counter-productive to encouraging self-sufficiency because family-based immigration has a positive impact on immigrant success. A couple of commenters said that the proposed income threshold particularly affects multigenerational households, a common practice among Asian American families, and that it would discourage people from supporting family members. An individual commenter suggested that placing an income threshold at 125 percent FPG would decrease the number of immigrant families with a stay-at-home parent, despite the benefits to the family of having a stay-at-home parent.

Response: DHS disagrees that the 125 percent income threshold standard would lead to family separation, or otherwise undermines family unity. The rule is not intended to separate families or otherwise undermine the family, but instead ensures that the statutory requirements, as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) are implemented, which mandate that USCIS must consider an applicant's assets, resources, and financial status in making a public charge inadmissibility determination. This approach is also consistent with congressional policy statements relating to self-sufficiency in 8 U.S.C. 1601, which provides that, ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own

[635] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[636] *See* 8 CFR 212.22(b)(4)(ii)(A)(*1*).

[637] *See* 8 CFR 212.22(b)(4)(ii)(A)(*2*).

capabilities and the resources of their families, their sponsors, and private organizations.'' [638] As discussed in the NPRM,[639] DHS chose a household income of at least 125 percent of the FPG (100 percent for an alien on active duty, other than training, in the U.S. Armed Forces), which has long served as a touchpoint for public charge inadmissibility determinations.[640] As discussed in the NPRM, DHS also cited data demonstrating that the percentage of people who receive public benefits generally decreases as income increases. In other words, the data established a correlation between having low income and the receipt of public benefits.[641] Therefore, DHS will maintain the 125 percent of the FPG standard. However, as reiterated in other areas, USCIS will not make a public charge determination based on one factor alone; rather, a determinations will be based on the totality of the alien's circumstances. Therefore, in addition to the household income determination, the review of public charge inadmissibility takes into consideration the other factors enumerated in this rule and all other relevant information.

DHS also disagrees that U.S. citizens will be directly harmed by the rule because they will be unable to petition for and sponsor family members. The rule does not directly impact who may file a family based immigration petition, or the sponsorship requirements under section 213A of the INA, 8 U.S.C. 1183a. DHS acknowledges that the rule may result in more family members of U.S. citizens being denied adjustment of status after being found inadmissible on public charge grounds, but believes that Congress intended that aliens be self-sufficient, and DHS has created through this rulemaking a fair and robust standard that is likely to have this this result in more cases than under the current policy.

Comment: One commenter stated that the proposed income threshold does not take into account the value of unpaid labor a family member may provide, such as a stay at home parent or grandparent providing childcare. Commenters also stated that the proposed rule could cause a shortage in direct care workers who are unable to remain in the United States, leaving many older and disabled Americans without access to caregivers.

Response: DHS understands that some applicants or some families may have household members or family members that provide services within the family, such as caregivers, stay at home parents, and others who will not be readily able to document either their work or income. To account for this, DHS will consider the applicant's household income, which may include the income of other household members who are more able to document their income and who provide the applicant with financial support. Accordingly, an applicant who provides care to a relative without pay may still be able to demonstrate that his or her household income meets the 125 percent FPG threshold. DHS notes that there is no evidence, however, that being a caregiver of others, or living in a household with a caregiver, in and of itself, is indicative of self-sufficiency or lack thereof. Although caregivers may benefit the household by eliminating the need for childcare expenses, each person must establish he or she is not likely to be a public charge based on the totality of the factors based an individual's circumstances. However, as discussed further below, DHS has added a separate provision under the Education and Skills factor that would allow DHS to take into positive consideration that the alien is a primary caregiver of another person within his or her household where there is evidence that the alien is currently unemployed, under employed or lacks an employment history but expects to rejoin the workforce. As discussed in this final rule, DHS has also defined primary caregiver as an alien who is 18 years of age or older and has significant responsibility for actively caring for and managing the well-being of a child or an elderly, ill, or disabled person in the alien's household.

Additionally, as discussed elsewhere in the rule, DHS acknowledges that, once the rule is effective, it will likely result in more adverse determinations. DHS also acknowledges the possibility that this rule, in turn, may impact the admissions of certain types of workers such as direct care workers. Congress did not exempt such workers from the public charge inadmissibility ground. DHS anticipates that the employment of such individuals as direct care workers may diminish the likelihood that they will be considered public charges, but, if the totality of the circumstances establish they, like any other applicant, are likely to become public charges, consistent with this rule, they will be deemed inadmissible. DHS believes a more effective implementation of the congressionally mandated self-sufficiency policy aims as articulated in this rule are paramount.

Comment: A few commenters stated this portion of the rule would strongly impact farmworkers and their families. Other commenters cited to a family income below 100 percent FPL and that farm labor's wages are among some of the lowest in the nation. Another commenter indicated that many of their patients, including agriculture workers, live below 150 percent FPL. Many commenters echoed this sentiment and remarked that farmworkers earn an average of around $17,500 per year. With low wages, these workers are highly unlikely to have assets to rule out this negative factor. Another commenter indicated that the proposed rule would particularly affect farmworkers in Michigan, as the work is largely seasonal and farmworkers in the state are not subject to the state minimum wage if they work on small farms. One commenter stated that farmworkers provide valuable and skilled labor that contributes greatly to our nation's agricultural productivity.

Response: As previously indicated in the section discussing extension of stay and change of status, and as explained in the notice of proposed rulemaking, DHS will not apply the public charge inadmissibility grounds under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) to nonimmigrants (including farmworkers present in the United States under the temporary worker program for agricultural services (H–2A)), seeking an extension of their stay or a change of status to another nonimmigrant classification. Instead, DHS imposes as one of the terms and conditions of granting an extension of stay or change of status, that the alien establishes that he or she had not received, since obtaining the nonimmigrant status that he or she is seeking to extend or change, any public benefits as defined in 8 CFR 212.21(b), for 12 months in the aggregate within a 36-month period. Based on this information, USCIS would then issue the decision on the application for extension of stay or change of status.

Comment: A commenter said that the FPL is a poor guideline due to differences in cost of living throughout the United States. Another commenter stated that differences in costs of living could mean that two people working full time at minimum wage could fall short of affording adequate housing in the district they represent. Another commenter stated that due to the high cost of living in many large cities, reliance on public assistance is not a

[638] *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

[639] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51187 (proposed Oct. 10, 2018).

[640] *See* INA section 213A(f)(1)(E), 8 U.S.C. 1183a(f)(1)(E).

[641] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51204 (proposed Oct. 10, 2018).

sign of a lack of self-sufficiency, but rather a symptom of a high cost of living. Other commenters stated that the proposed rule would trap immigrants in a cycle of poverty instead of giving them the opportunity to prosper.

Response: DHS agrees that the cost of living is different across the United States but disagrees that reliance on public assistance for housing is not a sign of lack of self-sufficiency. Through this rule, DHS has defined public charge as an alien who receives one or more public benefit as defined in the rule for longer than the designated threshold, to include public housing or housing vouchers. HUD programs are based on the cost of living in the area, which denotes that a person is unable to pay for local rent and therefore unable to be self-sufficient and instead must use public benefits in order to afford the rent. Therefore, DHS will consider 125 percent of the FPG threshold in the totality of the circumstances rather than the cost of living.

Comment: One commenter stated that the proposed factors institutionalize income bias and discrimination. According to the commenter, this income bias disregards the fact that many full-time workers earning a minimum wage would fall well below the threshold for being accorded positive weight. This commenter noted that such a stringent test creates a policy that is biased against working families, and perpetuates the myth that immigrants are a drain on our society and overly dependent on Government benefits. Some commenters stated that the proposed income threshold of 125 percent FPG would have an outsized and disproportionate impact on members of marginalized groups including children; families; immigrants of color; survivors of domestic violence and sexual assault; people with disabilities; elderly; low-wage workers; AAPI; South Asian Americans; Latino immigrants; those living with HIV and their families; immigrants with disabilities; older adults and families attempting to reunify; LGBTQ immigrants; and women, especially women with other intersecting identities regarding race, ethnicity, and sexuality. Additionally, another commenter remarked that the proposed standards would penalize victims of sexual and domestic violence; and pregnant women.

Response: DHS disagrees with the comments that this rule institutionalizes bias and discrimination. The Federal Government is responsible for ''regulating the relationship between the United States and our alien visitors,'' which includes regulating the manner and conditions of entry, as well as the residence of aliens.[642] DHS is the Federal agency with the authority to establish regulations regarding the public charge inadmissibility determination.[643] Section 212(a) of the INA, 8 U.S.C. 1182(a), sets forth the aliens who are ineligible for visas, admission, or adjustment of status, the public charge ground of inadmissibility and the minimum factors DHS is required to consider in the public charge inadmissibility analysis. DHS must consider an applicant's age, health, family status, assets, resources and financial status, and education and skills. The statute does not include the consideration of race, or any other characteristics and DHS did not propose to consider an alien applicant's race or any other characteristics when making a public charge determination. Similarly, DHS did not propose to take into account an applicant's ''social status.''

With respect to Immigration regulations applicable to aliens, the rational basis scrutiny applies.[644] DHS's public charge rule is rationally related to the Government's interest, as enacted in PRWORA, to minimize the incentive of aliens to attempt to immigrate to the United States, or to adjust status in this country, due to the availability of public benefits, as well as to promote the self-sufficiency of aliens within the United States.[645]

Comment: A commenter said the sum total of past income taxes paid by an individual, and their contribution to the welfare programs, should be balanced against the total value of benefits received by the individual. The commenter stated that taxes paid in the past are indicative of ability and future potential, and surely has a strong correlation with the likelihood of drawing from a benefits program in the future. Another commenter stated that the proposed income threshold would discourage immigrants from entering the country legally. Commenters also indicated that DHS's own conclusory assumption that receipt of this level of funding represents a lack of self-sufficiency was rebutted by the ample research showing that immigrants pay more into the United States healthcare system than they take out and that most immigrant pay taxes.

Response: DHS declines to adopt the commenters' suggestion to consider the amount of income taxes paid as an indicator of a likelihood to receive public benefits. The public charge inadmissibility determination looks at a person's individual circumstances to determine whether he or she is likely to become a public charge in the future. Not everyone is required to pay taxes and even if a person pays taxes, he or she may be eligible for public benefits. Given that Congress reiterated that the immigration policy continues to be that, ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations,'' [646] DHS believes that the proposed rule has properly and consistently balanced the value of assets and resources of the public charge determination to ensure that those seeking status in the United States do not become a public charge. With this rule, DHS is not seeking to deter immigration but to implement the congressional mandate given in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4).

Comment: A commenter stated that employment alone was not sufficient evidence of an immigrant's self-sufficiency and that the criteria should focus on an immigrant's ability to earn wages at least three times the FPL.

Response: DHS disagrees with the commenter's suggestions to consider three times the FPL as the threshold. DHS uses the FPG published by the HHS as a threshold in immigration matters. As explained in the NPRM,[647] the 125 percent household income threshold has long served as a touchpoint for public charge inadmissibility determinations as part of

[642] *Mathews* v. *Diaz,* 426 U.S. 67, 81–82, (1976).

[643] *See* Homeland Security Act of 2002 section 102, 6 U.S.C. 112; INA section 103, 8 U.S.C. 1103.

[644] *Korab* v. *Fink,* 797 F.3d 572, 577–79 (9th Cir. 2014) (''[F]ederal statutes regulating alien classifications are subject to the easier-to-satisfy rational-basis review . . . Although aliens are protected by the Due Process and Equal Protection Clauses, this protection does not prevent Congress from creating legitimate distinctions either between citizens and aliens or among categories of aliens and allocating benefits on that basis . . . The difference between state and federal distinctions based on alienage is the difference between the limits that the Fourteenth Amendment places on discrimination by states and the power the Constitution grants to the federal government over immigration.'') (citation omitted); *Lewis* v. *Thompson,* 252 F.3d 567, 570 (2d Cir 2001), citing *Lake* v. *Reno,* 226 F.3d 141, 148 (2d Cir.2000) (''We have recently recognized that a 'highly deferential' standard is appropriate in matters of immigration . . . .''). Generally, laws and regulations that neither involve fundamental rights nor include suspect classifications are reviewed under rational basis scrutiny, under which the person challenging the law must show that the government has no legitimate interest in the law or policy or that there is no rational link between the interest and the challenge law or regulation. *Heller* v. *Doe by Doe,* 509 U.S. 312, 319 (1993).

[645] *See* 8 U.S.C. 1601.

[646] *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

[647] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51187 (proposed Oct. 10, 2018).

affidavits of support and public charge. Therefore, DHS will continue to apply the 125 percent of the FPG threshold. DHS agrees, however, with the commenter that employment alone is insufficient evidence of self-sufficiency. The public charge determination reviews all factors in the totality of the circumstances and one factor alone, except for an insufficient affidavit of support when required, will not conclude that an alien is inadmissible based on public charge. An alien's education and skills, which reflect a person's ability to earn wages, are also considered in the totality of the circumstances.

Comment: One commenter suggested that community involvement be included when considering evidence of assets and resources.

Response: DHS recognizes that community involvement may be an asset to the community as a whole and appreciates the suggestion. However, community involvement does not establish the person's self-sufficiency or evidence of income, assets or financial status.

Comment: A commenter stated that the evidence of assets and resources requirement, namely the completion of the declaration of self-sufficiency as proposed in 8 CFR 245.4(b),[648] does not change the fact that someone could become gravely ill and be unable to work and never be self-sufficient. The same commenter stated that the evidentiary requirements encourage people to lie or discourages them from completing the process of seeking adjustment of status altogether.

Response: DHS agrees that individuals' future circumstances may be different than the ones that exist at the time of adjudication and the public charge assessment. However, the statute requires DHS to rely on present and past conditions and circumstances as the best available evidence to determine an alien's likelihood of becoming a public charge. Although it is a remote possibility that everyone could become sick and not be able to work, DHS is not assuming that this will happen. DHS would review reasonable possibilities in the future based on the person's current and parent circumstances.

Further, while it is true that some applicants may not provide USCIS with honest answers, DHS expects all applicants and petitions to provide honest and accurate information and requires information to be provided under penalty of perjury. DHS reiterates that not providing truthful information on immigration applications according to the best of an applicant's knowledge and ability may have immigration consequences, including denial of the benefit or ineligibility for benefits in the future.

DHS acknowledges that this rulemaking may discourage certain aliens from seeking adjustment of status that of a lawful permanent resident in the United States. However, with this rulemaking, DHS seeks to better enforce the public charge ground of inadmissibility codified by Congress. Additionally, DHS is also seeking to ensure that those seeking admission in the United States are self-sufficient upon admission and not likely to become a public charge at any time in the future.

Comment: Commenters indicated that the proposed rule seeks to set an income standard for income above 125% of the FPG, making it extremely difficult for low income immigrant young adults previously in foster care and earning less than 125 percent of the FPL ($31,375 annually for a family of four), meeting the new income threshold of the public charge test. Given that youth aging out of foster care often need to access public cash and shelter benefits to secure housing or to attend college or training, this could result in denying these young adults lawful permanent resident status. The commenter therefore believed that the proposed rule only serves to heavily favor immigrants with wealth, while punishing low-income immigrants, including immigrant young adults who are working in important, but low-wage jobs to sustain themselves and their families.

Response: With this rulemaking, DHS is seeking to better enforce the public charge ground of inadmissibility codified by Congress. DHS, therefore, disagrees with the commenters' statement that this rulemaking only serves to favor wealthy immigrants and to punish those with low-income. The determination whether somebody is likely at any time in the future to become a public charge is based on the totality of the alien's circumstances, and one factor alone, such as the financial status of the alien or the current receipt of public benefits, is not outcome determinative.

DHS acknowledges a possible impact of this rulemaking, once effective, on those in Federal, State, or tribal foster care or those who are aging out of foster care but may continue to obtain certain Federal, State, or tribal public benefits. DHS also acknowledges the possibility that individuals, including those aging out of foster care, may be likely to disenroll from public benefits because of this rulemaking. DHS notes, however, that individuals are typically placed in out-of-home care, such as foster care, because of abuse, neglect or other violence. U.S. law provides certain protections and statuses for aliens who have become victims of violence, such as refugee or asylee status, T nonimmigrant status for certain victims of human trafficking, U nonimmigrant status for victims of certain crimes, VAWA protections for victims of battery or extreme cruelty, and-Special Immigrant Juvenile status for victims of child abuse, neglect, abandonment, or a similar basis under State law. Generally, the public charge inadmissibility ground does not apply to these individuals and therefore, the level of income or the receipt of public benefits would be a consideration.

2. Evidence of Assets and Resources

Comment: Some commenters stated that the proposed rule penalizes immigrants for having a mortgage, despite real estate being a wise investment. Several other commenters said the criteria undervalues homeownership. A commenter stated that home ownership is a gauge of middle class status in the United States and that the longer an immigrant lives in the United States, the more likely they will own a home. Another commenter expressed doubts whether the assets and resources threshold would have the required predictive value for purposes of public charge. Additionally, the same commenter also expressed skepticism that real estate could be easily convertible into cash within 12 months. This commenter reasoned that such assets are typically the residence of the alien or his household, which cannot be readily liquidated without imposing offsetting new housing costs; and, in case of a commercial property, liquidation within twelve months is an unlikely prospect in most U.S. real estate markets. The commenter requested a better justification for the assets and resources threshold of five times the difference between the alien's household gross annual income and the FPG for the alien's household size, and the inclusion of real estate as an asset that could be converted into cash within 12 months; or, preferably, the elimination of these standards from the final rule.

Response: DHS disagrees that the rule penalizes immigrants for having mortgages. There is no requirement that

[648] The commenter referred to 245.5. 8 CFR 245.5 is the regulatory provision addressing the medical examination of individuals seeking adjustment of status. The NPRM proposed to amend 8 CFR 245.4 by requiring a new documentary requirement for purposes of the public charge determination under INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

an alien have a mortgage-free home; and an alien with a mortgage could use the total value of the home minus the amount of the mortgage to meet the assets threshold. In other words, homeownership could help the alien establish that he or she is meets the income threshold and is not likely to become a public charge where the alien can provide evidence that he or she has available assets through value in a home to overcome any negative factors of the absence of regular income through employment or substantial assets in bank accounts.

The ''five times equivalency'' test to establish significant assets to cover the difference between the 125 percent standard and the actual income has long been recognized for public charge inadmissibility in the affidavit of support context.[649] DHS disagrees that having assets to cover five times the difference between income below 125 percent of the FPG and the 125 percent amount fails to meet any predictive value, because such assets could be readily converted to cash and substitute for income, thereby helping ensure that the alien does not rely on public benefits to meet his or her basic needs.

DHS disagrees that typically the residence of the alien or his household cannot be readily liquidated without imposing offsetting new housing costs or in case of a commercial property, liquidation within twelve months is an unlikely prospect in most U.S. real estate markets. An alien may be able to liquidate the home and then obtain a new lower cost home or start renting.

Additionally, DHS also disagrees with the commenter about the assessment of the 12-month benchmark; this benchmark is used for affidavit of support purposes [650] which, again, has long been part of the public charge inadmissibility determination. The affidavit of support permits listing of assets that may be liquidated within one year only, and specifically includes the net value of the sponsor's or the sponsored immigrant's home as a permissible asset. Although the affidavit of support does not specifically address commercial property in terms of liquid assets, the commenter provided no evidence to support the proposition that an alien would be unable to liquidate commercial property within 12 months, and DHS sees no reason to treat commercial property differently from residential property in this context. In addition, 8 CFR 213a.2(c)(2)(iii)(B) does specifically consider real estate in the calculation of significant assets, and it is similarly reasonable to consider commercial property as assets in this context. Therefore, DHS will continue to use the 12-month standard for liquidation of assets.

Comment: A commenter stated that the income threshold in the NPRM fails to exclude income from illegal conduct, unlike what the commenter states is the definition of income used by DOS.[651] The commenter reasoned that no alien may work in the United States without authorization, either by operation of law or by specific application.[652] The commenter strongly recommended that income from unauthorized employment should be excluded from the calculation of gross annual household income, in the same manner as unlawful income from drug dealing, gambling, or smuggling. The commenter further suggested that no evidence of irregular income that is not documented on a tax return or equivalent document, such as an IRS Wage and Tax Statement (Form W–2) or Return of Organization Exempt from Income Tax (Form 990), should be accepted; that income earned under a taxpayer identification number rather than a Social Security number should be presumptively unacceptable; and that this approach would streamline the adjudication of public charge determinations, by eliminating consideration of most evidence of income other than recognized IRS documentation.

Response: DHS appreciates the comments and would like to clarify that an alien's employment and income derived from employment without an employment authorization card or status which authorizes employment will be considered as part of the assets, resources and financial status factor and the education and skills factor. DHS believes that limiting consideration of employment and income to only that derived from authorized employment goes beyond the narrow purpose of this rule, which is ensuring that aliens are self-sufficient and do not rely on the government to meet their basic living needs. For purposes of a public charge determination, the alien's household income is relevant to the determination of whether the alien's assets, resources and financial status make the alien more likely than not in the totality of the alien's circumstances to become a public charge. Whether or not the alien engaged in unauthorized employment and any immigration consequences flowing from such unauthorized employment is a separate determination.[653] DHS will therefore consider any past employment and any income derived from such employment in the public charge inadmissibility determination. In addition, as not all income is required to be reported in tax returns, DHS will continue to consider additional income that is not listed on the IRS forms as provided in the I–944 instructions.

However, DHS does agree that income derived from illegal activities or sources should be excluded from the calculation of gross annual household income including, but not limited to, income gained illegally from drug sales, gambling, prostitution, or alien smuggling.

3. Public Benefits

Comment: Some commenters referenced DHS's request regarding whether use of other benefits should be counted in the totality of circumstances test. Those commenters opposed considering the use of non-listed programs in the totality of circumstances test. Additionally, other commenters stated that DHS should not allow public benefits that are not explicitly enumerated in the rule to be weighted negatively in the totality of the circumstances review. Several commenters said that Federal assistance programs or public benefits should not be a deciding factor in the public charge inadmissibility determination. One commenter cited a study showing that immigrants have a lower unemployment rate than native-born citizens and requested the agency's rationale for focusing on discouraging immigrants from using public benefits, despite their lower unemployment rate as a demographic group.

Some commenters stated that receipt of benefits was not evidence of weak financial status, as benefits are used temporarily to help people get back on

[649] *See* 8 CFR 213a.2(c)(2)(iii)(B). *See also* 64 FR 54346, 54348 (October 20, 1997) (explaining the rationale for the significant asset rule as part of the interim affidavit of support rule) and 71 FR 35732, 35739 (June 21, 2006) (explaining the rational for adopting the current affidavit of support rule at 8 CFR 213a, which provides for additional standards for certain aliens). DHS has amended the public charge regulatory provision to reflect that DHS will adopt the three standards used in the significant asset provision for purposes of the public charge determination.

[650] *See* Form I–864, Instructions, Part 7.

[651] The commenter cited to the former FAM section on public charge at 9 FAM 40.41. The public charge FAM section is now located at 9 FAM 302.8.

[652] *See* INA sections 274A(a)(1), (h)(3), 8 U.S.C. 1324a(a)(1), (h)(3).

[653] Furthermore, a general limitation of the type suggested by the commenter could be in tension with USCIS policy. *See* USCIS Policy Memorandum PM–602–0119, *Qualifying U.S. Work Experience for Special Immigrant Religious Workers* (July 5, 2015), *https://www.uscis.gov/sites/default/files/USCIS/Laws/Memoranda/2015/2015-0705_Lawful_Status_PM_Effective.pdf*; *Shalom Pentecostal Church* v. *Acting Secretary DHS,* 783 F.3d 156 (3d Cir. 2015).

their feet. Another commenter stated that many of the public benefits considered under the proposed rule would in fact make someone less likely to be a public charge, especially when the benefits are received by children. A few other commenters expressed concern that using prior receipt of public benefits as evidence of financial status ignores the role public benefits play in promoting self-sufficiency. A commenter indicated that past receipt of benefits is not even mentioned by Congress as a factor that should be given any weight in the public charge determination. Another commenter cited a 1999 letter from HHS stating that it could not imagine any way in which an individual could become primarily dependent on public benefits. Another commenter asserted that the current provisions surrounding public benefits are sufficient to be used in public charge determinations. A few commenters stated that counting benefits as a negative factor when used by children in the public charge assessment is contrary to the purpose of the public charge ground of inadmissibility because benefits providing essential health, nutrition and housing assistance prepare children to be productive, working adults; counting it as a negative factor would unfairly base a child's future potential for self-sufficiency on their use of benefits as a child. A commenter stated that using prior receipt of benefits in public charge determinations is contrary to the totality of circumstances test. One commenter indicated that considering the use of public benefits as evidence of financial status would negatively and disproportionately impact LGBTQ immigrants and immigrants with disabilities. Another commenter stated that, since most applications for public assistance consider a wide range of benefits, immigrants would be kept from applying from all benefits, even those not mentioned in the proposed rule. Some commenters stated that including receipt of benefits as evidence of financial status would lead to a widespread chilling effect among immigrants and citizens alike. One commenter asserted that, unless DHS is willing to compel employers in agriculture and in other industries to provide a living wage and health benefits, it is cruel and unjust to punish hard-working immigrants who rely on public benefits but who also benefit the United States.

Response: DHS disagrees with the commenters and maintains that receipt of public benefits indicates weak financial status. DHS also disagrees rates of public benefits receipt among aliens as a whole would warrant abandoning this rule, which applies the public charge ground of inadmissibility to individual aliens. As provided in the NPRM,[654] and elsewhere in this regulation, current or past applications for, or receipt of, or certification for future receipt of public benefits, as defined in 8 CFR 212.21(b), suggests that the alien's overall financial status is so weak that he or she is or was unable to fully support himself or herself without public benefits, *i.e.,* that the alien will receive such public benefits in the future. Accordingly, as discussed more fully in the discussion on the public benefits threshold section, DHS believes that it is reasonable to consider any application, approval, or certification for, or receipt of, public benefits as a negative factor in the totality of the circumstances, as this is relevant to determining the likelihood of becoming, at any time in the future, a public charge. DHS understands however, that certain individuals may have become self-sufficient over time after having received or having been certified to receive public benefits, and therefore, either have disenrolled, or have requested disenrollment from the public benefits. To account for these positive developments in an alien's life, DHS decided to include as a consideration evidence of the disenrollment, or a request for disenrollment or withdrawal from public benefit receipt.

Overall, however, Congress implicitly recognized that past receipt of public benefits can be considered in determining likelihood of someone becoming a public charge when it prohibited consideration of benefits that were authorized under 8 U.S.C. 1641(c) for ''certain battered aliens.'' [655] Congress' prohibition of consideration of prior receipt of benefits by a specific class of aliens indicates Congress understood and accepted the agency's consideration of past receipt of benefits in other circumstances.

DHS agrees that public benefits play a role in promoting and helping people obtain self-sufficiency; however, the primary reason people seek public benefits is the inability to be self-sufficient. In addition, the 1999 Interim Field Guidance, in which other agencies commented, involved the ''primary dependence'' standard, which is different from the standard set forth in this final rule. While DHS understands that some people may choose not to apply for benefits, however, the rule does not intend to disproportionally affect any group of people as previously discussed.

Comment: A commenter indicated that the proposed regulation states only that DHS would consider whether a noncitizen has ''applied for'' or ''received'' benefits or fee waivers, without defining those terms. The commenter wrote that the proposed rule did not plainly state that DHS will only consider a noncitizen's application for benefits on her own behalf. These omissions, according to the commenter, would allow immigration officers to penalize a noncitizen during a public charge determination when she is the formal applicant for, or payee of, benefits for which her children or others are the true beneficiaries.

Another commenter expressed concern that many affected families will include U.S. citizens. The commenter explained that although the proposed rule stated that DHS did not intend to consider benefits received by a mixed status household where a noncitizen would not be entitled to receive a benefit or was not counted for purposes of calculating household size, the proposed regulatory text did not clearly implement DHS's stated intent. The commenter stated that as a consequence, an immigrant applying for benefits exclusively on behalf of U.S. citizen dependents could still face adverse consequences in a public charge determination for the family's receipt of such benefits, leaving the household with the choice of either not applying for benefits and facing food and housing insecurity, or the applying for the benefits and increasing the likelihood of adverse immigration consequences for some family members.

Similarly, a commenter stated that the proposed regulatory text fails both to clearly explain how DHS will identify ''the portion of the benefit that is attributable to the alien'' (for example, when the individual lives in a household that receives housing assistance and he or she would not be eligible to receive such assistance). The commenter wrote that the proposed rule did not plainly state that DHS will only consider a noncitizen's application for benefits on her own behalf. Another commenter stated that DHS should commission research on the cash value equivalence when determining the discount factor for housing benefits.

Response: DHS agrees with commenters that additional clarification of when DHS will consider application, certification, or receipt of public benefits will weigh negatively in the totality of the circumstances could be

[654] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51188 (proposed Oct. 10, 2018).

[655] INA section 212(s), 8 U.S.C. 1182(s).

helpful. Therefore, DHS has added a new definition of ''receipt of public benefits'' to 8 CFR 212.21(e) to clarify that DHS will only consider the alien to have received a public benefit if the alien is a named beneficiary of the benefit but not where an alien is applying, being certified, or receiving a public benefit not on his or her own behalf but on behalf of another person. For example, if a parent is applying for a public benefit on behalf of a U.S. citizen child, such application for public benefits will not be considered negatively against the parent. Similarly, if an alien is the legal guardian or power of attorney of the alien's lawful permanent resident parent and is applying for a benefit on behalf of such parent, such application and/or associated administration of the public benefit on behalf of the alien's parent will not count negatively against the alien. DHS would only count as a public benefit any benefit for which the alien is specifically listed as a beneficiary. The new definition also clarifies that application for a public benefit is not the same as receipt but is indicative of an alien's intent to receive such a benefit. Similarly, certification is not the same as receipt but may impact the likelihood that the alien will in the future receive such public benefit.

Comment: Commenters stated, in response to a call for comments in the proposed rule preamble, that DHS should not revise the rule to allow adjudicators to consider an alien's receipt of public benefits below the applicable threshold, as part of DHS's assessment of whether the alien is likely at any time in the future to become a public charge (*i.e.,* to receive benefits above the applicable threshold). A commenter wrote that all individuals, citizen or non-citizen alike, may have emergency situations or unanticipated job losses that could result in a need for benefits on a temporary basis. Another commenter wrote that if any benefit receipt below the threshold were to be considered in the totality of circumstances, the thresholds would become ''entirely meaningless.''

Response: No commenters established that receipt of designated public benefits below the applicable threshold has no bearing on whether the alien may, in the future, receive designated public benefits above the applicable threshold. In addition, the proposed rule, as drafted, would have effectively required DHS to be willfully blind to evidence of significant benefits use that fell short of the threshold. For instance, it was unclear whether the proposed rule would allow adjudicators to consider the fact that an alien had received non-monetized benefits for 11 consecutive months leading up to an application, even though such fact would be directly relevant to whether the alien is likely to exceed the applicable threshold in the future.

Following careful consideration of the issue, DHS has determined that it is reasonable to consider any application, approval, or certification for, or receipt of, public benefits as a negative factor in the totality of the circumstances, regardless of whether the benefits exceed the threshold for becoming a public charge. While DHS does not believe that past receipt of the benefits enumerated in this rule for 12 months or less, on its own, makes the alien likely to become a public charge in the future, such receipt will in some cases suggest that the alien is not self-sufficient, or may soon lack self-sufficiency. Accordingly, under the assets, resources, and financial status factor, DHS will consider it to be a negative factor (though not a heavily weighted negative factor) if the alien has applied for, been approved or certified for, or has received, public benefits for any amount of time.[656] The fact that an alien has in the past applied for, been approved or certified for, or has received public benefits for any amount of time, would never be dispositive on its own, but would be relevant to assessing an alien's likelihood of becoming at any time in the future a public charge. USCIS will consider the duration, amount, and recentness of an alien's past approval or certification for, or receipt of, public benefits, when deciding how much weight to give this past activity as part of the prospective totality of the circumstances determination.

Comment: An individual commenter stated that the proposed assets, resources, and financial status factors would treat immigrants who have been living in the country fundamentally different than those arriving at ports of entry and are therefore arbitrary. The commenter indicated that this difference in treatment is wholly inequitable and fundamentally wrong because an individual who has continually received public assistance in a foreign country could potentially be allowed to enter the United States. In contrast, individuals who are applying for adjustment of status within the United States could be denied adjustment of status for a brief, temporary use of a low dollar amount of public assistance.

Response: DHS disagrees that the proposal is arbitrary. DHS understands that public benefits and assistance programs exist in other countries. However, DHS did not propose and will not consider public benefits provided by foreign countries.[657] Public benefits in foreign countries have different standards and objectives. For example, in some countries, healthcare is provided on a national basis irrespective of income or need and is, therefore, not comparable to public benefits or to the public charge standard in the United States. In addition, the inadmissibility determination addresses whether a person is likely to become a public charge in the United States in the future.

Additionally, all applicants for admission and adjustment of status applicants must demonstrate that they are clearly and beyond a doubt not inadmissible to the United States.[658] The ground of inadmissibility under section 212(a) of the Act, 8 U.S.C. 1182, include the public charge grounds of inadmissibility under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). DHS explained in the proposed rule that it provided a more comprehensive framework to determining public charge inadmissibility, including certain and new paper-based applications, as additional evidence related to public charge considerations.[659] DHS also explained that, due to operational differences, this additional evidence would not generally be required at ports of entry.[660] Applicants for admission are inspected by immigration officers at or, when encountered, between ports of entry in a timeframe and setting distinct from the adjudications process. This, however, does not imply that DHS does not screen applicants for admission for grounds of inadmissibility, including public charge grounds of inadmissibility. Therefore, DHS does not fundamentally treat those who seek adjustment of status in the United States differently from those seeking admission to the United States.

Comment: One commenter stated that the proposed rule ignores that under PRWORA applicants for admission are and will remain ineligible for public benefits even after admission, and that applicants for adjustment of status are and will remain ineligible for most public benefits until they have green cards for five years. The same commenter stated that the rule's

[656] 8 CFR 212.22(b)(4)(ii)(F)(1), (2).

[657] *See* 8 CFR 212.21(b). *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51158–51174 (proposed Oct. 10, 2018).

[658] *See* INA section 235(b)(2)(A), 8 U.S.C. 1225(b)(2)(A).

[659] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51116 (proposed Oct. 10, 2018).

[660] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51116 (proposed Oct. 10, 2018).

''weighing scheme'' is impermissibly vague. The commenter pointed to one of the examples in the proposed rule as indicative of the unpredictable nature of the determination, namely that an individual who is in school and employed with an income of 120 percent of the FPG and does not have health insurance but has no other negative factors would not be deemed likely to become a public charge. But the commenter noted that if the individual was not precluded by immigration status from receiving public benefits, the individual would be income-eligible for SNAP, Medi-Cal, and Federal housing assistance. The commenter stated that it is not clear why DHS would not deem the individual likely to become a public charge at any time in the future.

Response: DHS disagrees with the commenter that the rule fails to consider the alien's immigration status in determining whether an alien could qualify for public benefits, and has added language in the rule to clarify. DHS also disagrees that the totality of the circumstances determination is impermissibly vague and unpredictable, or that the example the commenter cited illustrates the unpredictability of the determination. In the proposed rule, DHS established as one of the mandatory regulatory factors the consideration of the alien's prospective immigration status and expected period of admission. DHS notes that there are a number of legal and practical limitations on DHS's ability to consider eligibility for public benefits as part of its totality of the circumstances determination. For instance, DHS does not have the expertise to apply the varied and often complex framework of public benefit eligibility criteria, either on a state-by-state basis or according to general Federal standards; cannot reliably predict the alien's likely state of residence at any time in the future; and cannot assume that all aliens who are ineligible for the designated benefits in the near-term will not use them in the long term.[661]

But if an alien provides evidence from a Federal, State, local, or tribal agency specifically identifying that alien does not qualify for one or more public benefits, USCIS can use that information as part of its totality of the circumstances determination. DHS has therefore revised the regulatory text to make clear that DHS would consider evidence from a Federal, State, local, or tribal agency administering a particular benefit that shows the alien does not qualify for the public benefit, so long as the alien submits the necessary evidence and specifically identifies it as relating to eligibility.

For example, an alien could provide a letter from a benefit-granting agency indicating that the alien is not eligible for a particular benefit based on the alien's immigration status. In the alternative, the alien could provide information from a public benefit-granting agency listing the immigration classifications not eligible for public benefits and evidence of the alien's prospective immigration status that together indicate that the alien is not eligible for the benefit because the alien does not have an immigration classification that the public benefit-granting agency has identified as eligible. Similarly, the alien could provide evidence of his or her gross household income together with information from a public benefit agency's website showing the eligibility income threshold for the state in which the alien resides, or will reside upon becoming a lawful permanent resident, that specifically indicates that the alien's gross household income exceeds the threshold. DHS would consider such evidence in the totality of the circumstances. DHS notes that an assessment that an alien is not currently eligible for any or all designated public benefits may carry some weight in the totality of the circumstances, but will never be outcome determinative. DHS must consider all statutory factors to determine whether the alien is likely *at any time in the future* to become a public charge.

With respect to the specific example cited by the commenter, DHS notes that evidence of alien's income being below 125 percent of the FPG or evidence that the alien's immigration status may not be disqualifying, are not necessarily determinative factors in the totality of the circumstances. In the example commenter discusses (Table 34, example A in the proposed rule), DHS would determine that the alien is not likely to become a public charge notwithstanding the alien's lower income and lack of health insurance because the alien is fundamentally a young and healthy person (age 30) of a working age, with an employment history and education (attending a Bachelor's degree program), and the alien is an employment-based applicant for adjustment of status. In making this determination, DHS would take into consideration the fact that the alien is working while in school and thus that the nature and hours of employment may be limited by his need to attend classes. DHS would also look at the likelihood that the alien's earning capacity would increase as a result of his education—for example, U.S. Census data shows that a college degree nearly doubles earnings.[662] Similarly, there is no evidence that the alien had previously received, or even attempted to apply for, or been certified to receive public benefits.[663] Therefore, notwithstanding the commenter's observation about potential future eligibility for such benefits, the alien, based on the facts, would not be more likely than not receive public benefits at any time in the future. However, if there were evidence that, the alien was discontinuing his or her education, or had a chronic health condition that would impair the alien's ability to work, or that the alien had attempted to apply for public benefits but had been found ineligible based on his immigration status, such evidence could tip the determination the other way and USCIS may determine that the alien is more likely than not to receive public benefits above the designated threshold at any time in the future. Therefore, DHS appreciates that a real world circumstance is likely to include facts beyond those included in the hypothetical fact pattern that could lead to a different adjudication.

4. Fee Waivers for Immigration Benefits

Comment: Many commenters said the rule overweighs receipt of one-time immigration fee waivers to predict whether a person will become a public charge by double counting, as use of a fee waiver is a function of income.

[661] *See, e.g.,* Medicaid.gov, Medicaid, Children's Health Insurance Program, & Basic Health Program Eligibility Levels, *https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-eligibility-levels/index.html* (discussing Medicaid eligibility from state to state) (last visited June 5, 2019); State TANF Policies: A Graphical Overview of State TANF Policies as of July 2016, available at *https://www.acf.hhs.gov/sites/default/files/opre/wrd_2016_databook_companion_piece_05_15_18_508.pdf* (last visited June 5, 2019).

[662] *See College Degree Nearly Doubles Annual Earnings: https://www.thoughtco.com/college-degree-nearly-doubles-annual-earnings-3320979* (last visited June 27, 2019); *U.S. Census Bureau Educational Attainment in the United States: 2004: https://www.census.gov/data/tables/2004/demo/educational-attainment/cps-detailed-tables.html* (last visited June 27, 2019); *U.S. Census Bureau Post-Secondary Employment Outcomes (PSEO) (Beta) https://lehd.ces.census.gov/data/pseo_beta.html.*

[663] Even though some studies show that low income earners receive one or more public benefits at higher rates, DHS would not necessarily find this trend to be outcome determinative in the case of an individual enrolled in a Bachelor's degree program. *See, e.g.,* The New York Times, *Working, but Needing Public Assistance Anyway https://www.nytimes.com/2015/04/13/business/economy/working-but-needing-public-assistance-anyway.html* (April 12, 2015) (last visited July 26, 2019); U.C. Berkeley Labor Center: High Public Cost of Low Wages *http://laborcenter.berkeley.edu/the-high-public-cost-of-low-wages/* (last visited on June 27, 2019).

Another commenter stated that there is not enough data to determine whether one-time receipt of a fee waiver was related to a person being a public charge. A commenter noted that a separate consideration of the use of a fee waiver means that factors such as income would be unfairly counted twice—once based on their household income and a second time when the fee waiver is granted because of their income.

Response: DHS disagrees that the receipt of a fee waiver for an immigration benefit is over weighted. The fee waivers for immigration benefits is only one evidentiary consideration in the totality of the circumstances and it is not heavily weighted. As indicated in the NPRM,[664] since fee waivers are based on an inability to pay (*i.e.,* receipt of means-tested public benefits or income at the FPG level), a fee waiver for an immigration benefit suggests an inability to be self-sufficient. DHS recognizes that some of the factors required to obtain a fee waiver may be similar to those used as part of the public charge determination. These factors, however, are reviewed differently according to their respective purposes. For purpose of the public charge inadmissibility determination, all the factors and circumstances will be reviewed in the totality of the circumstances without a counting system currently used for fee waiver purposes, in which each factor is individually ranked or scored to assess whether a fee waiver is warranted. As such, DHS will consider the alien's financial liabilities and the request or the receipt of a fee waiver as evidence of financial liabilities and status in the totality of the circumstances. Other evidence may provide the same information and therefore, DHS would consider the evidence as a whole but not individually rank or score the evidence.

Comment: One commenter said it is impermissibly retroactive to consider the past receipt of a fee waiver because ''it impermissibly penalizes applicants for their financial status on the date of the application for the fee waiver and not on the date of application for admission, adjustment of status, or for a visa.'' Commenters indicated that often, an individual's economic situation improves after receiving immigration benefits for which applicants receive a fee waiver. A commenter stated that even immigrants who applied for a fee waiver and were rejected for having high income, would be counted under the proposed rule.

Response: DHS disagrees that the consideration of a fee waiver would be impermissibly retroactive. First, fee waivers applied for or received before the effective date will not be considered.[665] Second, any fee waiver received on or after the effective date of the rule, will be considered in the totality of circumstances and, alone, would not result in a finding that a person is likely at any time in the future to become a public charge. In the totality of the circumstances analysis, evidence of a change in circumstances, *e.g.,* steady employment and income, would also be taken into consideration. Third, simply because the regulation bases the consideration of public charge in part on an occurrence of a fee waiver on or after the effective date of the rule, does not make the regulation impermissibly retroactive.[666] Through this regulation, DHS simply specifies considerations as part of implementing the public charge determination, according to the best evidence available at the time of the adjudication, including past occurrences of a fee waiver request or grant as a consideration, in the totality of the alien's circumstances. Finally, and similar to the receipt of public benefits, DHS will, in the totality of the circumstances, consider how long ago the fee waiver was received. If the fee waiver was received recently, it would have more relevance to the public charge determination, whereas if the fee waiver was received some time ago, for example, before the alien obtained new, steady employment, the relevance of the fee waiver in the totality of the circumstances would be diminished.

Comment: Some commenters stated that the rule seemed to reduce or potentially eliminate the use of the application fee waivers and stated that the fee waiver program is founded on its own policy rationale, which, according to the commenters, is not the subject of this rule. A commenter stated that fee waivers are typically only available for applications not subject to the public charge ground of inadmissibility and stated that using fee waivers in public charge determinations will only serve to chill overall immigration applications. Another commenter further remarked that the inclusion of fee waivers in public charge determinations would result in fewer immigrants being willing and able to seek citizenship. A commenter stated that many of their clients were worried about whether using a fee waiver would impact their chances of having their applications approved. A commenter stated that the fee waivers would be limiting the options immigrants have to file for immigration benefits and would harm families, citing a story about a client in the process of applying for citizenship. An individual commenter stated that it is cruel to offer fee waivers and then hold the use of said fee waiver against immigrants in their application. Additionally, another commenter stated that the standards for fee waivers are often more lenient than the finding of inadmissibility under the proposed rule, and therefore should not be used in public charge determinations. A different commenter stated that the use of fee waivers in public charge determination would likely disadvantage naturalized citizens in efforts to reunite their families. A couple commenters stated that receipt of a fee waiver often serves as a step toward self-sufficiency and decreases the likelihood that an immigrant will be dependent on government assistance in the future. Another commenter stated that fee waivers are often used when applying for work authorization, as at that time immigrants have no income, and considering fee waivers would lead to longer unemployment periods and increase use of public benefits. A commenter stated that often immigrants apply for fee waivers when they need to file an application in a timely manner, but do not have the time to save enough money to afford the application fee. Another commenter stated that including a fee waiver in public charge determinations would increase the burden on immigrants.

Response: DHS disagrees that the rule eliminates fee waiver requests. Applicants would still be able to request fee waivers in accordance with the applicable regulations and form instructions.[667] The consideration of a fee waiver in the public charge inadmissibility determination is but one factor in the totality of the circumstances. As indicated in the NPRM,[668] requesting or receiving a fee waiver for an immigration benefit suggests a weak financial status. Since fee waivers are based on an inability to pay, seeking or obtaining a fee waiver

[664] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51188 (proposed Oct. 10, 2018).

[665] 8 CFR 212.22(b)(4)(ii)(G).

[666] ''A regulation has retroactive effect 'when it takes away or impairs vested rights acquired under existing laws, or creates a new obligation, imposes a new duty, or attaches a new disability, in respect to transactions or considerations already past.' '' *See Mejia* v. *Gonzales,* 499 F.3d 991, 995—99 (9th Cir. 2007) (quoting *INS* v. *St. Cyr,* 533 U.S. 289, 321 (2001)).

[667] *See* 8 CFR 103.7(c).

[668] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51188 (proposed Oct. 10, 2018).

for an immigration benefit suggests an inability to be self-sufficient. In addition, the Senate Appropriations Report for the Department of Homeland Security for FY 2017, stated that ''the Committee is concerned about the increased use of fee waivers, as those paying fees are forced to absorb costs for which they receive no benefit. In addition, those unable to pay USCIS fees are less likely to live in the United States independent of government assistance.[669] However, the House Report on Department of Homeland Security Appropriations Bill, 2019, said ''USCIS is expected to continue the use of fee waivers for applicants who can demonstrate an inability to pay the naturalization fee. USCIS is also encouraged to consider whether the current naturalization fee is a barrier to naturalization for those earning between 150 percent and 200 percent of the federal poverty guidelines, who are not currently eligible for a fee waiver.'' Therefore, DHS would not consider the request or receipt of reduced fee for the naturalization application as part of the public charge inadmissibility.

DHS also disagrees that this rule would deter individuals from applying for U.S. citizenship or otherwise imposes additional burdens on applicants. This rule addresses how DHS determines inadmissibility of aliens on account of public charge; and it does not apply to individuals seeking to be naturalized who would apply for a fee waiver request because the public charge ground of inadmissibility does not apply to naturalization proceedings.[670]

For clarification purposes, DHS has amended the regulatory text in 8 CFR 212.21(b) to provide that fee waiver requests submitted or granted as part of immigration benefits that are not subject to the public charge inadmissibility ground under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) will not be considered as part of the public charge determination. *See* 8 CFR 212.22(b)(4)(G).

Comment: One commenter stated that considering fee waivers would unfairly and disproportionately impact survivors of human trafficking and domestic violence who are less likely to have the ability to pay for fee-based forms. Another commenter further remarked that the use of fee waivers in public charge determination would disproportionately affect women, survivors of abuse, and people of color.

Response: As discussed in the NPRM, an alien who is a VAWA self-petitioner, a T nonimmigrant at time of admission, and an applicant for, or individual who is granted, U nonimmigrant status are generally exempt from the public charge ground of inadmissibility. For reasons discussed earlier in this preamble, DHS amended this final rule to clarify that T nonimmigrants seeking any immigration benefit subject to section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), are generally exempt from the public charge ground of inadmissibility, as previously discussed. Because these survivors of human trafficking and domestic violence are generally exempt from the public charge inadmissibility ground, they would not be impacted by this rule.

Comment: Several commenters stated that the consideration of receipt of a fee waiver would keep immigrants from accessing their right to justice in immigration proceedings.

Response: DHS disagrees that the consideration of requests for, and receipt of, fee waivers would prevent individuals in removal proceedings from applying for any benefits for which they are eligible. Although request and receipt of a fee waiver is a consideration in the public charge inadmissibility determination, it is but one factor in the totality of the circumstances, and could not, alone, form the basis of an inadmissibility determination. The consideration of fee waivers within public charge inadmissibility determinations conducted by immigration judges in removal proceeding is more appropriately addressed by DOJ in the context of their public charge rulemaking. DHS's rule only addresses the consideration of fee waivers in the context of matters before DHS.

5. Credit Report and Score

Comment: Several commenters noted that a credit scores and credit histories are not designed to assess an alien's likelihood of becoming a public charge, were not designed to be used in the immigration context, and do not assess an alien's self-sufficiency. A commenter also noted that credit reports do not address at all whether an alien can financially provide for himself or herself because credit reports do not reflect the subject's payment of rent, utilities, income, savings, or other financial resources. A few commenters stated that a person's credit history should not impact their ability to change immigration status. Many commenters said there is no correlation between a low credit score and the evaluation factor. Many commenters stated that credit reports are highly inaccurate. Further, a commenter remarked that credit reporting scores vary widely between agencies, and that the score reported to a consumer may not be the same as the score used by lenders. Many commenters asserted that an applicant's credit history could be impacted by factors outside their control from which they may recover. Additionally, a commenter indicated that credit report and income alone does not depict a clear picture of an immigrant's full financial situation or their ability to raise their credit score. A couple of other commenters stated that credit reports and scores do not contain enough information about an individual's earnings or incomes. Another commenter stated that many consumers who are credit invisible or unscoreable will be disadvantaged by the rule and provided data on the population who falls into these groups.

Many commenters stated that credit scores are a poor way to evaluate the past ability to pay bills, since scores do not reflect rent payments, which are often the largest recurring expense a household or individual will incur. Some commenters stated that medical debt is often reflected in credit reports and is not an accurate or reliable measure of an individual's financial status. One commenter stated that credit reports should not be included as a negative factor, but that individuals should be allowed to submit a good credit score as a positive factor if they so choose. An individual commenter stated that there may be additional credit data, which provides for non-traditional credit activity (*i.e.,* short-term payday lending, rent-to-own, auto lending data) that could be used in public charge determinations.

Response: A weaker financial status may, in the totality of the circumstances, lead to a public charge determination. As indicated in the NPRM,[671] USCIS would consider an alien's liabilities and information of such liabilities in a U.S. credit report and score as part of the financial status factor in the totality of the circumstances. As provided in the NPRM, a good credit score in the United States is a positive factor that indicates a person is likely to be self-sufficient and support the household. Conversely, a lower credit score or negative credit history in the United States may indicate that a person's financial status is weak and that he or she may not be self-sufficient. Credit reports and credit scores provide information about a person's bill paying history, loans, age of current accounts, current debts, as well as work, residences, lawsuits,

[669] *See* S. Rep. No. 114–264, at 125 (2016).

[670] *See* INA section 311–347, 8 U.S.C. 142–1458.

[671] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189 (proposed Oct. 10, 2018).

arrests, collections, actions, outstanding debts and bankruptcies in the United States.[672] Credit reports generally assist creditors to determine the credit worthiness or risk of a person, and affect the terms of the credit the person is offered.[673] DHS's use of the credit report or scores focuses on the assessment of these debts, liabilities, and related indicators, as one indicator of an alien's strong or weak financial status, so that in the totality of the circumstances and as part of all considerations affecting the alien, the alien is more or less likely to become, in the future, a public charge. DHS believes it is useful information in determining whether aliens are able to support themselves. However, DHS understands that not everyone has a credit history in the United States and would not consider the lack of a credit report or score as a negative factor. DHS also understands that the three main different credit reporting agencies do not provide identical scores. DHS believes that the credit report and score are nonetheless sufficiently reliable to be useful in reviewing a person's financial status in determining whether an applicant is likely to become a public charge.[674] As the Consumer Finance Protection Board has said ''A credit report generally is considered s reasonably reliable third-party record . . . for purposes of verifying items customarily found on a credit report, such as the consumer's current debt obligations, monthly debts, and credit history.'' [675] Further, if the alien has a confirmed error on the report or score, USCIS would not consider the report a negative factor. USCIS will review the latest credit report and score provided by the alien. DHS notes that a credit report or score alone would not lead to an inadmissibility determination based on public charge because the assessment of public charge is made in the totality of the circumstances and no one factor or consideration (with the exception of an insufficient affidavit of support or no affidavit of support, where required) is outcome determinative for being found inadmissible based on public charge.

Comment: A commenter expressed concern that inclusion of credit history in public charge determinations would amount to double counting of some of the evidence upon which such reports and scores are based and would already factor into the public charge determination.

Response: DHS recognizes that some of the factors enumerated in the public charge rule may be based on similar circumstances; however, some of the considerations may be reviewed differently depending on the factor. However, all the factors and circumstances will be reviewed in the totality of the circumstances without ranking the factors numerically. DHS would consider the alien's financial liabilities and past receipt of public benefits; the credit report and score would simply serve as evidence of financial liabilities and status. Other evidence may provide the same information and therefore DHS would consider the evidence as a whole but not individually rank or score the evidence.

Comment: One commenter stated that the guidelines in the proposed rule regarding credit score were broad and ambiguous. A commenter stated that using credit scores in public charge evaluation would lead to ''arbitrary, inconsistent, and unfair'' public charge determinations. The commenter further stated that the mechanics of going through immigrants' credit reports and scores are impractical.

Response: DHS disagrees that the language on credit scores is broad and ambiguous or that it would lead to an arbitrary, inconsistent and unfair public charge determination. As indicated in the NPRM,[676] USCIS would generally consider a credit score characterized as ''good'' or better to be a positive factor as it demonstrates an applicant may be able to support himself or herself and any dependents assuming all other financial records are sufficient. A ''good'' credit report is generally near or slightly above the average of U.S. consumers,[677] and therefore the person may be self-sufficient and less likely to become a public charge. A poor credit report is well below the average of U.S. consumers.[678]

Comment: Multiple commenters asked whether past poor credit would be used as a negative factor in a public charge determination.

Response: DHS would only consider the information included in the latest credit report and score as provided by the alien at the time of adjudication for public charge inadmissibility purposes. The fact that some had a previous negative or positive score will not be taken into account in the public charge inadmissibility determination.

Comment: One commenter questioned how DHS plans to collect, protect, and manage sensitive data surrounding credit report scores. Another commenter noted that USCIS would be required to comply with the storage and disposal requirements for credit information at 15 U.S.C. 1681x.

Response: DHS takes seriously its responsibility to properly protect sensitive information in its possession.[679] DHS follows the Privacy Act requirements, which apply to information that is maintained in a ''system of records'' from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The materials in alien files (A-files) are considered permanent records and are transferred to the National Archives and Records Administration 100 years after the subject's birth,[680] and therefore not subject to the disposal requirements of the Fair Credit Reporting Act (FCRA). To the extent that credit information subject to the FCRA is maintained in other agency records systems, such records will be destroyed in accordance with applicable General and/or Agency Records Schedules which would be in compliance with the FCRA requirements.[681] As with all forms and private identifiable information, DHS will follow all applicable regulations and procedures to safeguard and protect any sensitive information.

Comment: A commenter indicated that if DHS includes credit reports in the public charge determination DHS should not exclude non-U.S. credit reports because credit reporting in the United States is exclusively the province of private-sector corporations, this is not the case in many countries. The commenter cited the World Bank, which stated that at least 30 countries

[672] *See* USA.gov, *Credit Reports and Scores, available at https://www.usa.gov/credit-reports* (last updated July 18, 2019) (last visited July 26, 2019).

[673] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189 (proposed Oct. 10, 2018).

[674] *See generally Marting Realty, Inc.* v. *Marks,* 1986 WL 4647 (Ohio Ct. App. 9th Dist. 1986) (''Credit reports are held to be highly reliable by the business world and should be admitted where such reliability is not challenged.'') (citation omitted).

[675] Official Interpretation 43(c)(3)-3 to 12 CFR 1026.43(c)(3), published as part of Ability-to-Repay and Qualified Mortgage Standards Under the Truth in Lending Act (Regulation Z), 78 FR 6408, 6607 (Jan. 30, 2013).

[676] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189 (proposed Oct. 10, 2018).

[677] MyFICO, *Understanding FICO Scores* 5, *available at https://www.myfico.com/Downloads/Files/myFICO_UYFS_Booklet.pdf* (last visited July 26, 2019).

[678] MyFICO, *Understanding FICO Scores* 5, *available at https://www.myfico.com/Downloads/Files/myFICO_UYFS_Booklet.pdf* (last visited July 26, 2019).

[679] *See generally* Notice of Modified Privacy Act System of Records, 82 FR 43556, 43564 (Sept. 18, 2017) (''DHS/USCIS safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. USCIS has imposed strict controls to minimize the risk of compromising the information that is being stored.'').

[680] 82 FR 43556, 43564.

[681] *See* 15 U.S.C. 1681w; 16 CFR 682.3.

operate public credit registries, including seven nations in the European Union and 17 in Latin America and the Caribbean.

Response: DHS will not include credit reports from other countries in the public charge inadmissibility determination. DHS agrees that credit reporting systems vary significantly throughout the world, including but not limited to how they are established, the information collected, and the rating policy used.[682] As explained in the NPRM, the information obtained through a U.S. credit report may be indicative of a person's financial status and the person's self-sufficiency in the United States.[683] Given that the focus of the public charge determination is the alien's likelihood of becoming a public charge to the United States in the future, DHS believes that the U.S. credit report provides the best means to obtain relevant information regarding assets, resources and financial status. As it is the case with all factors, USCIS will assess the information obtained through a U.S. credit report or score and its impact on the public charge determination in the totality of the circumstances; USCIS will not base the inadmissibility determination solely on the results of the credit report or score.

Comment: Another commenter indicated that considering credit scores and reports as a negative factor is directly contrary to case law, citing to *Howe* v. *United States ex rel Savitsky,* 247 F. 292 (2d Cir. 1917). The commenter explained that in this case the immigration inspector found the alien to be a public charge for having drawn a check abroad which ultimately proved bad and that in a dispute arising from contractual matter, the alien had sold the equipment at issue and kept the proceeds.[684] The Second Circuit reversed the decision explaining that Congress meant the public charge provision to exclude persons who are likely to become occupants of almshouses for want of means with which to support themselves in the future.''

Response: DHS disagrees that considering credit scores and reports as a negative factor is directly contrary to the case law established in *Howe* v. *United States ex rel Savitsky.*[685] In *Howe,* the court criticized the public charge determination made by the immigration inspector, finding that immigration inspector's ''latitudinarian construction'' of the term public charge would render all other grounds redundant because everybody could be considered a public charge.[686] The court indicated that the public charge determination could not be simple conjecture but that there must be some indication that an otherwise physically fit individual were to become a public charge for want of means to support themselves in the future before he or she could be found inadmissible.[687] The court did not imply or mandate that any aspect of an individual's financial history be excluded from a public charge determination. Additionally, the case was decided based on the 1910 version of Section 2 of the Immigration Act of 1907; the provision at the time did not specifically require immigration officers to consider the alien's ''assets, resources and financial status'' as part of the public charge determination.[688] In contrast, with the 1996 amendments of IIRIRA, Congress specifically required immigration officers to consider these factors as part of the public charge determination.[689] As explained in the NPRM,[690] DHS considers an alien's liabilities and information of such liabilities in the U.S. credit report and score indicative of the state of an alien's assets, resources, and financial status and the person's ability to be self-sufficient.

Comment: Many commenters remarked that immigrants are more likely to have no credit history or an insufficient amount of information to generate a reliable score. A commenter stated that in their experience helping enroll immigrant populations in ACA open enrollment, credit scores were often either unavailable or inaccurate. A commenter stated that many immigrants are often victims of financial frauds and financial abuse, which could negatively affect their credit score. The commenter further stated that the only people to prosper from the proposed rule would be the credit repair industry.

A few commenters stated that credit reports are not available in languages other than English, which can disadvantage immigrants with limited English proficiency from accessing their score and disputing mistakes made to their credit. Adding to this a commenter stated that immigrants often are not aware or are not able to correct errors on their credit score. One commenter stated that not using credit cards can negatively impact one's credit score even though not using credit cards can be a financially responsible choice. Adding to this, a few commenters stated that many people lack credit history because they are frugal which shows a lack of likelihood of becoming a public charge.

Response: DHS recognizes that the credit reports and scores may be unavailable or inaccurate. As provided in the NPRM,[691] the absence of an established U.S. credit history would not be a negative factor when evaluating public charge in the totality of the circumstances. Absent a U.S. credit report or score, USCIS may give positive weight to an alien who can show little to no debt and a history of paying bills timely. An alien may provide evidence of regular and timely payment of bills, and limited balances on credit cards and loans. In addition, USCIS would not consider any error on a credit score that has been verified by the credit agency in determining whether an alien is likely to become a public charge in the future.

Comment: Several commenters stated that considering credit scores will disparately affect ''marginalized communities.'' Additionally, a few commenters stated that using an immigrant's credit history in public charge determinations would have a disproportionate impact on immigrants of color; women; survivors of sexual and domestic abuse; people with lower levels of education; and local communities where credit scores there are lower than the national average. A commenter stated that the use of credit scores in public charge determinations may have the unintended consequence of trapping immigrants in a cycle of payday loans.

Response: DHS disagrees that consideration of credit scores will disparately affect certain groups of aliens. DHS must consider an applicant's assets, resources, and financial status in making a public

[682] The commenter cited to Margaret Miller, ''Credit Reporting Systems Around the Globe'' (Washington; World Bank, June 2000*), available at, http://siteresources.worldbank.org/INTRES/Resources/469232–1107449512766/Credit_Reporting_Systems_Around_The_Globe.pdf* (last visited July 24, 2019).

[683] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189 (proposed Oct. 10, 2018).

[684] *Howe* v. *United States ex rel Savitsky,* 247 F. 292 (2d Cir. 1917) (He had drawn a check for $113 before leaving Canada which proved bad and that in a dispute with one Solomon Cohen arising out of the purchase of a milk route, Cohen charged him with having sold some of the equipment and kept the proceeds.)

[685] *See Howe* v. *United States ex rel Savitsky,* 247 F. 292 (2d Cir. 1917).

[686] *See Howe* v. *United States ex rel Savitsky,* 247 F. 292, 294 (2d Cir. 1917).

[687] *See Howe* v. *United States ex rel Savitsky,* 247 F. 292, 294 (2d Cir. 1917).

[688] *See Howe* v. *United States ex rel Savitsky,* 247 F. 292, 293 (2d Cir. 1917). *See* Comp. St. 1916, Sec. 4244.

[689] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[690] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51188–89 (proposed Oct. 10, 2018).

[691] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189 (proposed Oct. 10, 2018).

charge determination.[692] The rule abides by the statutory requirement as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and is consistent with congressional statements relating to self-sufficiency set forth in 8 U.S.C. 1601. DHS does not believe that the use of credit scores will trap people into a cycle of payday loans since the rule in general, and the use of credit scores in particular, do not require anyone to incur any debts.

Comment: A few commenters said that if public charge determinations are made using credit reports or scores, it must be in compliance with user duties under the FCRA. Specifically, the commenters noted that the FCRA applies to USCIS as a Government agency,[693] and that FCRA requires persons to provide the consumer with a written notice if it takes an ''adverse action'' against that person ''based in whole or in part'' on a credit report.[694] A USCIS denial would qualify as an ''adverse action'' since it would be denying a ''license or other benefit granted by a governmental instrumentality required by law to consider an applicant's financial responsibility or status.'' [695] USCIS would be required to provide the required written notice required under the FCRA. Some commenters stated that the burden caused by complying with the FCRA would outweigh the benefits from using the credit score.

Response: DHS appreciates the comments. DHS agrees that it would be subject to FCRA when it relied on whole or on part on a credit report or credit score obtained from a credit report or other consumer report to deny a benefit. In such cases, USCIS will include the information required by 15 U.S.C. 1681m(a) as part of its communication with applicants. However, DHS disagrees that the burden imposed upon USCIS would outweigh the benefits from using a credit score and will retain the score as part of the rule.

6. Financial Means To Pay for Medical Costs

Comment: One commenter supported the proposal to assess whether an immigrant has private medical insurance. Another commenter disagreed with the proposal to include financial means to cover medical costs. A couple commenters stated that the requirement that an immigrant have sufficient assets to cover the costs of medical care is vague and impossible to determine fairly. One commenter said considering lack of private health insurance seems ''outlandish'' when fewer than half of private employers in the United States provide health insurance to their workers. Similarly, a commenter said that many people who are employed do not have access to affordable healthcare coverage. Another commenter stated that immigrants are more likely than citizens to work in low-income industries that do not provide health insurance or pay enough for employees to afford health insurance. One commenter suggested the agency provide more information on how an immigrant can obtain insurance, since employer insurance is not always an option. Some commenters stated that low-wage workers should not be denied status because they lack health insurance. A couple commenters remarked that the lack of private health insurance in the United States provided the rationale behind the passing of the ACA. An individual commenter stated that the proposed financial means to pay for medical costs factor introduces a conundrum in deciding which will be weighted more heavily: Having private insurance now or previously having used public insurance. Another commenter stated that the proposed standard would be double counting with other factors in the public charge determination.

Response: As explained in the NPRM, USCIS will consider whether a person has health insurance or has the household assets and resources to pay for reasonably foreseeable medical costs.[696] In addition, as discussed in section III.R. below, based on DHS's review of the relevant data, DHS has determined to designate a heavily weighted positive factor for having private health insurance, so long as such insurance is appropriate to the expected period of admission, and the alien does not receive premium tax credits under the ACA for such insurance. DHS understands that certain individuals may choose to forego public health insurance, such as Medicaid, because of the impact on public charge. The rule, however, abides by the statutory requirement as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and is consistent with congressional statements relating to self-sufficiency in 8 U.S.C. 1601. As Congress indicated that the immigration policies continues to be that, ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.'' [697] Financial means to pay for reasonably foreseeable medical costs is part of being self-sufficient. In evaluating the alien's ability to pay for reasonably foreseeable medical costs, DHS will consider whether the alien has private health insurance (which, on its own, can constitute a heavily weighted positive factor in certain circumstances, as described below) or other household assets and resources. DHS notes that such an evaluation may in some cases require DHS to consider an alien's publicly funded or subsidized health insurance that is not defined as a public benefit under this rule. As previously indicated, DHS will not base the inadmissibility determination on simply one factor but will review all the factors and circumstances in the totality of the circumstances without a rating or numerical standard.

Comment: Some commenters stated that the proposed rule, with its statement that ''individuals in poor to fair health are more likely to access public benefits to treat their medical condition'' erroneously suggests that all immigrants suffer from preexisting conditions and that they will all access federally subsidized health insurance.

Response: DHS disagrees that the rule assumes that all immigrants suffer from pre-existing conditions and obtain federally subsidized health insurance. Whether a person has a medical condition is but one factor in the totality of the circumstances. DHS will also consider whether the alien has the resources to pay for reasonably foreseeable medical costs, and DHS will consider it a heavily weighted positive factor if the alien has private health insurance, so long as such insurance is appropriate for the expected period of admission and the alien does not receive premium tax credits under the ACA for such insurance.

Comment: Another commenter stated that requiring the financial means to pay for medical costs is in direct conflict with the goals of the ACA.

Response: DHS disagrees that requiring financial means to pay for medical costs is in conflict with the ACA. Although the ACA provides for affordable health insurance for a greater number of people, it also limits coverage to categories of immigrants eligible for subsidies and assistance through the

[692] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[693] 15 U.S.C. 1681a(b) (including government agencies in the definition of persons).

[694] 15 U.S.C. 1681m(a).

[695] 15 U.S.C. 1681b(a)(3)(D).

[696] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189 (proposed Oct. 10, 2018).

[697] *See* Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, section 400, 110 Stat. 2105, 2260 (Aug. 22, 1996) (codified at 8 U.S.C. 1601(2)).

ACA.[698] DHS is also not limiting the ability of people to receive subsidized health insurance, through the ACA or other programs. Insurance obtained from a private health insurance provider through the ACA marketplace would be considered private health insurance under this rule, although, as explained more fully in section III.R below, private health insurance for which the alien receives premium tax credits under the ACA would not qualify as private health insurance for purposes of the heavily weighted positive factor.

Comment: A commenter stated that the agency should provide the data used to determine the cost of caring for chronic disease treatment and that the agency should further their analysis to reflect the cost to taxpayers. They further stated that DHS should illustrate how immigrants could access health insurance.

Response: The NPRM included a discussion of healthcare costs, and the importance of considering an individual's health when making the determination of public charge. DHS does not believe a more detailed analysis of the costs associated with chronic disease treatment is necessary. DHS does not have current information on all available health insurance plans, however, an applicant can seek information through HHS or through their local government.

Comment: Many commenters stated that this factor would negatively and disproportionately affect people with disabilities; people with chronic health conditions; immigrants of color; Asian Americans; victims of human trafficking; farmworkers; and survivors of sexual abuse and violence.

Response: DHS does not intend to disproportionately affect such groups. The rule abides by the requirements as provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and is consistent with congressional statements relating to self-sufficiency in 8 U.S.C. 1601. As Congress indicated that the immigration policies continues to be that, ''aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations.''

M. Education and Skills

1. Education

Comment: A commenter said that it should be unlawful to preclude individuals from immigrating to the United States for lack of education and that the new definition of public charge, in general, benefits the wealthy, putting them above hardworking families that actually help the country's economy. Another commenter equated the education requirement to a wealth test with no bearing on an individual's potential. In contrast, a commenter stated that education should be considered in a public charge determination because it is a key indicator of welfare use. The commenter added that, while the majority of immigrants come for work and most are employed, their lack of education results in low average income and heavy use of means-tested benefits programs. The commenter expressed support for an even higher standard and suggested that if an applicant has only a high school education or did not graduate high school, the burden must be on the applicant to show they will not be a public charge. Another commenter stated that, while the proposed evidentiary criteria to support the education requirement are all reasonable to consider as contributing factors, it is critical that they not be treated as separate elements, but as distinct ways to prove education and skills. The commenter concluded that treating each of these elements as separate factors is inconsistent with congressional intent and the general concept of a totality of the circumstances approach.

Response: When Congress amended section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), it directed officers to consider the alien's education and skills, and the rule implements Congress's directive on this mandatory statutory factor. Additionally, DHS cited in the NPRM to various studies and data supporting the concept that a person's education and skills, including skills in the English language, are correlated to an individual's self-sufficiency and therefore a positive factor.[699] The goal of this rule is to ensure an alien's self-sufficiency and therefore, the implementation of this factor, as proposed by the NPRM, is consistent with congressional statements relating to self-sufficiency in 8 U.S.C. 1601. DHS will review and consider evidence brought forward by the applicant, including, but not limited to, evidence of the alien's employment history; an alien's degrees; occupational skills, licenses or certifications; and evidence of the alien's and proficiency in English.[700]

Comment: A commenter stated that the proposed rule assumes that individuals who have a highly recognized degree or a unique skill are more likely to succeed in the United States, but these individuals often experience downward mobility post-migration because their foreign degrees, credentials, and work experience are not directly transferable to the United States job market. The commenter further stated that recent data shows education is a misguided factor in a public charge determination citing one study that found that even though many first-generation Americans may face issues with lower education levels, subsequent generations dramatically improve their educational profiles. Another commenter stated that being employed or currently enrolled in STEM (science, technology, engineering, and mathematics) or information technology (IT) fields should be listed as a positive factor.

Response: As previously indicated, education and skills is a mandatory factor established by Congress.[701] DHS would individually review a person's education and skills to determine whether they are able to maintain or obtain employment to avoid becoming a public charge. As occupations vary in education and skills requirements, DHS is not limiting its review to specific education or occupations. Therefore, DHS does not find it necessary to specify in the rule education and occupations in STEM or other similar fields. It is DHS's intent that officer should examine every consideration, including education and skills, set forth by the alien in the totality of the circumstances when ascertaining whether an alien is likely to become a public charge based upon the applicability of the alien's education and skills to available employment at the time of adjudication.

Comment: Commenters stated that the education requirement discriminates against farm workers and other trade workers because they may not have a formal education, but could have been working in the United States for many years. A commenter indicated that, while individuals that lack a high school or equivalent education generally earn less than persons with more formal education, they have many opportunities for gainful employment. The commenter noted that there are numerous jobs with no formal educational requirement, primarily in the agricultural, food processing and preparation, and building trades sectors, which are essential to the economy.

[698] *See* Healthcare.gov, Immigration status and the Marketplace, available at *https://www.healthcare.gov/immigrants/immigration-status* (last visited July 24, 2019).

[699] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189–96 (proposed Oct. 10, 2018).

[700] *See* 8 CFR 212.22(a).

[701] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

Another commenter said consideration of an immigrant's educational level is impermissible under the governing statute, in light of that factor's failure to accurately predict a likelihood of reliance on public benefits. The commenter suggested that studies have shown that low-skilled and low-educated immigrant men demonstrate ''substantially higher rates of employment'' than do comparable native-born men, particularly because of migrant selectivity in deciding where to locate and work. The commenter concluded by saying lack of a formal secondary education does not indicate, among immigrant populations, a likelihood of becoming a public charge and indicates the contrary.

Response: As indicated above, education is one of the mandatory factors in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) that DHS must consider in the public charge determination. Employment history will also be considered in the public charge inadmissibility determination to determine whether the alien may obtain or maintain employment. Therefore, while the lack of formal education such as the lack of a high school diploma or other education, are generally a negative consideration, the alien's employment history as well as any occupational skills, certifications or licenses are generally positive considerations. DHS agrees that there are many opportunities for gainful employment, but DHS disagrees that consideration of an immigrant's educational level is impermissible as it is part of Congress' mandatory factors to consider in section 212(a)(4) of the Act, 8 U.S.C. 1182(A)(4). Additionally, the NPRM showed a clear link between increased education and increased employability, employment productivity, as well as earnings, and a reduction in public benefits use.[702]

DHS will consider a range of evidence as to education and skills. To clarify additional types of documentation that establishes a steady employment history, DHS has revised the evidentiary considerations in the rule to indicate that applicants should include federal tax return transcripts for the previous 3 years, if applicable, or, if the alien was not required to file federal income taxes, other probative evidence of the alien's employment history including Form W–2 for the previous 3 years.

Comment: Some commenters stated that an education requirement would be more difficult for immigrant women, stating that immigrant women from certain countries, such as Mexico, El Salvador, and China, are less likely to have completed high school, and are therefore, less likely to overcome a negative assessment based on this factor. Similarly, a commenter stated that the negative weight for lack of a high school diploma and lack of employment history would impact a significant portion of women from Asian countries who are adjusting their status.

Response: DHS will examine the totality of the individual's circumstances, regardless of the individual's nationality, sex or other characteristic, to assess whether the individual is likely to become a public charge in the future. Among the factors to consider, education and skills is but one factor and is not outcome determinative on its own. When evaluating whether the alien has adequate education or skills to either obtain or maintain employment, USCIS' considerations include, but are not limited to the alien's past employment history; whether the alien has a high school degree or its equivalent, or any higher education; whether the alien has any occupational skills, certifications or licenses; and the alien's proficiency in the English or other languages in addition to English. DHS also encourages the applicant to bring forward any consideration he or she believes are relevant to the determination whether the alien has sufficient education or skills to not become a public charge at any time in the future.

Comment: A commenter stated that the level and quality of the education attained by a prospective immigrant can help predict how likely they are to become a public charge and suggested prioritizing higher education in the immigration process. The commenter stated that immigrants with a high school education or less should not qualify for a green card unless the applicant holds a skill(s) that is in high demand and can be expected to earn a high enough salary that they would not need to enroll in any welfare programs. Another commenter said not enough weight is being given to an education standard, noting that while 37 percent of households headed by noncitizens with at least some college use welfare, the rate rises to 81 percent for households headed by noncitizens with only a high school diploma or less.

Response: Congress legislates which individuals should be qualified for lawful permanent resident status, and not DHS. Therefore, DHS cannot implement the suggestion that immigrants with a high school education or less should not qualify for lawful permanent resident status unless the applicant holds a skill that is in high demand and for which the market pays a high salaries. Additionally, DHS disagrees that it does not give sufficient weight to the education standard: The public charge assessment considers each factor and circumstance applicable to the alien and each factor is accordingly weighted to determine whether an alien will be self-sufficient while in the United States. The DHS standard recognizes, consistent with the statute, that it is possible that an alien's other positive factors may outweigh the lack of formal education with the result that an alien is not deemed to be likely at any time in the future to become a public charge.

Comment: Several commenters expressed concern over the negative assessments that individuals with disabilities may encounter under the education and skills factor in public charge determination. One commenter noted that in order to work and go to school, many individuals with disabilities rely upon Medicaid-funded services that would be considered in the public charge inadmissibility determination's assets, resources and financial status factor, and will also impact the education and skills factor.

A few commenters added that unemployment rates for individuals with disabilities are drastically higher than those for individuals without disabilities. Many commenters addressed how the education requirements might negatively affect immigrants with disabilities, arguing that disparity in education and educational barriers for people with a disability have been ongoing in the United States for generations, resulting in lower rates of high school completion, and great disparities exist when comparing the attainment of higher-level degrees. A couple of commenters said attaining education and employment are areas where many people with disabilities often face significant discrimination based on their disability.

Response: DHS appreciates the comments and understands that employment opportunities individuals with disabilities are different. Officers will not find an individual inadmissible solely on account of his or her education, skills, or his or her disability. Rather, officers will assess, based on the totality of the circumstances, whether the individual is likely to be self-sufficient. As indicated in the NPRM,[703]

[702] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189–97 (proposed Oct. 10, 2018).

[703] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51184 (proposed Oct. 10, 2018).

Federal laws [704] and regulations prohibit discrimination against individuals with disabilities. DHS recognizes that individuals with disabilities and other conditions make substantial contributions to the American economy. DHS has analyzed these laws and regulations, and has determined that assessing an alien's education and skills, including work history, is not inconsistent with adhering to non-discrimination requirements with respect to individuals with disabilities.

Comment: A commenter expressed concern that adjudicators would apply the education and skills factor inconsistently with respect to the mission and duties of certain religious workers. The commenter stated that qualifying religious workers come from diverse educational backgrounds and perform a diverse range of work duties, depending on the nature and mission of the religious order. The commenter stated that work duties may include duties that do not produce any income at all, such as meditation and prayer, in those orders that pursue a more monastic way of life. Another commenter stated that the proposed education and skills factor could negatively impact those seeking visas as religious workers.

A commenter suggested that DHS exempt special immigrant religious worker category [705] from public charge inadmissibility determinations or clarify that these workers would still be admissible. The commenter stated that the regulations define a religious vocation as a ''formal lifetime commitment . . . to a religious way of life'' and cover religious workers who have taken a vow of poverty. The commenter indicated that as part of the vow of poverty, many religious workers relinquish personal property and assets, and are not permitted by their religious order to receive compensation. Instead, their religious order or community obligates itself to provide non-salaried support to its vowed member, such as room and board, health insurance, a small allowance, etc. In addition, the commenter stated that a religious order may be obligated to support this member as long as they remain a member. Given that ''assets, resources, and financial status'' is one of the main factors in the public charge determination, the commenter expressed concern that religious workers would be immediately disadvantaged.

Additionally, the commenter expressed concern about the administrative and economic burden imposed on religious organizations to demonstrate that special immigrant religious workers are not likely to become a public charge. The commenter indicated that sponsors of religious workers may not possess the financial ability of typical U.S. employers. The commenter also stated that the imposition of additional documentary and form requirements to demonstrate that a religious worker is not likely to become a public charge would increase costs to the religious worker sponsor. The commenter indicated that these organization will maximize their resources to serve their mission in the Catholic Church, and that to impose additional economic burdens on U.S. religious organizations seems contrary to American values of religious freedom and liberty.

Finally, the commenter expressed concern about the rule's negative impact on individuals and communities in the United States. The commenter stated that many international religious workers play a vital role in the daily lives of individuals and families in the United States. In addition to the spiritual and ministerial role played, many religious workers also participate in activities and duties supporting the communities directly. Therefore, the commenter requested clarification these special immigrant religious workers continue to qualify for the status or be exempt from public charge.

Response: DHS acknowledges that special immigrant religious workers, and immigrants who perform religious work generally, provide valuable contributions to the United States and are in a special position, as acknowledged by Congress in the special immigrant religious worker classification.[706] Congress, however, did not exempt these workers from the public charge ground of inadmissibility and, therefore, DHS will not exempt them in this rule. As noted elsewhere in this final rule, DHS believes that this regulation, and other provisions of the INA and implementing regulations, can be administered consistently with the RFRA. DHS acknowledges that any individual or organization who identifies a substantial burden on his, her, or an organization's exercise of religion such that the RFRA may require specific relief from any provision of this rule may assert such a claim.[707]

Among the requirements for a special immigrant religious worker, the sponsoring religious organization must provide an attestation, attesting, among other things, that the employee will be employed at least 35 hours a week, and that the worker will be provided a complete package of salaried or non-salaried compensation.[708] As part of the petition, the employer provides detailed evidence as to the compensation package being offered to the religious worker, which may include salaried and non-salaried compensation, such as room, board and other remuneration.[709] Additionally, as part of the attestation, the sponsoring religious organization also has to demonstrate the ability and intention to compensate the alien at a level at which the alien and accompanying family members will not become public charges, and that funds to pay the alien's compensation do not include any monies obtained from the alien, excluding reasonable donations or tithing to the religious organization.[710] To the extent that the sponsoring religious organization complies with these evidentiary requirements with respect to the religious worker's compensation package, DHS does not anticipate, in general, that special immigrant religious workers, including those who have taken a vow of poverty are disadvantaged regarding consideration of their income, assets and resources because the sponsoring religious organization provides compensation to the religious worker such that the religious worker would generally be relying on private rather than on public benefits.

Additionally, DHS does not believe that considering the education and skills of a religious worker applicant may result in inconsistent adjudications or violate due process. As explained above, DHS is required to consider an applicant's education and skills as part of the public charge inadmissibility determination. As provide in the rule, when considering an alien's education and skills, DHS will consider whether the alien has adequate education and skills to either obtain or maintain

[704] *See, e .g.,* the Rehabilitation Act of 1973, Pub. L. 93–112, 87 Stat 355 (Sept. 26, 1973) (codified as amended, in pertinent part, at 29 U.S.C. 794), the Americans with Disabilities Act of 1990, Pub. L. 101–336, 104 Stat. 327 (July 26, 1990) (codified as amended at 42 U.S.C. 12101–12213), and the Individuals with Disabilities Education Act (IDEA), Pub. L. 108–446, 118 Stat 2647 (Dec. 3, 2004).

[705] *See* INA section 101(a)(27)(C), 8 U.S.C. 101(a)(27)(C).

[706] For example, special immigrant religious workers under INA section 101(a)(27)(C), 8 U.S.C. 1101(a)(27)(C) qualify for adjustment of status under INA section 245(a), notwithstanding certain bars under INA section 245(c).

[707] Note that that individuals ''located outside sovereign United States territory at the time their alleged RFRA claim arose'' are not ''person[s]'' within the meaning of RFRA. *Rasul* v. *Myers,* 512 F.3d 644, 672 (DC Cir.), *cert. granted, judgment vacated on other grounds,* 555 U.S. 1083 (2008).

[708] *See* 8 CFR 204.5(m)(7)(vi), (vii), and (xii).

[709] *See* 8 CFR 204.5(m)(10).

[710] *See* 8 CFR 204.5(m)(7)(xii).

employment in a lawful industry with income that is sufficient to avoid being more likely than not to become a public charge. In the context of a special immigrant religious worker, the relevant is question is whether the alien's skills are suitable for the alien's intended occupation. DHS will not assume that the religious worker will be likely to receive a public benefit because of the nature of the employment or lack of income at the indicated threshold. Instead, DHS would consider provisions for housing, food, and medical care provided by the religious institution as available resources.

Further, this rule is not intended to negatively impact special immigrant religious workers or communities in which such workers would reside. Rather, this rule is aimed at better ensuring that those seeking admission to the United States are self-sufficient and rely on their own resources and the resources of their sponsors and private organizations.

2. Language Proficiency

Comment: A commenter said that it should be unlawful to preclude individuals from immigrating to the United States because of a language barrier and that the new definition of public charge, in general, benefits the wealthy, putting them above hardworking families that actually help the country's economy. One commenter said the United States has no official language, so there should be no language requirement. Many commenters stated that requiring English proficiency would mark a fundamental change from the nation's historic commitment to welcoming and integrating immigrants. A couple of commenters stated that the rule acknowledges the centrality of English language skills to economic self-sufficiency, but individuals commonly improve their English skills through participation in education programs and rely on Medicaid or other public benefits to enable them to succeed in their English language classes. A commenter indicated that the expanded negative weights for English language proficiency and educational/skills attainment conflict with longstanding policy and principles that support upward mobility and self-sufficiency.

Some commenters indicated that individuals who rely on Medicaid or other public benefits to enable them to succeed in their English language classes could be discouraged from continuing their education and improving their employability by fear of being found a public charge. Some commenters cited research showing a strong connection between better basic skills and higher earnings, which means that as an immigrant improves their reading, math, and spoken English skills, they will be better able to contribute economically to American society. Stating that data demonstrates that the use of cash benefits by immigrant populations that are not English-proficient is so low as to be within the study's margin of error, a commenter reasoned that many immigrants with limited English proficiency (LEP) are taxpaying business owners, or work in white collar or blue-collar jobs. The commenter further noted that although lack of English-speaking skills may be a hindrance to obtaining certain employment, proficiency in a foreign language may bolster an immigrant's ability to obtain other employment. One commenter suggested investing in English language learning programs instead of ''punishing'' immigrants for lack of English language proficiency. Another commenter reasoned that the ability to immigrate lawfully increases opportunities and ability to improve English and by limiting access to legal immigration, the rule would perpetuate an underclass of immigrants who continue to be prohibited from service that could improve their lives, including their English.

Response: DHS disagrees with the commenters' suggestions to remove English language proficiency as a consideration in the public charge inadmissibility determination. DHS is not mandating English proficiency for admissibility. DHS recognizes that individuals who lack English proficiency may already participate in the workforce or may be able to obtain employment. However, as discussed in the NPRM,[711] people with the lowest English speaking ability tend to have the lowest employment rate, lowest rate of full-time employment, and lowest median earnings. Further as illustrated in Table 24 in the NPRM, among the noncitizen adults who speak a language other than English at home, the participation rates for both cash and non-cash benefits are higher among those who do not speak English well, or at all, than among those who speak the language well. The margin of error of an estimate, and likewise its standard error, are affected by the number of people surveyed to construct the estimate, which in the case of a percentage or rate will include those who respond that they have the characteristic and those who respond that they do not. A relatively large standard error should not be interpreted to mean that the underlying rate being estimated is low. Findings from the SIPP tables were only discussed in the text of the NPRM if they are significant at the 95 percent confidence level.

DHS understands that aliens may improve their English skills in the future. The Form I–944 does allow a person to identify any courses or certifications in English. Furthermore, DHS is not mandating English proficiency for admissibility. Proficiency in English is one positive aspect for purposes of the education and skills factor to establish an alien's ability to obtain or maintain employment and that the alien, therefore, would be self-sufficient. Lack of English proficiency alone would not establish public charge inadmissibility, but would be one consideration in the totality of the circumstances.

Comment: One commenter stated that requiring English language proficiency could extend to all kinds of visas, which could have a negative impact on tourism.

Response: DHS reiterates that is not imposing an English proficiency requirement on nonimmigrants or immigrants—it is merely a consideration within the totality of the circumstances when determining for an immigrant applying for adjustment of status whether the alien is more likely than not to become a public charge in the United States. As previously discussed, DHS has removed the forward-looking aspect of the public benefits condition for extension of stay and change of status applications. Therefore, lack of English proficiency will not impact nonimmigrant visitors or the tourism industry. Further, nonimmigrants seeking extension of stay or change of status are not subject to the public charge ground of inadmissibility under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). Nonetheless, B nonimmigrant visitors would have to establish that they have maintained their status and that they have not received, since obtaining the nonimmigrant status that they are seeking to extend or change, any public benefits as defined in 8 CFR 212.21(b), for 12 months in the aggregate within a 36-month period.

Comment: A few commenters stated that most people who settle here permanently will develop English proficiency by the time they become citizens. These commenters reasoned that this is why is there is no English language test until an individual is being naturalized and that this method provides several years for immigrants to

[711] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51195–96 (proposed Oct. 10, 2018).

immerse themselves in the English language. Another commenter stated that Congress made English proficiency a requirement for citizenship and not the initial stage of becoming a legal permanent resident and that imposing an English proficiency requirement in this rule bypasses Congress. A commenter stated that the rule penalizes people for speaking languages other than English, an English proficiency requirement places strain on shared heritage as a source of social support and resiliency, as well as creates redundancy given that our immigration systems requirement of English fluency for citizenship. A commenter asserted that while English has long been a requirement for those seeking to become naturalized citizens of the United States, the rule would create an English language requirement for nonimmigrant visas, family-based, and employment-based visas, even when a language requirement is already a consideration, and even where it is irrelevant. A commenter stated that the proposed English-language proficiency factor would reduce family reunification.

Response: DHS is not imposing an English proficiency requirement or as a factor that is outcome determinative in the public charge determination. English proficiency is among the considerations evaluated when assessing education and skills; the alien may submit any evidence relevant to the factor.

DHS understands that certain individual's English will improve over time in the United States and that the ability to read, write and understand the English language is tested as part of naturalization proceedings. However, DHS has established, through data presented in the NPRM, that an individual's inability to speak and understand English may adversely affect an alien's employability, and may increase receipt of public benefits.[712] Therefore, DHS will consider the applicant's proficiency as one of the consideration for purposes of assessing education and skills; DHS will consider any factor applicable to the alien in the totality of the circumstances. DHS would also consider whether the alien is already employed or has education and skills that would allow the alien to obtain or maintain employment and avoid becoming a public charge.

Comment: Some commenters suggested that including English proficiency in the factor discriminates against deaf immigrants, individuals with hearing or speech disabilities, individuals who communicate through assistive devices, and immigrants with intellectual and developmental disabilities.

Response: DHS disagrees that the rule discriminates against deaf immigrants or other disabilities. DHS does not mandate English proficiency as a pre-requisite for legal immigration or as a determinative factor within the public charge inadmissibility determination. Adjudicators would not consider it a negative factor for a deaf immigrant to read and write English but not speak it. And in view of ADA requirements applicable to employers, adjudicators would give equal weight to a deaf immigrant's ability to communicate through American Sign Language. An alien's Form I–693 may also establish that a person has a hearing or speech disorder, for which DHS would provide the appropriate accommodation for any interview. Although DHS may consider any medical condition in the totality of the circumstances, the fact that an alien is deaf or hard of hearing or has hearing or speech disabilities, communicates through assistive devices, or that the alien has intellectual and developmental disabilities will not alone lead to a determination of inadmissibility based on the public charge ground.

Comment: Some commenters stated that USCIS does not have the authority to impose an official language and that there is no law that allows the Government to prefer those who speak English over those with LEP. Others stated that considering English proficiency in the public charge determination violates constitutional and statutory mandates prohibiting language-based discrimination, which the Supreme Court has interpreted as a form of national origin discrimination. One commenter stated that by discriminating based on English language proficiency the proposed rule violates laws banning national origin discrimination. Several commenters cited several Federal civil rights acts that show LEP persons are protected from discrimination on the basis of English proficiency and those acts included Title VI, the Civil Rights Act, the ACA, and more. Other commenters indicated that the INA, the U.S. Constitution's Equal Protection Clause and other authority demonstrate that individuals cannot be discriminated against on the basis of LEP.

Many commenters stated that consideration of English language proficiency would disproportionately impact women with LEP, citing to studies indicating that women with LEP are less likely to participate in the labor force than men and more than twice as likely to work in low-wage service occupations as women with English proficiency, and older immigrants with LEP. Another commenter stated that the proposed rule will cause additional harm to trafficking survivors who have yet to gain proficiency in English because they have newly entered the United States or have been intentionally barred from learning English or accessing education by their traffickers. Another commenter said that DHS's analysis fails to account for the fact that many immigrants reside in multigenerational households where the English-speaking capacity of younger generations serves to benefit older generations that do not speak English as readily. The commenter also noted that the vast majority of immigrants to the United States have not been English-speaking and this has not prevented immigrants from becoming contributing members of their communities. Some commenters addressed the adverse impact of the rule on immigrants of Asian descent because nearly three out of four speak languages other than English at home and 35 percent have limited English proficiency. Other commenters stated that this requirement favors immigrants from wealthier, European countries and potentially disfavor immigrants from Latin America, Africa, Asia, the Caribbean, Asia, South America and more.

Response: DHS disagrees that the rule imposes a language requirement or impedes LEP individuals from entering the United States. DHS is not imposing an English proficiency requirement for admission to the United States, but solely uses English proficiency as one consideration among others when assessing an alien's education and skills. Additionally, DHS disagrees that considering an alien's proficiency in the English language as a consideration impermissibly discriminates on the basis of national origin or otherwise violates the Equal Protection Clause. Courts have applied rational basis scrutiny to immigration regulations applicable to aliens,[713] and there is a

[712] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51190–97 (proposed Oct. 10, 2018).

[713] *Korab* v. *Fink,* 797 F.3d 572, 577–79 (9th Cir. 2014) (''[F]ederal statutes regulating alien classifications are subject to the easier-to-satisfy rational-basis review . . . Although aliens are protected by the Due Process and Equal Protection Clauses, this protection does not prevent Congress from creating legitimate distinctions either between citizens and aliens or among categories of aliens and allocating benefits on that basis . . . The difference between state and federal distinctions based on alienage is the difference between the limits that the Fourteenth Amendment places on discrimination by states and the power the Constitution grants to the federal government over immigration.'') (citation omitted); *Lewis* v.

Continued

rational and non-discriminatory basis for consideration of English proficiency as an element of the education and skills factor. As explained in the NPRM, consideration of English proficiency in determining whether an applicant is likely to become a public charge is based on the fact that an inability to speak and understand English may adversely affect whether an alien can obtain employment,[714] which is consistent with the Census Bureau study cited in the NPRM.[715] During the drafting of this final rule, DHS also considered the Social Security Administration analysis published in that agency's notice of proposed rulemaking that showed high levels of labor market participation among individuals with LEP, and an increase in LEP labor market participants over time.[716] Upon considering this information, DHS believes, however, that while individuals with LEP may be working in the United States, the jobs these individuals may be holding low skilled jobs which are typically available at lower pay. Because the purpose of this rule is to ensure that aliens are self-sufficient, such lower paying jobs may not denote the same level of self-sufficiency as jobs that may be held by an individual who are able to effectively communicate in English and who may be employed in a higher skilled, higher paying job. Therefore, DHS has retained the consideration of English proficiency.

The consideration of English proficiency is thus based on the factually neutral likelihood of someone obtaining sufficient employment to avoid becoming a public charge and not on a discriminatory motive. The alien is not precluded from bringing forth any other consideration, which will be considered under the circumstances of the particular alien.

Comment: A commenter stated the agency should indicate how it would test English language proficiency, as developing a test similar to the citizenship test would be costly in terms of development, training for immigration officers, and the time it takes to conduct the test at each individual interview. A few commenters said the rule has no fair or narrowly tailored process for assessing language ability, which will result in arbitrary decisions and will lead to abuse of discretion and discriminatory conduct. The commenters also stated that the proposed rule does not explain how DHS will make this determination and does not explain what level of English language proficiency is needed, how individuals can demonstrate that ability, or how staff will verify the appropriate level. A few commenters stated that, if English proficiency is to be considered, there needs to be a clear definition for what that means and how it will be determined and not left to the USCIS' opinion or sole determination. Another commenter expressed similar concerns over how the English proficiency requirement would be measured, remarking that the NPRM does not indicate what tests might be employed, whether they would be standardized, what questions might be asked so that a test is administered uniformly, whether an adjudicator would perform the test, whether there would be exceptions or accommodations available, whether the test would be in writing or administered orally, and how an officer would evaluate an applicant's proficiency in other languages.

Response: DHS disagrees with some commenters' assessment that the current content of the NPRM and the related documents provided as part of the proposed rulemaking insufficiently outlines the considerations that DHS will be employing to assessing the alien's education and skills. Evidentiary requirements for purposes of the public charge determination are outlined in the rule and in Form I–944, which includes questions on education and language skills. In general, certifications in a language or other evidence demonstrating an alien's education in the English and any other languages, for example, may demonstrate that the alien has attained some proficiency in the English language or another language. DHS is not requiring an English proficiency written test or provide a reading or writing test. Instead, DHS would review the documentation of English proficiency such as certifications or an alien's transcript for a course of study that was primarily in English (such as a native speaker's secondary school transcript). In addition, USCIS may confirm an alien's speaking and understanding of the English language through the question and answer process of the I–485 form during the adjustment of status interview.

Comment: A commenter stated that English proficiency is not required for employment in the United States and cited employment statistics that indicate there is demand for a workforce that is not necessarily proficient in English. Other commenters asserted that the proposed rule fails to consider that immigrants may travel and secure employment in other areas where multiple languages are spoken alongside English. Similarly, other commenters indicated that this rule assumes that non-English speakers cannot perform jobs where English is not required, citing agriculture as an example and claiming the H–2A visa program itself does not require English to work temporarily in agriculture. Many commenters indicated that this rule would improperly reject many people with practical job skills doing essential work in our economy that have limited formal education and English proficiency and highlighted farmworkers as an example.

Response: DHS understands that English proficiency is not be required to be employed in the United States. DHS is not requiring or mandating English proficiency as a requisite to immigrating to the United States. English proficiency is a consideration in the assessment whether the alien possesses education and skills sufficient to maintain or obtain employment as to not likely to become a public charge. As explained in the NPRM,[717] data on the relationship between the level of English proficiency and employment as well as public benefits participation highlights that proficiency in the English language is a

Thompson, 252 F.3d 567, 570 (2d Cir 2001) (citing *Lake* v. *Reno,* 226 F.3d 141, 148 (2d Cir. 2000) (''We have recently recognized that a 'highly deferential' standard is appropriate in matters of immigration . . . .'')).

[714] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51195 (proposed Oct. 10, 2018).

[715] *See* Jennifer Cheeseman Day and Hyon B. Shin, U.S. Census Bureau, *How Does Ability to Speak English Affect Earnings?* 2 (2005), *available at https://www.census.gov/hhes/socdemo/language/data/acs/PAA_2005_AbilityandEarnings.pdf* (last visited July 26, 2019).

[716] Removing Inability To Communicate in English as an Education Category, Proposed Rule, 84 FR 1006, 1008 (Feb. 1, 2009). (''In absolute numbers, the working age population (ages 25–64) with LEP increased from approximately 5.4 to 17.8 million between 1980 and 2016, while more than doubling, from 5.1% to 10.5%, as a percentage of the population. Within this group, the number of individuals who spoke no English more than quadrupled from approximately 682,000 to 2.8 million (representing growth from 0.6% to 1.7%, as a percentage of the working age population). Between 1980 and 2016, the number of non-English speaking workers in the 25–64 age range grew from approximately 373,000 to 1.7 million. During the same period, the labor force participation rate for working age individuals who speak no English increased from approximately 54.7% to 61.5%.41. Notably, considering the working age population with ''less than high school diploma,'' the 2016 labor force participation rate for those speaking no English (60.5%) surpassed the labor force participation rate of those speaking ''only English'' (48.9%). In 1980, the reverse was true; working age individuals with less than a high school diploma speaking only English had a 60.7% labor force participation rate that exceeded the 54.5% rate for those speaking no English. The increase in labor force participation by individuals who lack English proficiency may be in part due to the increase in low-skilled work in the national economy.'' (internal citations omitted)).

[717] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51195 (proposed Oct. 10, 2018).

relevant consideration. DHS will consider all circumstances of the alien's case and all factors in the totality of the circumstances; therefore, no single factor is outcome determinative in this assessment, including the lack or the existence of English proficiency. In individual circumstances, DHS would also consider the alien's employment as a positive factor despite lack of proficiency in English.

Comment: Many commenters addressed the 2014 SIPP data about the use of benefits by populations at various levels of English language ability cited by DHS. A commenter asserted that DHS failed to provide any causal linkage between the data cited and its conclusions. A commenter stated that the survey relied upon cross-sectional studies that capture information from a given point in time and that DHS does not cite longitudinal studies that follow the same population and capture relevant information over time. The commenter said DHS cannot predict whether an individual non-citizen is likely to become a public charge in the future based on such studies. One commenter cited information showing that while children of newly-immigrated families speak a non-English language at home, English language learning children are amongst the most successful students at school in the United States, especially once they become fully proficient in English. The commenter stated that this information contradicts studies cited by DHS.

Response: DHS discusses English proficiency as an indicator of potential public benefits receipt, which does not rely on an assumption that the relationship is cause-and-effect. The cross-sectional analysis showed that not being proficient in English is an indicator of public benefit receipt in the near term, which is considered in the public charge determination. The DHS analysis shows a relationship between public benefit receipt and English proficiency among adults age 18 and over, and does not describe outcomes for the population of English language learning children, so the results of the studies do not appear contradictory.

Comment: Multiple commenters stated that DHS failed to consider alternative reasons that people who are LEP may be more likely to access benefits, adding that that states that have high numbers of LEP populations, such as New York and California, also have high income thresholds for Medicaid. The commenters concluded by stating that three out of the four studies DHS cited used data derived from Europe, while the fourth relies on Current Population Survey data nearly 30 years old, which is insufficient to support DHS's proposed change.

Response: DHS analysis showed that lack of English proficiency was a factor that affected the likelihood of receiving welfare. DHS does not dispute that likelihood of public benefits receipt may also be affected by the state of residency. DHS's findings were not interpreted to suggest that lack of English proficiency necessarily led to welfare receipt, or that there was any causal relationship between the two. As such, complex inter-relationships such as the one mentioned were not investigated. The studies provided by DHS regarding English proficiency included SIPP data representing U.S. noncitizens in 2013,[718] as well as a study using data from the 2000 Census.[719] One report that was referenced was international in its scope, and included a discussion of different European countries, as well as the United States.[720]

Comment: A few commenters stated multilingualism should be considered an asset. Another commenter indicated that DHS based its consideration of English proficiency or additional languages on the assumption that English skills are required to enter the U.S. job market. According to the commenter, however, the large number of Spanish speaking workers in the construction industry undermined the premise that English skills are required to enter the U.S. job market. The commenter acknowledged that DHS would consider other languages depending on their market value, but that the rule was silent on considerations guiding this determination, such as the market value assessment for Spanish skills. Therefore, the commenter suggested that the rule should explicitly indicate that Spanish skills have a high market value, at least in the construction industry.

Response: DHS will consider the ability to speak other languages in addition to English as part of the totality of the circumstances when evaluating all of the relevant skills that apply to an alien's employability, education and skills. The ability to speak a language or language proficiency may have differing impacts depending on the nature of the work and the employer, and is best considered individually in the context of each alien's application in the totality of the circumstances. DHS recognizes that certain professions or employment require that an alien speak another language in addition to English. However, the public charge assessment is geared toward becoming a public charge in the United States; the data presented in the NPRM[721] clearly demonstrated a connection between the inability to speak and understand English in relation to employment, public benefit receipt, and financial status. Therefore, DHS retained the English proficiency provision. However, nothing in the regulation precludes an alien from presenting evidence and consideration relating to education or skills other than the considerations mentioned in the regulation; all considerations will be evaluated based on the totality of the circumstances.[722]

3. Skills

Comment: A commenter indicated that the expanded negative weights for educational/skills attainment conflict with longstanding policy and principles that support upward mobility and self-sufficiency. Another commenter indicated that DHS failed to describe how DHS will consider, among other things, the education and skills requirement. The commenter stated that the rule could prejudice the many foreign-born workers in the construction worker industry, who have little formal education but skills that are in high demand and that these workers earn a good wage. The commenter suggested that DHS should change the requirement that it considers ''no high school diploma or other education or skills'' as a negative factor in the public charge analysis, and that DHS should instead consider education only as a positive factor. The commenter suggested that in the alternative, the lack of education should only be considered a negative factor when coupled with unemployment. The commenter stated that DHS fails to

[718] *See* Table 24, Inadmissibility on Public Charge Grounds, 83 FR 51114, 51196 (proposed Oct. 10, 2018).

[719] *See* Jennifer Cheeseman Day and Hyon B. Shin, U.S. Census Bureau, How Does Ability to Speak English Affect Earnings? 6 (2005), available at *https://www.census.gov/hhes/socdemo/language/data/acs/PAA_2005_AbilityandEarnings.pdf* (last visited July 26, 2019).

[720] Barry R. Chiswick & Paul W. Miller, Immigrant Earnings: Language Skills, Linguistic Concentrations and the Business Cycle, 15 J. Population Econ., 31, 31–57 (2002); Christian Dustmann, Fluency, Writing Fluency, and Earnings of Migrants, 7 J. Population Econ., 133, 133–156 (1994); Ingo E. Isphording, IZA Discussion Paper No. 7360, Disadvantages of Linguistic Origin: Evidence from Immigrant Literacy Scores (2013), available at *http://ftp.iza.org/dp7360.pdf* (last visited July 26, 2019); Org. for Econ. Cooperation & Dev./European Union, Indicators of Immigrant Integration 2015: Settling In (2015), available at *http://www.oecd.org/els/mig/Indicators-of-Immigrant-Integration-2015.pdf* (last visited July 26, 2019).

[721] *See* 83 FR 51114, 51195–97.

[722] *See* 8 CFR 212.22(a) and 8 CFR 212.22(b)(5).

define ''skills'' and expressed concern that the skills that workers have may be difficult to demonstrate as an evidentiary matter and that this could cause DHS adjudicators to improperly discount skills that often take many years to develop. Along with providing certain data noting that a significant percentage of both foreign-born (over 90 percent) and native-born workers (over 85 percent) in the construction industry do not have a four-year college degree, the commenter pointed out that, for example, a brick layer may be highly skilled but lacks a way of demonstrating a formal certification. The commenter requested that the final rule explicitly indicate that Spanish language skills have a high market value, at least for those in the construction industry. The commenter also suggested that Form I–944 be amended to clarify that DHS will consider experience-based construction skills in the analysis, as the form as currently drafted largely focuses on the certification.

Another commenter suggested that DHS amend its consideration of education and skills as a prerequisite to legal immigration because the legal immigrants that are entering the direct care workforce are entering a career pathway to a successful lifelong career. The commenter stated that although many such immigrants have increasing levels of responsibility, the workforce is not highly skilled. The commenter reasoned that preventing some of the most eligible individuals from entering the United States prevents them from addressing the direct care workforce deficit, which will negatively impact people with disabilities and the elderly in the United States, which rely on this workforce to maintain their well-being and quality of life.

A couple of commenters stated that although agricultural work is considered unskilled labor under some technical definitions, it is in fact a skilled occupation requiring years of experience to gain the necessary knowledge, precision, exercise of judgment, endurance, and speed that many of these workers already have and which contribute to their employer's profitability. The commenters concluded by arguing that that the proposed rule would improperly reject the value of many farmworkers' contributions to our economy and society. Similarly, a commenter expressed their concern that the ''skills'' component of the education and skills factor is undervalued by the proposed rule. The commenter stated that this narrow view of skilled work will have a particularly harmful impact on immigrants who staff many vital occupations, such as healthcare support and personal care, for which certification procedures do not exist, but on which many in the United States may depend.

Response: Education and skills are mandatory statutory factors as established by Congress under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). DHS disagrees that it did not sufficiently outline the consideration of the factors in the NPRM.[723] DHS appreciates the suggestions from commenters, including the suggestions relating to the construction industry. However, DHS will not remove the lack of a high school diploma or other education or skills provisions from the rule as a negative factor in the public charge analysis. Further, DHS will consider both the positive and negative factors associated with education and skills, as described in the NPRM. As evidenced by the commenters addressing various industries, each industry and area of employment may be different. The DHS proposed rule is flexible enough to account for all factors and circumstances in any particular industry and an individual's case so that each alien may set forth the considerations applicable to him or her demonstrating why the individual is not likely to become a public charge.

As discussed in the NPRM, education has been found to have a significant impact on public benefit usage. As it is possible for an alien to be employed and still be a public charge, the mere fact of employment cannot categorically remove education from an analysis of the totality of the circumstance because education is a statutorily mandated factor. Although education would certainly weigh positively, the exact nature of the education (or lack thereof) and employment would have to be considered. The level and quality of the education attained by a prospective immigrant can help estimate how likely they are to become a public charge. Therefore, while not having high school diploma or other education or skills are generally a negative factor, the lack of a high school diploma, for example, may be overcome by skills or other positive circumstances.

DHS agrees that skills gained as part of employment are positive even when certifications are not available. Regardless of occupation, an alien may demonstrate that he or she has skills through employment that are positive factors. This showing will not be focused on construction, but generally, be applicable to all job skills. Overall, education and skills will be considered as part of the totality of the circumstances. DHS is not mandating any particular level of education or skill to overcome a public charge inadmissibility determination.

Comment: One commenter stated that using both DOL, which already has education and skills criteria for immigrants entering the country to work, and DHS to evaluate labor needs and skills was redundant, unnecessary, and a waste of public funds.

Response: DHS disagrees that the rule conflicts with DOL's evaluation of labor needs and skills. Under this rule, DHS will be considering whether an alien possesses education and skills that would contribute to the alien being employable in the United States and thus able to be self-sufficient. This determination does not entail determining whether an alien meets an employer's minimum job requirements for a particular position or qualifies for employment in a particular occupational classification. In addition, even if an alien is found to not possess any education or skills but instead has sufficient financial means to support himself or herself and any dependents, DHS may determine in the totality of the circumstances that the alien is not likely to become a public charge. In contrast, DOL has a statutory mandate to certify before an alien may be admitted in certain employment-based immigrant classifications that there are no able, willing, qualified, and available U.S. workers to perform the job for which an employer seeks to hire the alien, and that the alien's employment will not have an adverse effect on the wages and working conditions of similarly employed U.S. workers. In doing so, DOL examines whether the alien's education, skills, and job qualifications meet the employers' stated minimum job requirements. Therefore, the two departments fulfill two different responsibilities in the immigration process.[724]

Comment: A commenter asserted that DHS does not have the ability to adequately evaluate occupational skills, certifications, or licenses, and many occupations do not require them. The commenter stated that this requirement would cause a great burden on employers and agencies who must comply with these new requests.

Response: DHS will evaluate all occupational skills, certifications, licenses, and any other evidence that

[723] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51189–51196 (proposed Oct. 10, 2018).

[724] *See* INA section 212(a)(5)(A), 8 U.S.C. 1182(a)(5)(A), 20 CFR and 656.1 (DOL's labor certification requirements for immigrant workers).

establishes a skill in an occupation, as presented by the alien. The alien has the burden to establish that he or she qualifies for the immigration benefit and is not inadmissible.[725] Generally, forms and their instructions outline, in detail, the necessary evidence to apply for a benefit; similarly Form I–944 and its instructions outline possible evidence that an alien can submit to establish that he or she has the requisite education or skills as to be able to maintain or obtain employment. If USCIS believes that the alien has not submitted sufficient evidence to establish that he or she is not likely to become a public charge, where applicable, it may issue a RFE or a NOID to obtain clarification.[726]

4. Employment

Comment: A commenter indicated that because immigrants who are in the United States without work authorization are not able to work legally, it will be impossible for many immigrants to demonstrate their past employment history. The commenter stated that the proposed rule will therefore place immigrants in an impossible situation: if they comply with the law that prohibits them from working without having first obtained employment authorization, they will forfeit the ability to obtain legal status because they will be unable to show current employment or a recent history of employment. Another commenter stated that DHS cannot accurately assess an individual's likelihood of becoming a public charge if DHS does not first grant work authorization to such an individual.

Other commenters stated that certain visas, such as the K–1 fiancé visa, do not permit a grantee to work. Another commenter stated that the use of an employability factor in a public charge determination would put many immigrants in a catch-22 where their options would be to either work illegally and be denied citizenship or not work and be denied immigration status due to lack of employment. Another commenter suggested that an applicant should be given time to enter the country and work before being subject to the public charge test.

Response: As discussed in the NPRM, DHS recognizes that not everyone subject to this rule is authorized to work in the United States. Although an applicant may not be authorized for employment in the United States at the time of filing the adjustment of status application, he or she may have employment history in a foreign country, or volunteer work experience in the United States, that will be considered as part of the totality of the alien's circumstances.

However, DHS notes that it would consider any employment history outside the United States as part of the public charge inadmissibility determination. Moreover, USCIS would also review the likelihood that the alien will work upon filing for or being granted adjustment of status, *i.e.,* when authorized to work. In addition, USCIS would consider whether the alien may have sufficient assets and resources, including a pension or a household member's assets and resources, which may overcome any negative factor related to lack of employment. The assets and resources would include those of the household, which may include a sponsor when the sponsor is part of the household.

DHS will not, however, include provisions in this rule to provide aliens subject to this rule time to enter the country and work before being subject to the public charge inadmissibility determination. As noted previously, the public charge ground of inadmissibility applies at the time of the alien's application for a visa, admission, or adjustment of status.

Comment: Some commenters provided input on how the employment history requirements impacts domestic violence survivors. These commenters indicated that DHS disregards the reality of many crime survivors who are faced with losing their jobs due to intense trauma, reduced productivity, harassment at work by perpetrators, and other reasons stemming from violence. One commenter stated that secure immigration status can help survivors of abuse access employment opportunities, escape violent relationships, and help alleviate the trauma they have suffered. This commenter stated that the proposed rule is actually setting up barriers to employment for survivors, which is also a barrier to self-sufficiency. Other commenters stated that several studies have documented how domestic violence perpetrators deliberately try to sabotage their victims' efforts to obtain and keep paid employment; that domestic violence survivors are forced to become dependent on their abusive partners' incomes; or that some survivors have had their work permits or lawful permanent residence cards taken by their abusers, making it impossible to show that they had legal authorization to work and had to, at times, pay filing fees to get their replacement documents. One commenter stated that half of women who experienced sexual assault had to quit or were forced to leave their job within the first year and stated that by heavily weighting the lack of employment, the proposed rule doubly penalizes a victim for the economic effects that domestic violence and sexual assault abusers perpetrate.

Response: DHS appreciates the commenters' input. As explained in the NPRM, USCIS will assess the alien's education and skills with the focus whether the alien has adequate education and skills to either obtain or maintain employment sufficient to avoid becoming a public charge.[727] As part of the assessment, USCIS will consider the totality of the alien's circumstances, including any and all factors and considerations set forth by the alien. Furthermore, T and U nonimmigrants, VAWA self-petitioners, and others listed in 8 CFR 212.23, are generally exempt from inadmissibility on account of public charge and therefore, they are not likely impacted by this regulation.

Comment: One commenter stated requiring employment history would be problematic for many international students attending American universities, arguing that that foreign nationals on student visas are generally not permitted to work while engaging in studies on the F–1 visa. This commenter stated that nearly one-quarter (20 out of 91) of the billion-dollar startup companies had a founder who first came to the United States as an international student, and stated that holding student loan and credit card debt against the students could have a negative impact. The commenter stated that, under the proposed rule, these individuals would be subject to the public charge test even as nonimmigrants when seeking to change status from that of a student to that of an employee on an employment-based visa.

Response: DHS does not require that the alien have an employment history as part of the public charge determination. As discussed above, DHS has removed the forward-looking determination for nonimmigrant applicants for extension of stay or change or status. Therefore, DHS would not be reviewing the factors for nonimmigrants applicant for extension of stay or change of status, such as students. Further, the NPRM indicates that for purposes of the assessment of employment and skills, USCIS' considerations include, but are not limited to the alien's employment history.[728] In general, students acquire skills as part of their studies; also, USCIS would not consider it to be a

[725] *See* INA section 291, 8 U.S.C. 1361.

[726] *See generally* 8 CFR 103.2.

[727] *See* 8 CFR 212.22(b)(5).

[728] *See* 8 CFR 212.22(b)(5).

heavily weighted negative factor if a student, applying for adjustment of status for a valid basis, is not working because she or he lacks employment authorization. For these reasons, DHS does not believe that students in universities in the United States will be adversely impacted by DHS's consideration of the education and skills factor, as set forth in this rule.

Comment: A commenter stated that pregnant women may be forced to leave the work force and stay home to deal with medical complications of a pregnancy or to care for a child during the first months, due to reasons such as the high cost of out-of-home daycare, and that therefore, they will be less likely to show employment history. A few commenters stated that consideration of employment history would unfairly discriminate against women, particularly those who stay home and care for their children. Another commenter stated that often the work of a caregiver, such as a stay-at-home parent or grandparent, is vitally important for the emotional and financial well-being of a family. One commenter remarked that the rule unfairly penalizes individuals who may have additional caregiving responsibilities due to a child's special needs, inability to afford child-care, or even religious beliefs.

Response: As indicated throughout this rulemaking, DHS will assess the likelihood of becoming a public charge based on the totality of the circumstances of the individual's case. While there are certain temporary medical conditions or other conditions that may require an individual to interrupt a certain employment activity or have a temporary absence, one can hardly regard such incidents as negating an individual's employment history, or his or her education or skills generally. Additionally, the applicant may bring forward evidence to establish that he or she has adequate education and skills to either obtain or maintain employment to avoid becoming a public charge.

DHS acknowledges that an MPI paper observed that women could encounter difficulty with the totality of circumstances analysis, because women comprised 70 percent of the over 43 percent of recent green card holders who were neither employed nor in school. MPI added that many immigrant women do not work because of child care responsibilities and child care costs.[729] In instances such as this where a mother is not currently employed and is raising children, DHS would not exclusively focus on the mother's lack of current employment. DHS would also take into full account other factors that could be favorable to the mother and could outweigh her current unemployment: her household's income, assets, and resources; an affidavit of support and relationship to her sponsor, if applicable; and her reasonable prospects to obtain and maintain lawful employment based on her age, education, skills, and any previous work history. This same level of consideration would also apply to other similarly situated parents, guardians, and caregivers who are currently unemployed or who are employed part-time.

Consistent with the above, and following consideration of these and other comments about contributions of caregivers, DHS is adding under the Education and Skills factor an additional positive consideration, namely whether the alien is a primary caregiver of another person in the alien's household. This will be taken into consideration in the totality of the circumstances, and is intended to account for difficult-to-monetize contributions by aliens who may lack current full time employment or recent employment history due to their unpaid engagement in the household. As with all other considerations, the consideration of whether an alien is a primary caregiver would not alone establish that an alien is not likely at any time in the future to become a public charge. Rather, DHS would not consider it a negative factor if an alien of a working age who would normally be employable lacks full time employment, or a recent employment history. This consideration could cover a range of circumstances, including, for example, a parent who stays at home to care for a newborn child, or an adult child who stays at home to care for an elderly parent. DHS has limited this consideration so that only one alien within the household can be considered the primary caregiver of the same person in his or her household. Because some commenters responding to various aspects of the totality of the circumstances analysis raised concerns about ''double counting'' negative factors, DHS notes that it will only take the primary caregiver role into consideration if relevant, *i.e.,* DHS will not use this consideration to negatively compound the absence of full time employment or recent employment history if the alien is *not* a primary caregiver. As indicated above, DHS has also added a definition of ''primary caregiver'' under 8 CFR 212.21(f) to correspond to this provision; primary caregiver means an alien who is 18 years of age or older and has significant responsibility for actively caring for and managing the well-being of a child or an elderly, ill, or disabled person in the alien's household.

Comment: Multiple commenters wrote that the rule misunderstands the nature of low-wage work, indicating that there are not simply ''people who work'' and ''people who receive benefits,'' rather there is an overlap between the two groups.

Response: DHS understands that there is an overlap between ''people who work'' and ''people who receive benefits.'' People who are employed but nonetheless receive public benefits may not be self-sufficient. However, the fact that an alien who is subject to a public charge inadmissibility determination has in the past received public benefits is not outcome determinative. Whether an alien is inadmissible because he or she is likely at any time in the future to become a public charge depends on a review of a range of factors, including work history, in the totality of the circumstances.

N. Affidavit of Support

Comment: Several commenters stated that the affidavit of support is sufficient to satisfy the standard because the sponsor agrees to provide the necessary financial support or to reimburse providing agencies. One commenter stated that the Form I–864 already provides a method for objective public charge analysis. Many commenters stated that Form I–864 creates a legally binding contractual agreement between the petitioner/sponsor and the government that the intending immigrant will not receive public benefits. Some of the commenters indicated that relegating the Form I–864 to a mere factor and proposing to replace it with a bond eliminates the true potential of the Form I–864: to deter new immigrants from applying for government assistance. The commenters stated that in lieu of the Form I–864, the government now proposes to increase the use of public charge bonds and the bond amount to levels that most immigrants will not be able to pay, and involves a third party private bond company. One commenter stated that the proposed heavily weighted factors do not achieve the stated goals of the rule; the commenter indicated that the agency has not stated a sufficient reason

[729] *See* Capps, Randy et al, ''Gauging the Impact of DHS' Proposed Public-Charge Rule on U.S. Immigration,'' Migration Policy Institute. (November 2018). Available at: *https://www.migrationpolicy.org/research/impact-dhs-public-charge-rule-immigration* (last visited July 26, 2019).

why the existence of a binding contract from a financially-capable sponsor, such as the affidavit of support that used to be sufficient for public charge purposes would not satisfy the standard for purposes of public charge, and others stated that this is especially the case, when the question addressed with the affidavit of support is whether an immigrant is likely to become a public charge. Another commenter stated that the affidavit of support, by statutory definition, requires the immigrant to demonstrate financial support to ensure that he or she is not a public charge, but the rulemaking arbitrarily relegates the affidavit of support to a non-substantial factor. The commenter disagreed that the affidavit of support should just be one factor and stated that the proposed rule allows for the possibility of a heavily weighted factor to outweigh the contractual showing of the sponsorship, as outlined by Congress. The commenter also stated that without according the affidavit of support any weight, the NPRM effectively eviscerated the affidavit of support process and goes against congressional intent to establish clear guidelines and a meaningful measure of likelihood of becoming a public charge.

Two commenters stated this proposed regulation diminishes the consideration of a sufficient affidavit of support in the determination of likely to become a public charge, and drastically diminishes the sponsor's role as they exist within the current standards. One commenter said the affidavit of support requirement can be hard to meet for some potential adjustment of status applicants. The commenter said if the petitioner's income and assets are not adequate, it can be difficult to find another person (a ''joint sponsor'') who is willing to hand over their sensitive identification and financial documents and sign a binding contract to ensure the intending immigrant will not depend on public benefits.

A few commenters indicated that the current system already places a high burden on petitioners and immigrants, and that the affidavit of support system has done a good job in making sure that immigrants will not become public charges after entry. One commenter said the demotion of the affidavit of support is another way that the re-framed totality of circumstances would allow only those already with resources to enter or remain in this county. Similarly, commenters stated this rule would make it harder for low-income immigrants to get their green card or visa, and tilt away from family-based immigration to a wealth-based system that would be both deeply unethical and entirely inconsistent with laws and policies in the United States.

Another commenter stated that the focus should remain on the sponsor and their ability to maintain the intending immigrant at 125 percent of the FPG, asserting that DHS should only consider the other heavily weighted factors in ''unusual cases.'' Another commenter stated that the proposed rule shifts the focus of an applicant's eligibility away from an applicant's sponsor and onto the applicant.

Response: DHS rejects the assertion that the rule shifts the emphasis away from the affidavit of support, as the statute does not require or even permit DHS to focus the public charge inadmissibility determination solely on the affidavit of support. In fact, the minimum mandatory factors that must be considered as part of the public charge inadmissibility determination under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), do not include the affidavit of support. Rather, Congress added that any affidavit of support under section 213A of the Act, 8 U.S.C. 1183a, may be considered in the public charge inadmissibility determination.[730] An affidavit of support is required for most family-sponsored immigrant applicants and certain employment-sponsored immigrant applicants, and the absence of a sufficient affidavit of support will result in an inadmissibility finding.[731] Because the lack of a sufficient affidavit of support, when required, automatically results in a finding of public charge inadmissibility, it would be inconsistent with the statute to place an emphasis on the affidavit of support in the public charge determination. Under this rule, DHS will give positive weight to a sufficient affidavit of support, but it would not, and cannot under the statute, be outcome determinative.

Comment: Another commenter asserted that the proposed rule does not provide any standards for evaluating factors or the likelihood that the sponsor would actually provide the required financial support to the alien, and that such vagueness invites officers to make decisions on the basis of their personal assumptions and biases, which will almost certainly result in inconsistent application of the standards. Another commenter also stated that DHS's justification for independently considering the sponsor's income and resources, relationship to the applicant and the likelihood of supporting the applicant, or any other related considerations, is inadequate as it fails to provide a standard for evaluating these standards, and will lead to inconsistent decisions that are also based on officer's assumptions and biases and exceeds the statutory wording in regard to affidavits of support. Additionally, referring to a 1998 DOS cable on the sufficiency of affidavits of support, the commenter indicated that the proposed provision upends, without justification, prior practice that instructed that the intent of the sponsor and the verification of the sources is not a consideration once a sufficient affidavit of support has been presented. The commenter furthermore indicated that DHS justification and evidence—referring to reports that are nine and sixteen years old—does not support the agency's position. Another commenter stated that the proposed rule creates opportunities for arbitrary decision-making when assessing one's family status or financial status, because the rule tasks the adjudicator with assessing the closeness of the sponsor-alien relationship and with the assumption that a close family member ''would be more likely to financially support the alien if necessary.'' The commenter indicated, however, that the closeness of a relationship is a subjective determination and not necessarily based on the existence of a blood relationship but rather on personal connections and history that an outside adjudicator would find difficult to comprehend. Similarly, another commenter provided that evaluating the relationship between a sponsor and an applicant may be particularly prejudicial if the agency fails to account for cultural differences in family dynamics. A commenter stated that, once an affidavit of support is determined to be legally sufficient, DHS should not substitute its agents' judgment for that of Congress by requiring a different income threshold or encouraging them to speculate about a sponsor's relationship to an applicant.

Another commenter said the guidance in the FAM, which explains that a joint sponsor ''can be a friend or a non-relative who does not reside in and is not necessarily financially connected with the sponsor's household'' was consistent with the statutory language at section 213A of the Act, 8 U.S.C. 1183a that defined the requirements of a ''sponsor'' but does not include a requirement that a joint sponsor have a familial relationship to the immigrant.

Response: DHS does not believe that the proposed public charge inadmissibility determination, including the consideration relating to

[730] *See* INA section 212(a)(4)(B)(ii), 8 U.S.C. 1182(a)(4)(B)(ii).

[731] *See* INA section 212(a)(4)(C) and (D), 8 U.S.C. 1182(a)(4)(C) and (D).

the affidavit of support, is not sufficiently detailed or nebulous. DHS put forth a detailed assessment of the factors and how they are applied in the NPRM. Additionally, DHS provided additional information in the proposed forms and the form's instructions. As provided in the NPRM, a sufficient affidavit of support does not guarantee that the alien will not receive public benefits in the future and, therefore, DHS would only consider the affidavit of support as one factor in the totality of the circumstances.[732] The inability or unwillingness of the sponsor to financially support the alien may be viewed as a negative factor in the totality of the circumstances. DHS expects that a sponsor's sufficient affidavit of support would not be an outcome-determinative factor in most cases; the presence of a sufficient affidavit of support does not eliminate the need to consider all of the mandatory factors in the totality of the circumstances.

USCIS would assess the sponsor's annual income, assets, resources, and financial status, relationship to applicant, the likelihood that the sponsor would actually provide financial support to the alien, and any other related considerations. In order to assess the sponsor's likelihood of meeting his or her obligation to support the alien, DHS would look at how close of a relationship the sponsor has to the alien, as close family members would be more likely to financially support the alien if necessary. DHS would also look at whether the sponsor lives with this alien, as this could be indicative of the sponsor's willingness to support the alien if needed. Additionally, DHS would look at whether the sponsor has submitted an affidavit of support with respect to other individuals, as this may be indicative of the sponsor's willingness or ability to financially support the alien.

DHS furthermore disagrees with the commenters' assessment in regard to the weight provided to a sufficient and properly executed affidavit of support. The statute, under section 213A of the Act, 8 U.S.C. 1183a does not mandate that the affidavit is outcome determinative, nor does it limit DHS's discretion how to weigh the affidavit in the totality of the circumstances: It simply puts forth that ''[n]o affidavit of support may be accepted by the Attorney General or by any consular officer to establish that an alien is not excludable as a public charge under section 1182(a)(4) of this title'' and provides the requirements for a valid affidavit of support. The guidance of how to assess it is contained in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), which specifically provides that the lack of an affidavit of support, where required, renders an applicant inadmissible on the public charge ground; the statute further states an officer may consider any affidavit of support under section 213A of the Act, 8 U.S.C. 1183a, when assessing the public charge ground of inadmissibility.[733] DHS, therefore, determined that it will consider the affidavit of support as a factor in the totality of the circumstances.[734]

The statute under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) also does not mandate how much weight an affidavit of support must be given. Therefore, it is appropriate for DHS to regulate that the weight should be assessed based on the sponsor's annual income, assets, resources and his or her financial status, as well as the closeness of the relationship which would be indicative of the willingness and ability of the sponsor to financially support the alien.[735] DHS appreciates the reference to DOS' guidance on that issue, but DOS guidance is not binding on DHS.

In sum, the INA does not preclude DHS from establishing a framework for officers to provide the appropriate weight of the affidavit of support within the totality of the circumstances. In cases where the statute requires an alien to submit an affidavit of support and the alien fails to do so, the statute mandates a finding of public charge inadmissibility.[736] As explained in the NPRM,[737] however, the submission of a sufficient affidavit of support does not guarantee that the alien will not receive public benefits in the future. The submission of a sponsor's sufficient affidavit of support also does not eliminate the need to consider all of the mandatory factors in the totality of the circumstances.

Comment: A commenter suggested that DHS codify as a ground of exclusion on public charge, that a beneficiary sue the sponsor for reimbursement of listed public funds received, or else be deemed a public charge. The commenter explained beneficiaries have the option, but not the obligation, to initiate a private legal action against a sponsor who fails to fulfill their contract obligations to support the alien financially. The commenter stated that integrating this as a factor or ground would significantly facilitate DHS's goal of ensuring self-sufficiency. The commenter also said the sponsored beneficiary could also meet this obligation if the sponsor was sued for reimbursement by the funding Government agency. Another commenter stated that, if the concern of DHS is to lessen the financial strain Federal public benefit programs create, then a more effective and less harmful to public-health-and-safety alternative would be to enforce the affidavit of support, which is a binding contract as signed.

Response: DHS does not have the authority to create such a required ground of inadmissibility under authority of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). Additionally, DHS does not believe adding an additional factor to this rule regarding sponsor reimbursement of any amount of public benefits provided by an applicant is consistent with the public charge ground of inadmissibility, or that enforcing the sponsor's affidavit of support obligation is relevant to the public charge inadmissibility determination.

DHS notes that while the existence of a sufficient affidavit of support, where required to be submitted, is considered as a positive factor in any public charge inadmissibility determination, the sponsorship obligation set forth on the affidavit of support does not attach until *after* the application for an immigrant visa or adjustment of status is granted.[738] The subsequent action of enforcing the affidavit of support is distinct from the actual inadmissibility determination. Therefore, DHS will not, in adjudicating an adjustment of status application, consider the sponsor's potential future reimbursement in a public charge inadmissibility determination when there is not yet a reimbursement obligation. Rather, DHS will consider the existence of a sufficient affidavit of support and the likelihood that the sponsor would actually provide the statutorily-required amount of financial support to the alien, and any other related considerations.

Moreover, the statute is forward-looking and requires DHS to determine whether the alien is likely at any time to become a public charge. While past receipt of public benefits is a factor to consider, the fact that the beneficiary or the funding Government agency seeks

[732] Inadmissibility on Public Charge Grounds, 83 FR 51114, 51197 (proposed Oct. 10, 2018).

[733] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[734] *See* 8 CFR 212.22(b)(7).

[735] *See* 8 CFR 212.22(b)(7); *see also* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51198 (proposed Oct. 10, 2018).

[736] *See* INA section 212(a)(4)(C) and (D), 8 U.S.C. 1182(a)(4)(C) and (D).

[737] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51198 (proposed Oct. 10, 2018).

[738] *See* INA section 213A, 8 U.S.C. 1183a; 8 CFR 213a.2(d).

reimbursement for such receipt is unrelated to an alien's likelihood of becoming a public charge in the future. Imposing such a requirement would not meaningfully contribute to DHS's goal of ensuring self-sufficiency of those foreign nationals in the United States. For these reasons, DHS will not include reimbursement of the cost of public benefits provided to an alien as part of the factors is an appropriate consideration.

O. Additional Factors To Consider

Comment: A commenter stated that being a past recipient of public benefits should not be a heavily weighted negative factor and suggested that certain positive factors, or considerations, should offset negative factors such as being a caregiver for a U.S. citizen child, being an elderly person or an individual with disabilities, having a child under the age of five, being recently pregnant, being someone who had a temporary health condition which caused the individual to be unable to work which has since improved, and those receiving Medicaid.

Response: Aside from the above-referenced clarification with respect to caregivers, DHS will not add additional factors or considerations to the rule along the lines proposed by the commenter. There is no evidence that these listed factors, such as being a caregiver for a U.S. citizen child, being an elderly person or an individual with disabilities, having a child under the age of five, or being a Medicaid recipient, is indicative of self-sufficiency. Although caregivers may benefit the household by eliminating the need for childcare or eldercare expenses, each person must establish he or she is not likely to be a public charge based on the totality of the factors of an individual's circumstances. However, as noted above, USCIS, on an individual basis, may take into consideration that a person is a caregiver for others in the household as part of the Education and Skills factor or that a sponsor provides sufficient support for the alien. When considering whether the alien is likely to become a public charge, DHS will consider the totality of the alien's circumstances. The alien is not precluded from advancing any argument or providing evidence that would indicate that, in the totality of the circumstances, the alien is not likely to become a public charge.

Comment: One commenter suggested that DHS should take reimbursement (or the possibility of reimbursement) of public benefits into account when determining whether an individual is likely to become a public charge. The commenter, while noting that benefits such as costly long-term institutional care were unlikely to be reimbursed, stated that there was no reason to think that very modest amounts of Medicaid or SNAP benefits would not be reimbursed if the public entity providing the benefits sought reimbursement. This commenter noted that the Government has the authority to obtain reimbursement from a sponsor under an affidavit of support. The commenter noted that the current SNAP, Medicaid, SSI, and TANF programs permit reimbursement. This commenter stated that lower thresholds for public charge determinations increase the likelihood of receiving reimbursements of benefits that would push the amount of benefits received below the public charge threshold as set by DHS. And finally, the commenter requested that consideration of reimbursement, and how it will be determined, as part of the regulatory action on public charge, should be done with notice and comment because it is such a major aspect of the rule.

Response: Although an adjustment of status applicant who is required to submit a sufficient affidavit of support must submit Form I–864 with his or her application, the sponsor's obligations with respect to the applicant do not become effective until the adjustment of status application is granted. Therefore, at the time the applicant files an application for adjustment of status, there would not be anyone responsible for reimbursing a public benefit-granting agency. The reimbursement of public benefits may be more applicable in the deportability context and out of scope of this rule.

P. Heavily Weighted Factors General Comments

Comment: A commenter opposed proposed establishment of heavily weighted positive and negative factors in a public charge inadmissibility determination. The commenter indicated the proposed system of heavily weighted negative and positive factors effectively limits an adjudicator's ability to consider the totality of circumstances. Many commenters stated that the proposed rule would yield inconsistent outcomes as there is no clear guidelines to what extent heavily weighted positive or negative factors should inform a final decision. Another commenter stated that the proposed weighting scheme unreasonably under-weighs the most important factors (ability to work in the future and having potential family support) and overweighs several other marginal factors in public charge determinations. The commenter also indicated that the general considerations are turned into a complex, variable-factor test that always involves more than five factors, and that it will massively increase the error rate for public charge decisions. The commenter indicated that the example in Table 35 in the NPRM and rule specify quantitative weights to the factors. The commenter indicated that the factor labeled ''not applicable'' has a presumed weight of zero and is not included in the numerator or denominator of any quantitative or qualitative final ''score'' of the proposed test; and that ''heavily weighted factors'' have a much greater weight than all other factors. The commenter further assumed that the agency intends each of the applicable factors to have a weight equal to one, and heavily weighted factors have a weight equal to two. The commenter concluded that that while this would be the most straightforward reading of the factors and the tables included in the NPRM, the commenter stated it is actually unclear what the rule requires.

Response: DHS disagrees that the standard of identifying heavily weighted factors limits an officer's ability to consider the totality of the circumstances.[739] The heavily weighted factors provide guidance as to how to weigh all the factors present in an alien's case. Each case has different circumstances that will be reviewed in the totality of the circumstances. DHS believes that while the heavily weighted factors are more indicative of an alien's likelihood to become a public charge, these factors, under the totality of the circumstances framework, are still evaluated in conjunction with the other relevant positive and negative factors, and accorded the weight they are due in an alien's individual circumstances. Further, one factor alone, even those that are heavily weighted, will not determine whether an alien is likely at any time to become a public charge.

The totality of the circumstances approach is consistent with the statutory requirement that DHS consider certain minimum factors, as well as a body of administrative case law that has developed over the past 50 years, which generally directs the agency to ''consider all the factors bearing on the alien's ability or potential ability to be self-supporting.''[740] Additionally, as discussed in the NPRM, DHS has determined that certain factual

[739] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51178 (proposed Oct. 10, 2018).

[740] *See Matter of Vindman* 16 I&N Dec. 131, 132 (Reg'l Comm'r 1977).

circumstances would weigh heavily because DHS considered them to be particularly indicative of an alien being more of less likely to become a public charge.[741] In the sections that follow, DHS addresses public comments regarding specific heavily weighted factors.

Again, the inclusion of heavily weighted factors does not change that the public charge inadmissibility determination is one that is made based on the totality of the alien's individual facts and circumstances. Therefore, DHS disagrees with the commenter's assessment on the quantitative weight assessment of the factors. DHS does not review the factors quantitatively, so there is not a factor that has a weight equal to zero, one, or two. The use of the term ''neutral'' in the ''Weight of Factor'' column in Table 35 of the NPRM refers to the fact that the factor is not heavily weighted. The factors would still be positive or negative unless designated as heavily weighted factor.

Comment: A commenter stated that the heavily weighted negative factors are highly correlated and ''puts a thumb on the scales'' against low-income immigrants. A couple of commenters stated that the heavily weighted factors ignore the positive contributions of immigrants to society. A commenter stated that the heavily weighted factors in the proposed rule are not realistic given the realities of the current job market in the United States. A commenter stated that negatively weighted factors in the proposed rule, such as family size or being under the age of 18, are misaligned with efforts to grow the U.S. economy. Another commenter expressed concern that the negative weighted factors ignore the positive impacts receiving public benefits have on future self-sufficiency.

Response: As explained in the NPRM, the mere presence of any of the factual circumstances listed in the rule would not, alone, be outcome determinative. A circumstance that the rule designates as warranting heavy weight might be outweighed by countervailing evidence in the totality of the circumstances.[742] Other evidence may also be probative of an alien's likelihood to become a public charge in the context of an alien's individual circumstances.[743] Therefore, the public charge inadmissibility determination, as proposed in the NPRM and as set forth in this final rule, is neither a formulaic scheme nor will it ignore important considerations in an alien's case, such as the alien's ability to work or the family support that she or he receives, or any other positive contributions by the alien that demonstrate self-sufficiency.

DHS also disagrees that the heavily weighted factors are not realistic given the realities of the current job market in the United States and that these factors are misaligned with efforts to grow the U.S. economy. This rule is designed to better ensure that those seeking to come to and remain in the United States either temporarily or permanently are self-sufficient, as directed by Congress.[744] However, DHS notes that as addressed elsewhere in this rule, this rule does not aim to address the U.S. economy or the U.S. job market.

Comment: Several commenters stated that four in ten noncitizens who entered the United States without a green card would have characteristics that would be considered heavily weighted negative factors. Many commenters stated that the heavily weighted factors would disproportionately affect immigrant women; survivors of domestic and sexual abuse; immigrants with disabilities; immigrants with HIV and other chronic health conditions; LGBTQ immigrants; children and families; seniors; multigenerational families; racial and ethnic minorities; and AAPI immigrants. For example, several commenters stated that the employability factor would negatively and disproportionately impact survivors of sexual and domestic violence. A commenter stated that women are more likely to be victims of harassment at work, and are more likely to face negative consequences if they speak out. Another commenter stated that the employability factor and receipt within the previous 36 months of one or more public benefits above the threshold would unfairly affect individuals with disabilities. Some commenters stated that survivors of domestic and sexual abuse would be disproportionately affected by heavily weighting recent receipt of one or more public benefits. A commenter stated that the proposed rule's lookback period will negatively impact pregnant women as well as women and families with children because they are eligible to receive benefits for a longer period of time. Another commenter stated that using recent receipt of public benefits as a heavily weighted negative factor would have disastrous effects on those receiving Medicaid. Several commenters stated that the heavily weighted negative factor for lacking financial means to pay for reasonably foreseeable medical costs would disproportionately harm immigrants with disabilities, and those living with chronic medical conditions. Several commenters stated that this proposed factor would disproportionately affect survivors of domestic and sexual abuse, and certain subpopulations of Asian Americans.

Response: DHS understands that the rule may result in more public charge inadmissibility findings, which may have specific effects on certain groups. For example, the rule will affect some aliens who have low incomes; however, income is relevant to the alien's assets, resources, and financial status, which DHS is required to consider in determining whether an alien is likely at any time to become a public charge in the totality of the circumstances. Similarly, DHS understands that the rule will affect aliens who do not work, but employability has obvious relevance to whether a person is likely at any time to become a public charge. Again, an officer evaluates all of the factors in the totality of the circumstances and an alien may have positive factors that outweigh lack of past, current, or future employment. Finally, an alien's recent receipt of public benefits (or an alien's continuing enrollment in public benefits such as Medicaid) is also relevant to the alien's assets, resources, and financial status, which DHS is also required to consider in determining whether an alien is likely at any time to become a public charge. However, as noted previously, this is one relevant factor in the totality of the circumstances, and an alien could always show evidence of disenrollment, or evidence that the alien obtained private health insurance or other means of support to offset this heavily weighted negative factor.

As noted elsewhere in this rule, Congress has generally exempted certain vulnerable populations from the public charge ground of inadmissibility, such as VAWA, T, and U applicants, and DHS included these exemptions in the regulatory text in this final rule. DHS, however, will not adjust the statutory factors to otherwise accommodate specific groups whom Congress has made subject to the public charge ground of inadmissibility.

Q. Heavily Weighted Negative Factors

1. Lack of Employability

Comment: One commenter supported lack of employability as a heavily weighted negative factor, and stated that lack of employability should be the only disqualifying factor. Another commenter stated that employment

[741] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51198–206 (proposed Oct. 10, 2018).

[742] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51198 (proposed Oct. 10, 2018).

[743] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51198 (proposed Oct. 10, 2018).

[744] *See* 8 U.S.C. 1601.

alone does not guarantee an immigrant's economic self-sufficiency, because much of the work done by immigrants is low-wage and does not fully cover the cost of living in the United States.

Response: DHS agrees that employment alone does not guarantee that a person will be self-sufficient. DHS disagrees, however, with the comment suggesting that the lack of employability should be disqualifying in the public charge inadmissibility determination. All the factors as listed in the statute and this final rule, including the heavily weighted negative factors, are reviewed in the totality of the circumstances. The fact that an alien is not a full-time student and is authorized to work but cannot demonstrate employment history or a reasonable prospect of future employment will not be the sole factor that would lead to a determination that the applicant is inadmissible as likely at any time to become a public charge.[745] Even where an alien has this heavily weighted negative factor, that factor, in and of itself, will not render an applicant likely at any time to become a public charge in the totality of the circumstances analysis.

DHS will not implement the suggestion that the lack of employability be the only disqualifying factor. As noted above, none of the heavily weighted negative factors is disqualifying and further, DHS has determined that there are other factual circumstances (*e.g.,* income, assets, resources at or above 250 percent) apart from employability that are also particularly indicative of an alien being more of less likely to become a public charge and therefore, are heavily weighted negative factors.

Comment: A commenter stated that the factor is misleadingly characterized in the preamble as a ''Lack of Employability.'' The commenter indicated that it is not clear how recently a person needs to have worked, or how they would demonstrate the prospect of future work, or even the type of work that would avoid the application of this heavily weighted negative factor. Some commenters stated that the employability heavily weighted negative factor was vague and poorly defined.

Response: DHS does not believe that the heading for this factor is misleading. The factor relates to whether an alien who is not a full-time student and is authorized to work, is able to demonstrate current employment, recent employment history, or a reasonable prospect of future employment. Because this factor assesses whether an alien who has work authorization has worked or can demonstrate the ability to work in the future, it goes directly to whether the alien is employable, which DHS believes is particularly indicative of whether an alien is more likely to become a public charge.

With respect to the commenter's objections regarding vagueness, DHS believes it is reasonable and consistent with a totality of the circumstances approach to not limit the review of employability to specific time periods or specific types of employment. Form I–485 requests information on the last 5 years of employment. An applicant may be able to demonstrate prospects of future employment through their employment history and education and skills.

2. Current Receipt of One of More Public Benefit

Comment: A few commenters stated that considering current receipt of one or more public benefits is not in keeping with the totality of circumstances test. In addition to this, one commenter stated that including receipt of one or more public benefits to the public charge determination was a drastic change in the scope of the test. One commenter stated that including public benefits as a heavily weighted negative factor ignores the contributions of low-wage workers to society and the economy. A few commenters stated there was not sufficient evidence to state that receipt of one or more public benefits is indicative of someone becoming a public charge. Other commenters said that some people who are self-sufficient will access benefits, and that this has been supported by congressional intent.

Response: DHS disagrees that considering prior or current receipt of public benefits is inconsistent with the totality of the circumstances test. As discussed in the NPRM, DHS believes that receipt of benefits is a key gauge to determining the likelihood of future use of public benefits and becoming a public charge. All else being equal, a person who is currently receiving public benefits is more likely to receive public benefits in the future than a person who is not currently receiving such benefits. The 1999 Interim Field Guidance recognizes this by directing officers to consider current and past receipt of covered benefits.[746] DHS appreciates that low-wage workers contribute to society and the economy but believes that including public benefits as a heavily weighted negative factor is an appropriate consideration in determining who is likely to become a public charge.

Comment: One commenter stated that the heavily weighted factors would impair rather than advance the financial stability of immigrants. A commenter stated the negative factors in the rule ignore the role public benefits and family support play in advancing self-sufficiency. Another commenter stated that using receipt of one or more public benefits as a heavily weighted factor would hurt the ability of public benefit-granting agencies to combine multiple benefits that work in concert to improve self-sufficiency of the recipients.

Response: DHS agrees that public benefits can assist in advancing self-sufficiency but believes the rule is a proper interpretation of the congressional mandate regarding the public charge provisions.[747] Further, the rule does not prevent public benefit-granting agencies from working to improve the self-sufficiency of recipients, although it does create consequences for an alien's receipt of certain public benefits.

Comment: One commenter said this factor was appropriately weighted but indicated that an alien's reliance on a foreign government assistance program should not be considered as a negative factor, as in many cases, the dependence on such programs is customary, or the program is designed to be one where the immigrant would not have had to opt into.

Response: DHS appreciates the comment and agrees that the factor is appropriately weighted. DHS did not propose and will not consider public benefits provided by foreign countries.[748] Public benefits in foreign country have different standards and objectives. For example, in some countries, such as Canada, healthcare is provided on a national basis and is not based on income eligibility and not aligned to a need-based standard. In addition, the inadmissibility determination is whether a person is likely to become a public charge in the United States.

3. Receipt of Public Benefits Within 36 Months Before Filing

Comment: Some commenters stated that a retrospective test is inconsistent with the prospective nature of the

[745] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51178 (proposed Oct. 10, 2018).

[746] *See* Field Guidance on Deportability and Inadmissibility on Public Charge Grounds, 64 FR 28689, 28690 (May 26, 1999).

[747] *See* 8 U.S.C. 1601.

[748] *See* 8 CFR 212.21(b). *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51158–74 (proposed Oct. 10, 2018).

public charge inadmissibility determination. Other commenters asserted that weighing receipt of public benefits within the previous 36 months is inconsistent with the totality of circumstances test, and represented a significant and troubling departure from current federal policy. A commenter commented that the ''studies provide zero evidence that previous receipt of the newly added benefits is an indicator of future use.'' A few commenters commented that receipt of public benefits is a clear benchmark that an immigrant was deemed eligible for a benefit by another Federal agency and it is therefore inappropriate to consider previous receipt of public benefits. Several commenters stated that if the specific circumstances that led to the use of public benefits no longer apply, the previous use of benefits is irrelevant. One commenter added to this and said that they opposed the proposed addition of receipt of public benefits within last 36 months of filing application as there are many cases where someone needs help only temporarily. Another commenter stated that many individuals would just disenroll from benefits for 3 years and re-enroll once they receive adjustment of status, but in the meantime could suffer. Many commenters stated that a lookback period disregards the positive effects of public benefits, including future self-sufficiency. Several commenters stated that the 36-month rule is retrospective and has no place in a rule that is meant to be forward looking, and commented that prior receipt of public benefits has no bearing on whether an individual will be dependent on the Government in the future. A commenter indicated that the past receipt of public benefits should receive no weight. One commenter expressed concern that by using a lookback period, even individuals who were able to increase their earnings to a point where assistance is no longer needed will be penalized. Adding to this, a commenter that the proposed lookback period will disproportionately hurt those who are gainfully employed and may therefore be eligible to access benefits for longer than those who are not employed.

Response: DHS understands that a person may no longer need public benefits in the future if the circumstances that led to the use of public benefits no longer apply, and DHS would take that into consideration. DHS would take into consideration that the public benefit was used temporarily and that the person may not be likely to receive public benefits in the future. No longer receiving public benefits because of stable employment or income would be a consideration in the totality of the circumstances. However, DHS believes, as discussed in the NPRM, that past receipt of public benefits for more than 12 months in the aggregate within 36 months is an indicator that an alien will continue to receive (or again receive) public benefits, and therefore is likely to become a public charge.

Comment: A commenter indicated that the 36-month standard is unreasonable because the study conducted by HHS in 2001 is outdated and does not appear to provide a reasonable basis for the 36-month period that DHS has included in this proposed rule. A couple of commenters stated there was not adequate rationale to support negatively weighting receipt of public benefit within the prior 36 months. Another commenter stated that it was unclear how prior benefit use would be weighted. A couple of commenters stated that the 36-month rule is unfair because no one could have predicted this rule or can predict their circumstances, and would cause great fear and confusion.

Response: As discussed in the NPRM, some studies suggest that although most people who leave welfare programs are working after they leave those programs, people may come back to receive additional public benefits.[749] As explained in the NPRM, DHS would view past receipt of public benefits within 36 months as an indicator that an alien will continue to receive (or again receive) public benefits, and therefore is likely to become a public charge. With respect to the statement that the study is outdated or insufficient, DHS notes that although there are limitations to the data, this study was particularly of interest in that it examined repeated return to public benefit programs.

As explained elsewhere in this rule, DHS has also clarified as part of the definition of receipt of public benefits, that although an application or certification for public benefits is not considered receipt, DHS believes that the application for, or being certified to receive in the future to receive public benefits may suggest a likelihood of future receipt. Correspondingly, DHS also amended the heavily weighted factor to state an alien's receipt, being certified to receive, or approval to receive one or more public benefits, as defined, for more than 12 months within any 36 month period, beginning from 36 months prior to the alien's application for admission or adjustment of status, will be considered a heavily-weighted negative factor in the totality of the circumstances assessment.

The NPRM explains that the weight given to public benefits will depend on whether the alien received multiple benefits, how long ago the benefits were received, and the amounts received.[750] For example, the receipt of a public benefit five years ago may be a negative factor; however, a public benefit received six months before the adjustment of status application would be considered a heavily weighted negative factor. DHS will consider receipt of (or application or certification for) public benefits after the effective date of the rule. DHS will also consider those benefits that were previously considered under the 1999 Interim Field Guidance including SSI, TANF, State and local cash assistance programs that provide benefits for income maintenance (often called ''General Assistance'' programs), and those benefits received (including Medicaid) to support the alien's institutionalization for long-term care. The publication of the rule and effective date provides sufficient notice for people to cancel current receipt of public benefits.

Comment: One commenter requested an explanation of the necessity of the 36-month lookback period as most immigrants who would qualify for public benefits are either exempt from public charge determinations or have already adjusted status.

Response: As explained previously, the 36-month component of the public charge threshold is an appropriate timeframe to determine whether an alien is more likely than not to become a public charge at any time in the future. That said, DHS will not make a public charge inadmissibility determination with respect to aliens who are exempt from public charge inadmissibility or who have already adjusted status to that of a lawful permanent resident, and would not otherwise be considered applicants for admission. Therefore, DHS will not consider whether such aliens have received public benefits. With respect to other aliens, as discussed in this final rule, DHS has added the consideration of credible and probative evidence presented by the

[749] *See* Lashawn Richburg-Hayes & Stephen Freedman, *A Profile of Families Cycling On and Off Welfare* 4 (Apr. 2004), *available at https://aspe.hhs.gov/system/files/pdf/73451/report.pdf* (last visited July 26, 2019). *See* also U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning & Evaluation, *Status Report on Research on the Outcomes of Welfare Reform* app. B (Aug. 2001), *available at https://aspe.hhs.gov/report/status-report-research-outcomes-welfare-reform-2001* (last visited July 26, 2019).

[750] This proposed policy is generally consistent with longstanding policy affording less weight to benefits that were received longer ago in the past.

alien from a Federal, state, or local government agency that demonstrates the alien is not eligible for one or more public benefits. This information will be taken into consideration in the totality of the circumstances.

4. Financial Means To Pay for Medical Costs

Comment: Some commenters stated that many people do not have the ability to afford their own healthcare due to low wages and the high cost of healthcare, making this factor unfair to low-wage workers and immigrants. Another commenter expanded on this and remarked that this factor will simply exclude individuals without substantial resources and who do not understand the complicated healthcare system in the United States. One commenter expressed concern that the rule asserts that a sign of self-sufficiency is having enough cash on-hand to deal with serious illness, asserting that most Americans born in this country could not pass this test. Another commenter stated that it is impossible to predict an individual's future healthcare costs.

Response: The basis for including Medicaid in the rule is discussed earlier in this preamble. Even if the alien does not have health insurance, he or she should have sufficient funds to provide for any reasonably foreseeable medical costs, which is only one consideration in the totality of the circumstances. Further, DHS will not consider assistance for an ''emergency medical condition'' as provided under section 1903(v) of Title XIX of the Social Security Act, 42 U.S.C. 1396b(v), and in implementing regulations at 42 CFR 440.255(c) as part of the public charge inadmissibility determination. Having health insurance or being able to pay for medical expenses is only one factor in the totality of the circumstances. This factor does not call for the alien to be able to pay for medical costs that are not reasonably foreseeable.

Comment: Commenters suggested that DHS eliminate the proposed heavily weighted negative factor for an alien who (1) has been diagnosed with a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide for himself or herself, attend school, or work, and who (2) is uninsured and has neither the prospect of obtaining private health insurance, nor the financial resources to pay for reasonably foreseeable medical costs related to a medical condition. A commenter stated that the factor is applicable even if the applicant has not used public benefits and would keep most people with disabilities from entering or remaining in the United States. The commenter further stated that assigning the factor a heavy weight would codify discriminatory assumptions regarding people with disabilities. The commenter stated that disability should remain a factor to be measured on a case-by-case basis free of an automatically assigned heavy negative weight.

Response: DHS will retain the heavily weighted negative factor based on the applicant's lack of financial means to pay for reasonably foreseeable medical costs if the alien does not have private health insurance. As established in the NPRM, certain chronic medical conditions can be costly to treat and certain conditions may adversely affect an applicant's ability to obtain and retain gainful employment, or to otherwise support himself or herself. Evidence outlined in the NPRM also indicated that individuals in poor to fair health are more likely to access public benefits to treat their medical condition. DHS agrees with the commenter that this factor may be applicable even if the applicant has not received any public benefits, but disagrees that this factor would keep most people with disabilities from entering or remaining in the United States. Since the public charge inadmissibility determination is made on a case-by-case basis and in the totality of the alien's individual circumstances, an applicant could overcome this heavily weighted negative factor through presentation of other evidence.

Additionally, DHS notes that the fact that an applicant has a disability does not mean that the applicant has this heavily weighted negative factor, and disagrees that the rule codifies discriminatory assumptions. As is the case with any other applicant, individuals with disability may establish their self-sufficiency notwithstanding their medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide for himself or herself, attend school, or work. Such applicants may do so by providing proof of income, employment, education and skills, private health insurance, and private resources.

Comment: One commenter expressed concern that this factor would allow DHS personnel to overrule the opinions of medical professionals in a move that would invite ''unbridled speculation and discrimination.''

Response: DHS disagrees that this heavily weighted negative factor would permit DHS to overrule the opinions of medical professionals. In reviewing the Form I–693 or DOS medical examination form, USCIS will be relying on the diagnoses set forth by the civil surgeon or designated panel physician on such forms submitted in support of the application for the diagnosis of any medical conditions; USCIS will also rely on evidence, as provided by the applicant, of a medical condition that is likely to require extensive medical treatment or institutionalization after arrival, or that will interfere with the alien's ability to care for himself or herself, to attend school, or to work. DHS will not speculate as to the cost of medical conditions or the ability of a person to provide for himself or herself or go to school or work.

Comment: Multiple commenters stated that farmworkers often lack health insurance, even if offered by their employer, because they cannot afford it, and stated this factor is unfair to these workers.

Response: For nonimmigrants' admission, DHS will also consider the proposed length of stay of the nonimmigrant and the assets, resources and financial status of the applicant. Some employers may provide for medical assistance for the duration of the alien's stay. Whether a person has the ability to pay for reasonably foreseeable medical costs is but one factor in the totality of the circumstances. As previously indicated for extension of stay and change of status purposes, DHS removed the forward looking determination and will only consider whether the nonimmigrant received public benefits during the stay.

5. Alien Previously Found Inadmissible or Deportable Based on Public Charge

Comment: Some commenters asserted that by using whether a person was previously found inadmissible or deportable as a public charge as a heavily weighted factor, DHS would be ignoring the prospective nature of the public charge assessment. One commenter stated that since the prior finding of *not* being a public charge is not accorded comparable weight in the proposed rule this factor would be arbitrary and unfair. The commenter stated that in addition, because the only heavily weighted positive factor that could counterbalance this one is income or assets above 250 percent of the FPG, reliance on such a factor would arbitrarily impose a more difficult evidentiary hurdle for immigrants below that level than for immigrants above it without rational justification, as well as disproportionately harm immigrants of color, who are less likely to earn above that level, as described infra in our

comments on the 250 percent criteria. Another commenter warned that this factor would be an arbitrary addition and would serve no purpose other than to deter individuals from applying for adjustment of status out of fear it would ruin their future attempts to gain lawful permanent residence status.

Response: DHS disagrees that considering a prior inadmissibility determination as a heavily weighted negative factor would be arbitrary and unfair or that considering an alien's prior admissibility under the public charge ground would merit comparable favorable treatment. A previous finding of inadmissibility on public charge grounds would likely be documented. By contrast, there would not necessarily be a statement of the Government's reasons for admitting the alien or approving his or her application for adjustment of status.

DHS acknowledges that an alien's circumstances may have changed since a previous application for admission or determination of inadmissibility or deportability based on the public charge ground. DHS would take those new circumstances into account in the totality of the circumstances when making a new public charge inadmissibility determination. There is no requirement to specifically ''balance out'' a heavily weighted negative factor with a heavily weighted positive one. Rather adjudicators will consider the alien's specific circumstances within the totality of the circumstances framework when assessing the alien's likelihood of becoming a public charge, and will afford specific facts the weight they are due in the context of this rule's adjudicative framework.

R. Heavily Weighted Positive Factors

1. Proposed Standard

Comment: Several commenters stated that having the 250 percent threshold as the sole heavily weighted positive factor in the public charge test would represent a fundamental change to immigration policy and the immigrant population. A commenter stated a bright-line positive or negative income threshold subverts the totality of circumstances consideration. Some commenters stated that the 250 percent threshold was another example of double counting in public charge inadmissibility determinations under the proposed rule. Another commenter stated the 250 percent threshold was there to prevent immigration through administrative means. Another commenter stated that those falling between 125 percent and 250 percent of the FPG would have their cases improperly adjudicated. One commenter stated the 250 percent threshold does not go far enough to help qualified individuals overcome the public charge test. Other commenters stated that the proposed heavily weighted positive factor ignores the positive contributions of immigrants. One commenter stated that using 250 percent as the sole positive factor undermines and minimizes the value of other key economic and wealth building milestones. Additionally, some commenters stated that the proposed heavily weighted positive factors undervalue those who contribute to society in nonmonetary ways, such as stay at home parents. Another commenter stated that the 250 percent threshold functions as a ''wealth-test.'' Another commenter said that most legally present noncitizens would not meet the 250 percent FPG threshold. Similarly, other commenters stated that much of the U.S. population would not qualify to have a heavily weighted positive factor. Many commenters said the threshold for a family of four is higher than the 2017 median household income for the United States ($63,000 vs. $61,372). One commenter stated that in some regions of the United States those earning above 250 percent FPG would be among the wealthiest in their communities. One commenter stated that the proposed 250 percent FPG threshold would do little to improve the systemic issues of income inequality in the United States.

Response: DHS disagrees that the rule provides a wealth test. The 250 percent FPG standard is a heavily weighted positive factor and not a requirement that aliens need to meet in order to overcome a public charge inadmissibility finding. As previously stated, income is one factor in the totality of the circumstances, and any income above 125 percent of the FPG is a positive factor.

Comment: Several commenters cited research showing there was not a statistically significant difference in receipt of benefits between immigrants above and below the 250 percent threshold. Some commenters stated that the 250 percent FPG threshold would have a perverse effect of discouraging people from supporting family members out of fear it would change their public charge determination.

Response: DHS acknowledges that certain tests involving estimates of noncitizens yielded results in Table 28 of the NPRM that were not statistically significant, which in some cases was a consequence of small sample sizes due to forming estimates on only noncitizens instead of foreign-born more generally. DHS chose to study noncitizens specifically despite the inherent issues in making inferences from small sample sizes, since the population of noncitizens more closely corresponded to the individuals who would be subject to the public charge rule than foreign-born generally, which includes naturalized citizens. In Table 27 of the NPRM, DHS showed that there is lower public benefit program participation rates among those in higher income categories for the population of citizens in the tables listed in the NPRM. Lower participation rates may also be shown in the overall population by averaging across both citizens and noncitizens (*i.e.,* Tables 27 and 28 of the NPRM). Table 28 of the NPRM is not inconsistent with such a relationship. The justification still holds for using income as a percentage of FPG in the public charge determination, and persons with an income at a higher percentage of the FPG are less likely the to receive public benefits than those at a low percentage. Further, DHS disagrees that the 250 percent threshold would discourage people from supporting their families as 125 percent is the threshold for positive consideration in the totality the circumstances and the 250 percent threshold a heavily weighted positive factor but not a requirement. DHS acknowledges that the income threshold may be harder to meet if the alien has a larger household size, however, DHS would also take into account any income, assets, or resources the other household members also provide. Nevertheless, family status is still a mandatory factor as established by Congress.[751]

Comment: One commenter stated that heavily weighing household income at or above 250 percent FPG would confuse the threshold for the affidavit of support.

Response: The affidavit of support is a different requirement and has a specific form associated with it. The affidavit of support threshold is 125 percent of the FPG of the sponsor's income and that threshold is not being changed with this rule. The income threshold for the alien's household is part of this rule's totality of the circumstances public charge assessment is 250 percent of the FPG. Income at this level is considered a heavily weighted positive factor (as opposed to income at the 125 percent of the FPG (100 percent for member of the U.S. Armed forces in active duty), which is a positive consideration).

[751] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

Comment: Another commenter stated there may not be enough time for migrants under certain visa classifications to seek, obtain, and begin a job with the income necessary to meet the 250 percent of FPG level.

Response: The burden is upon the alien to establish that he or she is eligible to be admitted into the United States. Further, certain nonimmigrant and immigrant classifications require the employment to be established before the nonimmigrant visa is issued. That said, DHS notes that there is no requirement that an applicant subject to the public charge ground of inadmissibility demonstrate that he or she has income at or above 250 percent of the FPG in order to gain admission or adjustment of status. Rather, the fact that an applicant who has income at or above 250 percent of the FPG will weigh heavily in favor of finding the applicant is admissible in the totality of the circumstances, but is not outcome determinative. Therefore, an applicant who has household income below 250 percent of the FPG will not, based on that fact alone, be denied admission or adjustment of status.

Comment: Several commenters stated the proposed 250 percent heavily weighted positive threshold would disproportionately affect members of marginalized communities; hard-working low- and middle-income families; immigrants of color; South Asian immigrants; Latino immigrants; Muslim immigrants; immigrants with disabilities; those with pre-existing health conditions; women and single mothers; victims of domestic and sexual abuse; families with children who have special healthcare needs; and the health and well-being of children of immigrant parents.

A few commenters stated that the proposed heavily weighted positive factor would increase family separations and would have a negative impact on family-based immigration. Many commenters stated that the proposed heavily weighted positive factor would effectively bar lower income immigrants; disregards the efforts and contributions of low-wage workers; and that the majority of legally present noncitizens would fail to meet the 250 percent FPG threshold.

Response: DHS understands that the rule may affect certain groups who may have low incomes; however, income is but one factor in the totality of the circumstances and will not serve as the sole reason to find an alien inadmissible based on public charge grounds. As previously indicated, if an applicant has household income at or above 250 percent of the FPG it will be treated as a heavily weighted positive factor because it is particularly indicative of an alien being less likely to become a public charge. An applicant subject to the public charge ground of inadmissibility is not required to demonstrate that he or she has income at or above 250 percent of the FPG in order to establish admissibility, and an alien's failure to demonstrate such income does not receive ''negative'' weight in the totality of the circumstances unless that income is below 125 percent of the FPG. The standard only serves to assist individuals in establishing self-sufficiency.

Comment: A commenter stated that many couples seeking adjustment of status would be affected by the 250 percent threshold, as many of these visas prohibit immigrants from working. The commenter stated that according to one analysis, about 31 percent of foreign-born spouses were unemployed when they applied for a marriage-based green card, as many were prohibited from working on their nonimmigrant visas, such as the F–1 or F–2 student visas, or B–2 visitor visas. For those who did work, about 22 percent of them held jobs that would unlikely meet the 250 percent income threshold, and even if DHS were to allow both spouses to pool their income to meet the new threshold, 36 percent of couples could still find themselves unable to qualify for a marriage green card. The commenter stated that it is basic common sense that a student who is prohibited from working would likely have some student loans, potentially credit card loans, and would not have significant savings, and that the rule would allow primarily the independently wealthy to be eligible for marriage-based adjustment of status.

One commenter said the proposed heavily weighted positive factor creates a ''Catch-22'' for nonimmigrants on student visas who are married to U.S. citizens because they are not allowed to work. Some commenters cited a study that many H–1B visa holders make less than the amount necessary to support a family of five and qualify for the proposed income threshold of 250 percent of FPG. Another commenter stated that the proposed rule would negatively impact skilled workers who are supporting families and are making prevailing, middle-class wages. One commenter mentioned that the vast majority of scientific researchers applying for permanent resident status based upon an approved EB–1A, EB–1B or NIW petition do not meet this 250 percent income requirement. Another commenter also stated that some highly skilled employees such as post-doctoral research fellows may not make enough money to qualify for the heavily weighted positive factor. Some commenters remarked that many skilled workers are compensated with stock options as part of their regular income, and it is unclear if this will be considered under the heavily weighted positive factor. One commenter expressed concern that the 250 percent threshold does not take into account that many workers will increase their income the longer they work. A few commenters stated that that the 250 percent threshold would pose a unique challenge for California, where it would make it more difficult to extend the status of H–1B visa holders and create a labor shortage for California's agriculture industry, which heavily relies on the H–2A visa program.

Response: DHS understands that not everyone is authorized to work or needs to work in order to be self-sufficient. As previously indicated the 250 percent of the FPG standard is not a requirement to establish admissibility and is one consideration in the totality of the circumstances. Further, when adjudicating a nonimmigrant's application for extension of stay or change of status, USCIS will review whether the alien has established that he or she has not received, since obtaining the nonimmigrant status he or she is seeking to extend or change, any public benefit as defined in 8 CFR 212.21(b), for more than 12 months, in the aggregate, within a 36 months period. The heavily weighted factors do not apply in that context.

2. Additional Positive Heavily Weighted Factors

Comment: One commenter said that the 250 percent of the FPG standard should be downgraded from ''highly positive'' to just considered. Some commenters stated that earning 125 percent of the FPG should be a heavily weighted positive factor.

Response: DHS declines to adopt the commenter's suggested changes in this final rule. The rule already provides for 125 percent of the FPG as a positive factor in the totality of the circumstances. Making 250 percent of the FPG a general positive factor instead of a heavily weighted positive factor would further limit an alien's ability to establish admissibility. An alien would not need to establish income at or above 250 percent of the FPG in other to be admitted into the United States. Any income between 125 percent and 250 percent of the FPG is still a positive factor in the totality of the circumstances. The 125 percent income

threshold is based on the income threshold set by Congress for sponsors for a Form I–864, which is required for most family-based AOS applications and some employment-based AOS applications. In order to maintain consistency with the income threshold set forth in the Form I–864 context, DHS believes that the 125 percent threshold is appropriate for use in the public charge rule and will not lower the threshold. Any household income between 125 percent and 250 percent of the FPG is considered a positive factor in the totality of the circumstances.

a. Affidavit of Support

Comment: A commenter stated that the proposed rule mandates denial for anyone who cannot provide an affidavit of support, yet the presence of one is not a heavily weighted positive factor under the proposed rule. Several commenters stated the filing of a legally enforceable affidavit of support by a sponsor should be a heavily weighted positive factor and it should be sufficient to overcome any heavily weighted negative factors.

Response: DHS appreciates the comments but declines to establish the affidavit of support as a heavily weighted positive factor. The submission of an affidavit of support under section 213A of the Act, 8 U.S.C. 1183a is a requirement for certain categories of immigrants. See section 212(a)(4)(C) and (D) of the Act, 8 U.S.C. 1182(a)(4)(C) and (D). Not all aliens are required to submit the affidavit of support. According to section 212(a)(4) of the Act, 8 U.S.C. 1182 (a)(4), the lack of a sufficient affidavit of support, where required, renders an alien inadmissible on the public charge ground. Congress mandated the presence of an affidavit of support in certain cases as a separate requirement, but did not establish submission of the affidavit of support as a mandatory factor in all public charge inadmissibility determinations.

There is no indication that Congress believed that a sufficient affidavit of support would warrant a finding that the alien is not likely becoming a public charge. Had Congress believed that to be true, Congress would have specified such a provision in the statute. Instead, Congress listed the other factors as the minimum mandatory factors in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), which do not include the affidavit of support. For these reasons, and consistent with congressional intent, DHS will retain the affidavit of support as a factor considered in the totality of the circumstances, but will not make it a heavily weighted positive factor.

b. Family Relationships

Comment: Commenters suggested that the rule add close family relationship to the U.S. citizen or lawful permanent resident, or having a relative in the United Stated providing support, as a heavily weighted positive factor because it is strongly associated with self-sufficiency. The commenter notes that immigrants overwhelmingly come to the United States to work and advance their own and their families' financial prospects. The commenter cited their own report that estimates that 2.25 million undocumented persons and 212,000 nonimmigrants have a qualifying family relationship to a U.S. citizen or lawful permanent resident living in their household that makes them potentially eligible for an immigrant visa or adjustment to lawful permanent resident status. The report further indicated that out of this population, 982,000 live in families that earn at least 250 percent of the FPG.

Response: DHS will not add a close family relationship to the U.S. citizen or lawful permanent resident as a heavily weighted positive factor. There is insufficient evidence that the fact that an applicant's household includes a U.S. citizen or lawful permanent resident is indicative of self-sufficiency, or that having family members in the United States is in and of itself indicative of self-sufficiency. As with every mandatory factor, an applicant's family status will not serve as the sole basis of a finding of inadmissibility, as this factor must be considered in the totality of the circumstances.

c. English Ability

Comment: One commenter suggested that the ability to speak English well or very well should be a heavily weighted positive factor. The commenter indicated that the totality of the circumstances test affords insufficient weight to factors strongly associated with self-sufficiency and requested additional heavily weighted positive factors. The commenter's study found that 1.32 million of the 2.25 million that would be directly affected by the proposed rule speak English well or very well.

Response: DHS will consider whether the alien is proficient in English or proficient in other languages in addition to English as part of the public charge inadmissibility determination. The ''speaking English well or very well'' language comes from the SIPP survey analysis in which people assessed their own speaking abilities. As provided in the NPRM, the better the person spoke English, the higher the income he or she obtained. People who spoke a language other than English at home were less likely to be employed, and less likely to find full-time work when employed.[752] The SIPP data provided in the NPRM indicates that the rate of coverage of non-cash benefits among those who spoke English either well or very well (about 15 to 20 percent) was significantly lower than the rate among those who either spoke English poorly or not at all (about 25 to 30 percent). Further, DHS understands that not all employment requires English proficiency. DHS believes that while it is appropriate to consider English proficiency in the consideration of likelihood to become a public charge in the future, it is inappropriate to include English proficiency as a heavily weighted positive factor in light of the fact that many jobs do not require it.

d. Education

Comment: One commenter suggested that a high school education or beyond should be a heavily weighted factor. The commenter stated that the totality of the circumstances test affords insufficient weight to factors strongly associated with self-sufficiency and requesting additional heavily weighted positive factors.

Response: The rule provides that DHS would consider whether the alien has a high school degree or higher education as positive factors. However, a person's education may or may not assist him or her in becoming self-sufficient, depending on other factors specific to the alien's circumstances, such as the job market where the alien lives, outstanding liabilities and support obligations, or other personal or family circumstances. Therefore, DHS will not include education as a heavily weighted positive factor.

e. Private Health Insurance

Comment: One commenter suggested that private health insurance coverage should be considered as a heavily weighted positive factor, as it is strongly associated with self-sufficiency. The commenter explained that 1.1 million individuals have health insurance (out of the 2.25 million that would be directly affected by this rule based on a study conducted by the commenter, a non-profit think-tank and educational institute focused on international migration) and argued that the rule's totality of the circumstances test affords

[752] *See* Jennifer Cheeseman Day and Hyon B. Shin, U.S. Census Bureau, *How Does Ability to Speak English Affect Earnings?* 6 (2005), *available at https://www.census.gov/hhes/socdemo/language/data/acs/PAA_2005_AbilityandEarnings.pdf* (last visited July 26, 2019).

insufficient weight to factors strongly associated with self-sufficiency.

Response: DHS agrees that having private health insurance is a strong indicator of self-sufficiency. DHS analyzed the SIPP data and found that individuals who have private health insurance are significantly less likely to be receiving one or more enumerated public benefits in this rule than those individuals who do not have private health insurance. The rate of receipt of public benefits among those covered by private health insurance was 4 percent for citizens and 6 percent for noncitizens, while the rate of receipt for those not covered by private health insurance was 40 percent for citizens and 30 percent for noncitizens. DHS has therefore revised the rule to include a heavily weighted positive factor for an alien who has private health insurance, subject to two provisos. First, the health insurance must be appropriate for the expected period of admission.[753] Second, the health insurance may not be subsidized via premium tax credits (including advance premium tax credits) authorized under the ACA. Although individuals receiving such benefits have significantly lower odds of concurrently receiving the public benefits designated in this rule, they receive government subsidies to fulfill a basic living need, and qualify on a means-tested basis.[754] DHS does not believe it is appropriate to include a heavily weighted positive factor for this type of health insurance, although this type of health insurance would generally be considered positively as part of the consideration of the totality of the alien's circumstances, such as with respect to the alien's ability to pay for reasonably foreseeable health care costs. Private health insurance purchased through an ACA Marketplace without such credits will count for purposes of this heavily weighted positive factor.

f. Work History

Comment: One commenter stated that work history, without regard to wage history, should be a heavily weighted positive factor. This commenter stated that the essence of a ''public charge'' is where an individual is not willing or able to work and the rule should not focus on workers that earn low wages. This commenter explained that farm workers toil in extremely difficult conditions, performing work few others are willing to do, and at a low compensation rate that cannot possibly sustain a family, through no fault of their own. Another commenter stated that entrepreneurship should be considered a heavily weighted factor, as it is strongly associated with self-sufficiency.

Response: The rule provides for employment history to be considered as a positive factor. However, every factor must be considered in the totality of the circumstances. There might be instances where a person has long-term employment, but is not able to be self-sufficient and must receive public benefits and conversely, there might be instances that a person does not have long-term employment and would otherwise be self-sufficient. DHS believes that income is a proper consideration in the totality of circumstances and as a heavily weighted positive factor since it is indicative of self-sufficiency. DHS also recognizes that different types of employment may provide additional income, however, DHS does not believe it is appropriate to specify just one form of employment as a heavily weighted positive factor. Therefore, DHS will not include entrepreneurship as a heavily weighted positive factor.

g. Receipt of Grants, Contracts, and Licensures

Comment: A commenter suggested that receipt of grants, contracts, and licensures should be a heavily weighted positive factor. The commenter stated that excluding grants, contracts, and licensures from consideration was not appropriate and that an individual's receipt of a grant, contract, or license is likely demonstrative of their ability to support themselves without recourse to public benefits, as such receipt is indicative of ongoing work, skills/proficiencies, and qualifications recognized by the relevant government entity. The commenter further indicated that grants, contracts, and licensures may have a direct bearing on the future likelihood of an individual becoming a public charge and thus should be recognized as a positive factor.

Response: DHS is not excluding grants, contracts, and licensures from the public charge inadmissibility determination. DHS agrees that grants, contracts, and licensures are indicative of an alien's likely self-sufficiency. As with other signs of likely self-sufficiency, these would be positive considerations in the totality of the circumstances. However, DHS does not agree that these specifically should be included as heavily weighted positive factors.

h. Caregivers

Comment: A commenter suggested that being a caregiver should be a heavily weighted positive factor. This commenter shared an anecdote regarding a single father petitioning on behalf of his elderly mother so she could enter the United States to provide care to his children while he worked full time and pointed out that some contributions may not be monetary or employment-based but will instead have a ''trickle down'' effect that benefits others.

Response: DHS declines to adopt this recommendation. As previously discussed, although caregivers may provide assistance to the overall household, the public charge inadmissibility determination is based on the totality of the alien's individual circumstances and being a caregiver does not establish self-sufficiency or strongly suggest that the person is not likely to receive the designated public benefits above the designated threshold. Although caregivers may benefit the household by eliminating the need for childcare or eldercare expenses, DHS does not believe that a person's status as a caregiver warrants a heavily weighted positive factor. DHS, as previously

[753] *See* USCIS analysis of private health insurance in Wave 1 of the 2014 Survey of Income and Program Participation (SIPP). Private health insurance includes coverage through another person in the household and Medigap, and does not include Medicaid, Medicare parts B or D, or military- or government-provided insurance.

[754] USCIS was unable to identify a variable in the SIPP data for private health insurance paid for using a premium tax credit. USCIS also analyzed the SIPP data on private health insurance and receipt of public benefits, while controlling for income levels. The data support the proposition that having private health insurance, regardless of income level, is a significant determinant of whether the individual receives the designated public benefits. For example, 13.2 percent of individuals *with* private health insurance at an income level between 125 percent and 250 percent of FPG receive the designated public benefits. By contrast, 54.8 percent of individuals *without* private health insurance, at that same income level, receive the designated public benefits. Similarly, 10.3 percent of individuals *with* private health insurance at an income level between 250 percent and 400 percent of FPG receive the designated public benefits. By contrast, 47.5 percent of individuals *without* private health insurance, at those same income levels, receive the designated public benefits. *See* USCIS analysis of private health insurance and income level in Wave 1 of the 2014 Survey of Income and Program Participation (SIPP).

In addition, the data also appear to show a relationship between income level and receipt of public benefits, within the population of individuals who have private health insurance. For example, 15.3 percent of individuals with private health insurance below 125 percent of the FPG receive the designated public benefits. Receipt levels decline as income rises (13.2 percent for individuals with income levels between 125 percent and 250 percent of FPG; 10.3 percent for individuals with income levels between 250 percent and 400 percent of FPG; and 3.2 percent for individuals with income levels above 400 percent of FPG). *See* USCIS analysis of private health insurance and income level in Wave 1 of the 2014 Survey of Income and Program Participation (SIPP).

discussed, did include a provision regarding caregivers within the Education and Skills factor.

i. Ability To Work in the Future

Comment: A commenter indicated that the ability to work in the future should be a heavily weighted positive factor and stated that it, along with having potential family support, had been one of the two heavily weighted factors for over a century under Federal law. The commenter questioned why work ability and having legally enforceable family support should be weighted less heavily than past receipt of Medicaid or SNAP. The commenter indicated that this kind of disparate treatment might be justifiable if Congress had drafted the public charge test in a way that explicitly directed the agency to give heavier weight to past receipt of benefits than to future employability and family support, which Congress did not. The commenter provided a list of twenty occupations that the commenter stated would have the most job growth over the next decade. The commenter stated that in nine of the 20 occupations, a full-time worker in a household of one who earns the median salary for such occupation would not meet the 250 percent of the FPG standard. The commenter also stated that in 14 of 20 occupations, a full-time worker in a household of two who earns the median salary for such occupation would not meet the 250 percent of the FPG standard. The commenter indicated that the agency provides no reason or evidence for a standard that effectively classifies millions of full-time, year-round workers in high-demand occupations as public charges, or as not self-sufficient.

Response: DHS disagrees that it is classifying millions of full-time, year-round workers in high-demand occupations as public charges. Under the education and skills factor, DHS would consider whether the alien has adequate education and skills to either obtain or maintain employment sufficient to avoid becoming a public charge if authorized for employment. The evidence DHS will consider includes the alien's employment and income derived from such employment. As noted above, the fact that the alien does not qualify for a heavily weighted positive factor does not render the alien likely to become a public charge. In fact, many of the median wages identified by the commenter would generally result in a positive consideration, because they exceed 125 percent of the FPG.

S. Public Charge Bonds for Adjustment of Status Applicants

1. Standard

Comment: Several commenters supported the requirement that all new immigrants post a bond when they apply for entry into the United States. A commenter requested that DHS allow ''any alien determined inadmissible'' on public charge grounds to apply for a public charge bond.[755] One commenter stated that the public charge bond would be most useful in the category of immigrants that have an income between 125 percent and 250 percent of FPG.

Response: DHS appreciates these comments regarding the applicability of the public charge bond. However, DHS will not require all aliens seeking admission as immigrants to post a public charge bond. Section 213 of the Act, 8 U.S.C. 1183, neither requires all such aliens to post a public charge bond, nor authorizes DHS to require one from every intending immigrant. Instead, consistent with its statutory authority, USCIS will offer the public charge bond to certain applicants for adjustment of status, who are inadmissible only due to the likelihood of becoming a public charge and when a favorable exercise of discretion is warranted, based upon the totality of the alien's facts and circumstances.

Comment: One commenter noted that the public charge bond process might lead to pressure on DHS officials to make inadmissibility findings and offer public charge bonds.

Response: USCIS will not find an applicant is likely at any time in the future to become a public charge for the sole purpose of collecting a public charge bond. Although Congress has created certain exceptions and waivers to inadmissibility, the determination that an alien is inadmissible is mandatory where the alien meets any of the grounds described in section 212 of the Act, 8 U.S.C. 1182. USCIS is required to find an alien inadmissible if the alien is likely to become a public charge. As noted in the NPRM, a public charge bond in the adjustment of status context would generally only be offered in limited circumstances in which the alien has no heavily weighted negative factors and when offering the option of a public charge bond to an alien is warranted based upon the totality of the alien's facts and circumstances.

Comment: A number of commenters noted the standard DHS will use to determine when to offer a public charge bond. One commenter stated that the public charge bond must be offered only in rare cases. A few commenters further stated that the NPRM does not provide a clear standard defining who should qualify for a public charge bond and that the proposed public charge bond system is vulnerable to an abuse of discretion. A commenter suggested that DHS codify a criteria for exercising discretion regarding whether or not to offer the bond in this rule, noting that there should be uniformity and predictability of enforcement on the part of DHS, and that the manner in which this discretion is utilized should be clear and objective. One commenter asked for the justification of warranting a public charge bond in certain circumstances and asked that DHS almost always allow for an individual to post a bond. Another commenter requested that DHS clarify when a public charge bond would be used and also provided recommendations, including that public charge bonds should be available only if the applicant has obtained private medical insurance, and the applicant is part of an existing family unit whose only reason for separation would be an adverse public charge inadmissibility determination. The commenter further stated that DHS should only offer a public charge bond to applicants who can demonstrate hardship such as extreme hardship or exceptional and extremely unusual hardship.

Response: DHS disagrees that the rule is unclear in describing how DHS will exercise its discretion to offer a public charge bond. Public charge bonds will be offered only in limited circumstances to those inadmissible aliens USCIS has determined warrant a favorable exercise of discretion, in the totality of the alien's facts and circumstances, and by weighing all positive and negative factors available. As noted in the NPRM, offering a public charge bond in the adjustment of status context, generally, will only be warranted if an alien has no heavily weighted negative factors, such as those that are particularly indicative of the likelihood that an alien would become a public charge. However, and as noted in the NPRM, the presence of heavily weighted negative factors will not automatically preclude USCIS from offering a public charge bond. Rather, as with any discretionary determination, USCIS could also find that the heavily weighted negative factor(s) are outweighed by certain positive factors like those that benefit national security, or would be justified for exceptional humanitarian reasons.

DHS thanks the commenters for the suggestion to codify a more ''predictable'' criteria for determining whether to offer an alien an opportunity to post a public charge bond, but

declines to do so. The criteria outlined in the rule balances the need for certainty and predictability with that for flexibility USCIS adjudicators need to account for a wide array of facts and circumstances. For similar reasons, DHS also declines to limit its discretion to only permit submission of a public charge bond by aliens who have obtained and will maintain private health insurance, or to aliens who are members of an existing family unit whose only reason for separation would be an adverse public charge inadmissibility determination. DHS believes that limited approach would not account for the variety of factual scenarios USCIS may encounter. Furthermore, DHS believes that limiting the opportunity to post a public charge bond to only a particular narrow range of circumstances would unreasonably exclude from the possibility of a bond applicants who might otherwise merit a positive exercise of discretion.[756] Given that a bond is offered to applicants as a matter of discretion on a case-by-case basis, USCIS reserves the right to determine, based on the particular facts of the case, when the alien's individual circumstances warrant a favorable exercise of discretion.

USCIS also disagrees that it should only offer public charge bonds to applicants who have demonstrated hardship. As is the case with any discretionary determination, USCIS may consider any of a range of positive and negative factors applicable to the alien's case when determining whether the alien should be offered the option to post a public charge bond and be admitted to the United States on bond. USCIS respectfully declines to limit its consideration in this regard.

Comment: A commenter stated that DHS should not offer a public charge bond to any applicant with a heavily weighted negative factor. Other commenters were concerned that an applicant with a heavily weighted negative factor, such as use of Medicaid to pay for services associated with his or her disability that are not covered by private medical insurance, will not be considered for a public charge bond. One commenter added that individuals with one or more heavily weighted factors will not have access to sufficient resources to be able to submit a public charge bond. Another commenter asked if USCIS would provide guidance, such as via the USCIS Policy Manual, with guidelines for officers to follow and that will be available for public review.

Response: DHS appreciates the comments and will retain the provision that if an alien has one or more heavily weighted negative factors, as defined in 8 CFR 212.22, present in his or her case, USCIS generally will not favorably exercise discretion to allow the alien to submit a public charge bond. USCIS notes that a disability that affects an applicant's ability to care for himself or herself, to attend school, or to work is not in itself a heavily weighted negative factor, but rather, one factor USCIS will consider in the totality of the circumstances. Accordingly, a disability alone could not be the sole basis for a determination that the alien is likely at any time in the future to become a public charge.

Similarly, an alien's disability, alone, will not serve as the sole basis for USCIS deciding not to exercise its discretion to permit an alien to submit a public charge bond.[757] In determining whether to offer the alien a public charge bond, USCIS will consider all of the positive and negative factors applicable to the alien's case. The NPRM provides examples where a bond may be offered, including instances where allowing the alien to become a lawful permanent resident would offer benefits to national security, or would be justified for exceptional humanitarian reasons. As provided in the NPRM, DHS believes that offering a public charge bond in the adjustment of status context will generally only be warranted in limited circumstances in which the alien has no heavily weighted negative factors, but the presence of any such factors will not automatically preclude USCIS from offering the alien the opportunity to submit a public charge bond.

As this rule is implemented, USCIS will provide training and guidance in the USCIS Policy Manual to all officers in making these discretionary determinations to allow an alien to submit a bond.

Comment: A commenter asked for clarification on ''permitting an alien who is found inadmissible as a public charge but is otherwise admissible to submit a public charge bond is within DHS's discretion.''

Response: An alien who is found to be inadmissible only on the public charge ground may be permitted to submit a public charge bond. In other words, under section 213 of the Act, 8 U.S.C. 1183, the alien cannot be inadmissible under any other ground but the public charge ground in order for USCIS to consider exercising its discretion to permit the alien to submit a public charge bond. The decision whether to issue a public charge bond is at the sole discretion of USCIS; there is no right or entitlement to a public charge bond. Generally, USCIS will not favorably exercise its discretion in situations where the alien has one or more heavily weighted negative factors. In addition, USCIS is formulating training and policy guidance related to the exercise of this discretion to ensure that discretionary decisions on whether or not to offer a public charge bond are fair and consistent.

Comment: A commenter asked that DHS eliminate public charge bonds. A few commenters stated that the NPRM bond section lacks justification for changing current and longstanding procedure.

Response: DHS disagrees that the public charge bond should be eliminated. The public charge bond provision was established by Congress in the Immigration Act of 1952, in section 213 of the Act, 8 U.S.C. 1183,[758] and, as discussed in the NPRM,[759] has existed without essential variation since 1907.[760] Public charge bonds allow an alien who would otherwise be inadmissible because of the likelihood of becoming a public charge to nonetheless be admitted to the United States. Since the changes to immigration law implemented by IIRIRA, DHS has lacked a formal mechanism for the issuance of public charge bonds.[761] This rule creates a formal public charge bond procedure that conforms with both the statutory language and past practices.

Comment: Other commenters suggested that public charge bonds should be eliminated based on the history of monetary bonds in the criminal pre-trial context, which have been discredited as inefficient and unfair.

Response: DHS reiterates that public charge bonds are authorized under the Act,[762] and the Act provides a mechanism whereby DHS can nonetheless admit aliens who are inadmissible only under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). DHS cannot ignore this authority and must consider whether to exercise its discretion on a case-by-case basis to allow such aliens to submit a public charge bond.

DHS disagrees that a public charge bond is directly comparable to a pre-trial appearance bond. The Act states that the purpose of the public charge is

[756] *See* INA section 213, 8 U.S.C. 1183.

[757] *See* INA section 213, 8 U.S.C. 1183.

[758] *See* INA of 1952, section 213, 66 Stat. 163, 188.

[759] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51134 (proposed Oct. 10, 2018).

[760] *See* Act of February 20, 1907, ch. 1134, section 26, 34 Stat. 898, 907.

[761] *See* Public Law 104–208 (Sept. 30, 1996).

[762] *See* INA section 213, 8 U.S.C. 1183.

to hold the United States, and all states, territories, counties, towns and municipalities and districts harmless against bonded aliens becoming public charges.[763] USCIS will provide officers with guidance and training to ensure that discretion is exercised in a fair, efficient, and consistent manner.

Comment: A commenter opposed the implementation of a public charge bond and stated that while DHS created a distinction between the affidavit of support and the public charge bond in this rule, it did not provide support for the idea that the affidavit of support is an insufficient safeguard. A commenter stated that affidavits of support already give the Government sufficient assurances that an individual will not become overly reliant on the social safety net, without forcing immigrants to freeze significant assets in Government-held bonds.

Response: DHS disagrees that the affidavit of support sufficiently safeguards against an alien becoming a public charge after admission. Had Congress intended a sufficient affidavit of support to be the sole basis to safeguard against an alien becoming a public charge after admission, Congress would not have added the mandatory factors in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), to determine an applicant's likelihood of becoming a public charge. Congress would have simply required all applicants subject to public charge inadmissibility to submit a sufficient affidavit of support without requiring an assessment of the applicant's age, health, family status, assets, resources and financial status, and education and skills.

Additionally, had Congress considered the affidavit of support alone to be the best way to safeguard against an alien becoming a public charge, Congress would have eliminated the public charge bond provision altogether, and certainly would not have provided in section 213 of the Act, 8 U.S.C. 1183, for DHS to exercise its discretion to offer a public charge bond to aliens who may also be subject to the affidavit of support requirement at section 213A of the Act, 8 U.S.C. 1183a.[764] That Congress created the mandatory factors for consideration in a public charge determination at the same time it created the enforceable affidavit of support as a non-mandatory factor for consideration, while also retaining the public charge bond provision in section 213 of the Act, 8 U.S.C. 1183, suggests that Congress did not believe the enforceable affidavit of support, on its own, sufficiently safeguarded against an alien becoming a public charge after admission.

Comment: A few commenters stated that a public charge bond system is ''redundant and nonsensical,'' stating that the Government has not provided sufficient reasoning for adding the public charge bond system to the immigration process while the affidavit of support already exists and allows the Government to recoup the cost of public benefits received by immigrants.

Response: DHS disagrees with the comments that the public charge bond provisions are redundant and nonsensical in light of the affidavit of support requirement. Although the public charge bond provision pre-dates the creation of the affidavit of support requirements in IIRIRA, Congress expressly amended the public charge bond provision in IIRIRA by amending section 213 of the Act, 8 U.S.C. 1183, to reference the affidavit of support and require it as a condition for admission in some cases in addition to the posting of a public charge bond.[765] This means that Congress was aware at the time it created the enforceable affidavit of support and amended the public charge bond provision that a public charge bond could still be offered to certain aliens at the agency's discretion, in addition to the alien's submission of a sufficient affidavit of support. DHS's inclusion of public charge bonds in this rule is consistent with Congress' intent in maintaining public charge bonds after IIRIRA created the enforceable affidavit of support.

Comment: Commenters stated that the bonds would have a disproportionately negative impact on minorities, communities of color, and their families, citing studies on custodial bonds. Another commenter said that the changes to public charge bonds will not prevent individuals from bypassing new regulations and will affect average immigrants by restricting access to services. A few commenters stated that DHS should not expand the use of bonds because studies have shown that bonds have been proven to be highly discriminatory and increase financial instability. Many commenters provided research on the effects of custodial bonds and stated that bonds cause long-term hardship and increase the likelihood of financial instability. Many commenters said the use of public charge bonds would place an impossible burden on immigrant families, and there is no evidence that public charge bonds will prevent them from becoming dependent on government assistance in the future. Multiple commenters stated that families will face years of annual fees, non-refundable premiums and liens on the homes and cars put up as collateral charged by for-profit surety companies and their agents. A commenter stated that the bond system would result in a loss of money and adverse immigration consequences if the immigrant suffers an unexpected issue and is forced to forfeit their bond.

Response: As indicated above, DHS does not believe that the rule itself disproportionately negatively impacts certain groups, and does not believe the public charge bond provisions disproportionately impact particular groups. Although commenters cited studies on the effects of custodial bonds on particular communities, DHS does not believe the public charge bond is directly comparable to custodial bonds, and thus does not believe that such studies are directly applicable. Rather, public charge bonds offer an opportunity for an alien who is inadmissible, based only upon the likelihood of becoming a public charge, to be admitted to the United States. Breach of a public charge bond may result in loss of money and adverse immigration consequences. This is a result of the alien's action, and the longstanding statutory scheme. As noted above, USCIS will provide officers with guidance and training to ensure that USCIS' discretion to offer this opportunity is exercised in a fair and consistent manner.

Comment: A commenter stated that the public charge bond process would further complicate and increase inefficiency in the adjustment of status process. Specifically, the commenter said the creation of two new forms, and the accompanying processes and training, as well as the collection of any information therein, will be a waste of Government and applicant resources given the existence and ongoing adjudication of Form I–864. The commenter further stated that the public charge bond is unjust because it removes the intending immigrant as a

[763] *See* INA section 213, 8 U.S.C. 1183. While there is currently no statutory mechanism for DHS to directly reimburse benefit-granting agencies, the breached bond amounts will be deposited into an account designated by the U.S. Treasury for collecting breached immigration-related bond amounts.

[764] INA section 213, 8 U.S.C. 1183 reads, in part: ''An alien inadmissible under paragraph (4) of section 1182(a) of this title may, if otherwise admissible, be admitted in the discretion of the Attorney General (*subject to the affidavit of support requirement and attribution of sponsor's income and resources under section 1183a of this title*) upon the giving of a suitable and proper bond or undertaking approved by the Attorney General, in such amount and containing such conditions as he may prescribe, to the United States (. . .). [*Emphasis added*].

[765] *See* IIRIRA, Public Law 104–208, div. C, section 534(f), 110 Stat. 3009–546, 3009–684 (Sept. 30, 1996).

party to the agreement, such that he or she neither has power to act against the obligor, nor has the ability to reply to the Government's decisions.

Response: DHS disagrees that the bond process would increase inefficiency or that the process and training would be a waste of Government and applicant resources. DHS also disagrees that the existence of the Form I–864 obviates the need for new forms to facilitate the public charge bond process. The public charge bond is authorized by statute (separately from, and in addition to, the affidavit of support).[766] USCIS may choose to exercise its discretion to allow an alien to submit a bond in a particular case, allowing for aliens who are inadmissible to the United States based only upon the likelihood of becoming a public charge to nonetheless be admitted to the United States. DHS cannot decide to never exercise this public charge bond authority. USCIS will review its resources and personnel to ensure that it will be able to efficiently carry out its discretionary public charge bond authority. DHS does not believe the public charge bond would be a waste of Government resources or creates an undue burden on aliens. DHS also disagrees that the public charge bond is unjust in that it removes the intending immigrant as a party to the agreement. Although the commenter states that this leaves the alien unable to defend himself or herself against a breach of contract action, a breach of contract action against the alien in the case of an alien with a surety bond could only be asserted by the obligor, with whom the alien would be in contractual privity. With regard to appealing a USCIS breach determination or a denial of a request to cancel a surety bond, the process will be similar to the existing process for seeking review of such determinations in the custodial immigration bond context: *i.e.,* the obligor may challenge the determination before the Administrative Appeals Office (AAO) pursuant to 8 CFR part 103, subpart A. Like the appeals process in the long-established custodial bond context, an alien with a surety bond lacks standing to seek review in public charge bond context and is not ''removed'' from the process. In the case of an alien with a cash or cash equivalent bond, the alien would be the obligor and thus have standing to appeal a denial of a cancellation request or a breach determination. DHS disagrees that this longstanding process is unjust.

Comment: A few commenters stated that the NPRM creates a new market segment for commercial bond companies, but imposes an unfunded mandate on state and local insurance and financial services regulators. Similarly, these commenters and others said many non-citizens may accept the ''exceptionally harsh'' procedures and penalties and ''crippling surety bond terms'' to avoid family separation. The commenters stated that, in many cases, the non-citizen would have to pay the bond company up to 15 percent up-front, which could prove destabilizing for low and moderate-income families and stifle their ability to become self-sufficient. A commenter also stated that any new investment of USCIS resources to assess nonimmigrants on public charge would be an unnecessary administrative burden. Another commenter stated that broad and vague conditions governing breach of bonds heighten the risk of exploitation by for-profit companies managing public charge bonds.

Response: DHS understands the concerns about exploitation concerning public charge bond terms and conditions, and about the potential challenges that bond terms and conditions may pose to aliens with limited resources. However, Congress has determined that the public charge ground of inadmissibility is necessary. DHS has congressional authority to consider whether to allow an alien, inadmissible only on the public charge ground, to submit a public charge bond, (including a surety bond), on a case-by case basis in the exercise of its discretion. DHS has decided to exercise its authority in cases involving applicants for adjustment of status who are inadmissible only under section 212(a)(4), 8 U.S.C. 1182(a)(4). As provided in the NPRM, DHS will accept surety bonds only from sureties certified by the Department of Treasury and listed in the Treasury Department Circular 570.[767] Department of Treasury-certified sureties have agents throughout the United States from whom aliens could seek assistance in procuring an appropriate bond.[768] The Department of the Treasury certifies companies only after having evaluated a surety company's qualifications to underwrite Federal bonds, including whether those sureties meet the specified corporate and financial standards. Under 31 U.S.C. 9305(b)(3), a surety (or the obligor) must be able to carry out its contracts and must comply with statutory requirements, including prompt payment of demands arising from an administratively final determination that the bond has been breached. DHS believes these safeguards reduce the risk that aliens will be exploited. DHS also notes that whether the availability of public charge bonds imposes an unnecessary administrative burden on USCIS is a question for Congress, not DHS.

DHS also disagrees that it imposes an unfunded mandate on state and local insurance and financial services regulators through this rulemaking. As part of the NPRM,[769] DHS analyzed any impact on State, local, and tribal governments in accordance with the Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) [770] and with E.O. 13132 (Federalism). The obligation to regulate various aspects of the financial and securities markets within states is already a function of the Federal Government; DHS does not further impose any new unpaid mandate on State, local or tribal governments by implementing a public charge bond procedure in accordance with section 213 of the Act, 8 U.S.C. 1183. It is up to financial institutions, authorized to conduct business according to the provisions implemented by states, to offer public charge bond products. This rule does not impose any new obligations on states.

2. Bond Amount

Comment: One commenter said DHS should reduce the proposed bond amount. Commenters stated that a $10,000 bond was excessive and would create an opportunity for private bond companies to exploit immigrant families, the elderly, and minorities. Similarly, a few commenters stated that even the minimum amount may be beyond the means of most families. A couple of commenters stated that increasing the minimum amount of the bond by one thousand percent was grossly unfair. Many commenters added that the cost was prohibitive for applicants who earn low incomes. Many commenters stated that a family's self-sufficiency would be destabilized and provided example scenarios where families would be required to pay up to 15 percent of $10,000.

A commenter stated that DHS provided no guidance on how evaluation of public charge bond sizes will be made. Another commenter asked that the value of the public charge bond

[766] *See* INA section 213, 8 U.S.C. 1183.

[767] *See* 8 CFR 103.6(b); *see also* proposed 8 CFR 103.6, as published in 83 FR 25951 (June 5, 2018).

[768] *See* Dep't of Treasury Circular 570, *Listing of Approved Sureties* (July 1, 2018).

[769] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51276 (proposed Oct. 10, 2018).

[770] *See* Pub. L. 104–4, 109 Stat. 48 (Mar. 22, 1995).

be based on the value provided for monetizable benefits under 8 CFR 212.21, which is 15 percent of the per-month Federal Poverty Guidelines for a single person. A few individual commenters asked that the minimum public charge bond be set to specific amounts, such as $1,000 or $8,100.

In contrast, another commenter asked that DHS increase the minimum bond amount to $25,000 for the least educated or individuals with the most dependents. Similarly, a commenter stated that the $10,000 bond does not cover the potential cost of supporting individuals who need food, shelter, or medical treatment.

Response: DHS agrees with the commenter that for consistency with prior agency practice, a minimum bond amount of $8,100, adjusted annually for inflation, is appropriate, as this is equal to the prior bond minimum adjusted for inflation. The amount of the bond represents liquidated damages to compensate the Government for all harms caused by a bonded individual who violates the terms, not simply the value of the benefits used. Furthermore, some public benefits do not have an easily quantifiable dollar value. Operational challenges make separate determinations for public benefits that are distributed in quantifiable and non-quantifiable values unfeasible. Making liquidated damages in an amount similar to historical precedent is a reasonable remedy.

Under this rule, public charge bonds permit DHS to admit, in its discretion, an adjustment of status applicant who is inadmissible based only on the public charge ground. Should DHS not exercise its public charge bond authority in a particular case based on a review of the individual facts and circumstances of that case, DHS will deny the adjustment of status application. DHS acknowledges that an individual offered a bond has already been found likely to become a public charge and that bond expenses may further destabilize an applicant's self-sufficiency. However, the additional assurance provided by the bond is necessary to overcome the finding of inadmissibility due to likelihood of becoming a public charge. Each applicant offered the opportunity to post a public charge bond will have to evaluate whether accepting the obligations of the public charge bond is the right decision given his or her circumstances.

As part of the implementation of the public charge bond, USCIS will provide training and guidance to all officers in making these discretionary determinations to allow an alien to submit a public charge bond, and the amount of any such bond.

3. Public Charge Bond Cancellation

Comment: A commenter stated that the terms of cancellation of the public charge bond are unreasonable. The commenter stated that since DHS only predicts less than three percent of immigrants would be able to cancel their bond, surety companies would set costly parameters and payment schedules. The commenter further stated that the process of cancelling the public charge bond is difficult because an obligor must apply to have the bond cancelled, the application must be approved by DHS, and bonds are not automatically released after completion.

Response: DHS disagrees that the bond cancellation terms are unreasonable. Consistent with the statute, public charge bonds may be cancelled where an alien is no longer likely to become a public charge, either because the alien naturalized, died, or permanently departed the United States. Additionally, an alien may apply for cancellation of the bond if the alien obtains a different immigration status that is exempt from the public charge inadmissibility provisions, or if the alien has reached his or her five-year anniversary since becoming a lawful permanent resident. Cancellation is not automatic and does not limit the duration of the bond, which remains in effect until canceled.

DHS also disagrees that the cancellation process is unreasonable. An application for cancellation must be made so that DHS can verify that the alien or surety have met their burden of demonstrating that one of the public charge bond cancellation conditions has been met, including that the bond was not breached, before the public charge bond can be cancelled and the funds released. DHS carefully considered the suggestion that public charge bonds be automatically released upon completion of the terms of the bond, but determined that no viable mechanism would ensure that the necessary conditions have been met in each case.

4. Breach of Public Charge Bond

Comment: A few commenters stated that the NPRM prioritizes the revenue streams of private bond companies over family unity because in the event of a breach of public charge bond, the principal would have to reimburse the bond company the full amount of the breach penalty. Several commenters stated that DHS should not be entitled to recoup the entire bond amount in the event of a breach by receipt of a public benefit. The commenter also stated that DHS should allow use of Medicaid as an exception to the breach of the full bond.

Response: DHS disagrees that the rule prioritizes the revenue of bond companies over family unity. The public charge bond allows aliens who are inadmissible to nonetheless seek admission to the United States upon posting of a public charge bond, which facilitates family unity. Additionally, the fees and collateral submitted to the bond company are compensation for the risk a bond company takes in guaranteeing the alien's conduct under the bond. This rule is not aimed at enriching private bond companies, but rather at ensuring that aliens subject to the public charge ground of inadmissibility are self-sufficient and are relying on their resources and those of their family, friends, and sponsors.

As explained above, DHS will collect the full amount of the public charge bond, as liquidated damages, because DHS considers it difficult, if not impossible, to calculate the alien's public benefit receipt as well as the government's costs. DHS will not exempt Medicaid from the benefits listed that count towards the breach of a public charge bond. A public charge bond is issued on the condition that the alien does not become a public charge by not using the public benefits, as defined in 8 CFR 212.21(b) for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months). As is generally the case for the benefits listed in 8 CFR 212.21(b), Medicaid is one of the public benefits that constitute a major expenditure for the United States and the use of it generally indicates to DHS that the person may not be self-sufficient. Correspondingly, a public charge bond is issued under the condition that the alien does not use the benefits listed in 8 CFR 212.21(b), including Medicaid, and DHS declines to exempt its use from being a breach condition.

Comment: A commenter presented research and stated that monetary bonds would not be efficient or effective. Other commenters stated that the minimum bond amount bears no real relationship to the value of the public benefit that is received. Several commenters stated that breach of public charge bond would lead to economic destabilization for families.

Response: The face value of the public charge bond constitutes liquidated damages for a breach of the conditions of that bond. As explained in the NPRM, liquidated damages are an appropriate remedy in situations such as the public charge bond, where the total damages to

the Government are difficult, if not impossible to calculate.[771] Additionally, these damages go beyond the simple amount of the benefits received (which are not always calculable), but also the overhead of the benefit agency in administering the benefit. DHS disagrees that monetary bonds are ineffective. The purpose of a bond is to provide some reimbursement for harms incurred should the alien violate the terms of the bond. As stated above, the $8,100 minimum amount of the public charge bond is consistent with the historical public charge bond minimum, that has been found reasonable and enforceable, adjusted for inflation.

Comment: A commenter said the rule's requirements around breach of the public charge bond are unfair, put immigrants in economic jeopardy, and are a huge departure from previous policy. The commenter also stated that the rule removes the phrase ''substantial violation'' from the conditions for breaching bond, meaning that any breach of the terms of the bond, which are not fully outlined in the rule, would render the obligor liable for the full amount of the bond. The commenter stated that this creates a punitive policy against intending immigrants instead of fulfilling the purported purpose of recouping losses from public benefits use. The commenter also stated that this unnecessarily puts immigrants at great financial risk.

Response: DHS disagrees with these comments. The conditions that constitute breach of a public charge bond are listed in 8 CFR 213.1(h)(1) and (2), and state that a public charge bond is breached if the alien received public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months) after the alien's adjustment of status to that of a lawful permanent resident or if any other condition of the public charge bond is violated, with limited exceptions. In particular, public benefits that are exempt from being considered, as outlined in 8 CFR 212.21(b), including while present in a status exempt from public charge, do not count towards the breach determination as explained in the NPRM. To make the bond provisions consistent with the amended public benefits definition of 8 CFR 212.21(b), DHS has also amended the regulatory bond provision to clarify that public benefits received after having been granted a waiver of inadmissibility from public charge will not be considered as part of the breach determination.[772] As detailed in 8 CFR 213.1(h)(3), DHS will determine whether the conditions of the bond have been breached, and 8 CFR 213.1(h) provides that an administratively final determination that a bond has been breached creates a claim in favor of the United States. Such a breach determination is administratively final when the time to file an appeal with the AAO pursuant to 8 CFR part 103, subpart A, has expired or when the appeal is dismissed or rejected.

As explained in the NPRM,[773] under the breach of bond provisions at 8 CFR 103.6(e), an immigration bond is considered breached if there has been a substantial violation of the stipulated condition. The term ''substantial violation'' is generally interpreted according to contractual principles.[774] However, in the NPRM, DHS proposed to incorporate the substantial violation standard via incorporating principles that govern the public charge and public benefits definitions.[775] As explained in the statute, the public charge bond is intended to hold the United States, and all states, territories, counties, towns and municipalities and districts harmless against aliens becoming a public charge.[776] Whether the public charge bond is unnecessary or punitive is a question for Congress, not DHS.[777]

Comment: Some commenters stated that the Government receiving full bond payment in those circumstances when the public benefits paid out are less than the full amount of the bond is unfair, unjust, and unlawful. A commenter further stated that the proposed regulations imposed an unlawful and strict standard for accidental, or inadvertent violations of bond conditions. Another commenter said the NPRM does not offer a coherent explanation for why recovery of the entire amount is appropriate, asserting that it makes little sense to forfeit the entire bond since DHS itself asserts that the purpose of the bond is to ''recoup [the] cost of public benefits received.'' A commenter stated that in the case of a breach of public charge bond, the individual should only be responsible for the specific amount of benefits received rather than ''arbitrary liquidated damages award.''

A commenter indicated that the proposal to require forfeiture of the entire amount of the bond upon a showing that an alien has obtained any public benefit whatsoever is arbitrary, capricious and, as the commenter stated that DHS acknowledges, contrary to past practice, under which only the amount of the benefit would be forfeited. The commenter also indicated that this makes little sense particularly since many immigrants may be unclear as to the precise conditions that would result in forfeiture. The commenter stated that total forfeiture should be limited to the rare instances in which DHS can prove by a preponderance of the evidence that the alien intentionally sought public benefits with the knowledge that such benefits would result in bond forfeiture; in other instances, the commenter suggested, forfeiture should be limited to the amount of benefits received plus a surcharge for the administrative costs of collection.

Response: DHS disagrees. As explained in the NPRM, liquidated damages are an appropriate remedy in situations such as the public charge bond, where the total damages to the Government are difficult, if not impossible to calculate and the amount of the damages is reasonable.[778] Additionally, these damages go beyond the simple amount of the benefits received, encompassing not only the monetary value of the benefits received (which frequently are not calculable) but also the overhead of the benefit agency in administering the benefit.

As stated in the NPRM,[779] the minimum amount of the public charge bond is consistent with historical public charge bond amounts, adjusted for inflation, that have been found reasonable and enforceable. Historically, public charge bonds have been forfeited in their entirety upon breach.[780] The conditions that constitute breach of a public charge bond are delineated fully in 8 CFR 213.1(h)(1) and (2), and any alien offered a bond has ample opportunity to review the conditions and terms before agreeing to these terms. Additionally, as explained in the

[771] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51226 (proposed Oct. 10, 2018).

[772] *See* 8 CFR 213.1(h)(4).

[773] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51125 (proposed Oct. 10, 2018).

[774] *See, e.g., Aguilar* v. *United States,* 124 Fed. CL 9, 16 (2015) (discussing substantial violation under 8 CFR 103.6(a) in relation to a delivery immigration bond.)

[775] *See* 8 CFR 212.21(a) and (b).

[776] *See* INA section 213, 8 U.S.C. 1183.

[777] *See* INA section 213, 8 U.S.C. 1183.

[778] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51226 (proposed Oct. 10, 2018).

[779] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51221 (proposed Oct. 10, 2018).

[780] *See, for example, United States* v. *Goldberg,* 40 F.2d 406 (2d Cir. 1930); *see Matta* v. *Tillinghast,* 33 F.2d 64 (1st Cir. 1929); *Ill. Surety Co. v United States,* 229 F. 527 (2d Cir. 1916); *United States* v. *Rubin,* 227 F. 938 (E.D. Pa 1915); *Matter of B-,* 1 I&N Dec. 121 (BIA 1941).

NPRM,[781] under the current breach of bond provisions of 8 CFR 103.6(e), an immigration bond is considered breached if there has been a substantial violation of the stipulated condition. The term ''substantial violation'' is generally interpreted according to contractual principles.

Comment: A commenter stated that the NPRM's proposals for the appeal of public charge bond decisions are unfair because the obligor must pay a $675 fee to have the same officer who issued the initial denial review that decision, and because throughout the process, the alien must rely on the obligor to complete the steps, as the alien is not a party to the bond contract. A commenter further stated that the proposed rule would hinder the ability of noncitizens to meaningfully challenge harsh or arbitrary breach determinations.

Response: DHS disagrees. The public charge bond appeal process as described in the NPRM is a long established and accepted method of disputing initial USCIS determinations. It is possible for obligors to appeal errors in either law or fact through well-established administrative remedies via the AAO without having to resort to bringing suit in a Federal court. Although the alien is not a party to the surety bond contract with DHS, the rule does not impair his or her ability to pursue or defend against traditional contract actions with regard to the obligor, with whom he or she is in contractual privity. Similarly, if the alien is the obligor in that the alien submits a cash equivalent bond, the alien would be able to defend against a breach determination. Requiring USCIS to set up a separate and distinct review process for bond appeals would be unnecessarily burdensome and redundant.

Comment: An individual commenter said the NPRM would add further fees and expenses to an already costly process. Some commenters provided a discussion of the costs associated with filing a public charge bond application and filing an appeal. The commenters said immigrants would be inflicted with expensive fees and fines.

Response: USCIS is primarily funded by fees. Congress mandated that DHS may set IEFA fees in a manner commensurate with the expense of adjudicating the benefits in question.[782] The cost of filing a public charge bond may be assessed in the USCIS fee rule, as are other USCIS fees.

Comment: A commenter stated that the bond requirement should not be limited to surety bonds but should instead allow for cash, cashier's check, or money order. Another commenter stated that USCIS should accept only surety bonds, not cash or equivalents, until the effectiveness of the bonding process can be assessed in practice. This commenter recommended that only limited-duration bonds be accepted, at least initially. The commenter indicated that a periodic bond renewal process would provide valuable private sector monitoring of the alien's compliance, especially where the time period between bond acceptance and eligibility for cancellation extends over multiple years.

Response: DHS agrees that bonds should not be limited to surety, and plans to accept cash equivalents once the proper accounts and procedures can be established. DHS disagrees that it is necessary to wait until the effectiveness can be established before accepting cash bonds. The nature of cash bonds makes it unlikely that any situation would arise where DHS would have more difficulty collecting for a breached cash bond than for a breached surety bond. DHS also disagrees that only limited duration bonds be accepted initially. As a commenter has noted, public charge bonds of limited duration place an additional burden in both time and money on both the bonded alien and DHS, as they must be periodically renewed and these renewals must be reviewed by DHS. For this reason, DHS will only accept public charge bonds of unlimited duration.

Comment: One commenter stated that if immigrants can afford to pay the high cost of a guide to cross the border illegally, they can probably afford a bond to guarantee their stay in the United States.

Response: DHS appreciates concerns raised about illegal entry but stresses that the public charge inadmissibility rule assesses an applicant's likelihood of becoming a public charge at any time in the future. Whether an alien paid a guide to enter the United States without permission, in and of itself, is not relevant to the public charge inadmissibility determination, or to whether DHS should exercise its discretion and allow an alien inadmissible only on the public charge ground to submit a public charge bond.

Comment: A commenter stated that the government receiving full bond payment in those circumstances when the public benefits paid out are less than the full amount of the bond is unfair, unjust, and unlawful.

Response: DHS disagrees that forfeiture of the full bond amount in the event of breach is unfair, unjust, or unlawful. The amount is based on a review of the amount originally provided by 8 CFR 213.1 in 1964,[783] adjusted for inflation, to represent present dollar values.[784] Further, the face value of the bond constitutes liquidated damages for a breach of the conditions of that bond. As explained in the NPRM,[785] liquidated damages are an appropriate remedy in situations such as the public charge bond, where the total damages to the government are difficult, if not impossible to calculate. Additionally, these damages go beyond the simple amount of the benefits received, encompassing not only the monetary value of the benefits received but also the overhead of the benefit agency in administering the benefit.

The public charge bond is offered to allow aliens who are otherwise inadmissible due to a likelihood of becoming a public charge an opportunity to overcome that finding of inadmissibility. The conditions that constitute breach of a bond are delineated fully in 8 CFR 213.1(h)(1) and (2), and any alien offered a bond has ample opportunity to review them before agreeing to these terms. Additionally, as explained in the NPRM,[786] under the current breach of bond provisions of 8 CFR 103.6 an immigration bond is considered breached if there has been a substantial violation of the stipulated condition. The term ''substantial violation'' is generally interpreted according to contractual principles.[787] However, in the NPRM, DHS proposed to incorporate the substantial violation standard via incorporating principles that govern the public charge and public charge benefits definitions.[788] Whether the public charge bond is punitive is a matter for Congress; however, per the Act, the public charge bond's purpose is to hold the United States, and all states, territories, counties, towns and municipalities and districts harmless

[781] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51125 (proposed Oct. 10, 2018).

[782] *See* INA section 286(m), 8 U.S.C. 1356(m).

[783] Miscellaneous Amendments to Chapter, 29 FR 10579 (July 30, 1964).

[784] DHS uses the semi-annual average for the first half of 2018 and the annual average from 1964 from the historical CPI–U for U.S. City Average, All Items. *See https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-201806.pdf* (last visited July 26, 2019).

Calculation: Annual average for 1st half of 2018 (250.089)/annual average for 1964 (31) = 8.1; CPI–U adjusted present dollar amount = $1,000 * 8.1 = $8,100.

[785] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51226 (proposed Oct. 10, 2018).

[786] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51125 (proposed Oct. 10, 2018).

[787] *See, e.g., Aguilar* v. *United States,* 124 Fed. CL 9, 16 (2015) (discussing substantial violation under 8 CFR 103.6(a) in relation to a delivery immigration bond.)

[788] *See* 8 CFR 212.21(a) and (b).

against bonded aliens becoming public charges.[789]

Comment: A commenter indicated that sponsors of religious workers may not possess the financial ability of typical U.S. employers, and may not be able to afford a bond.

Response: DHS acknowledges that special immigrant religious workers, and immigrants who perform religious work generally, provide valuable contributions to the United States and are in a special position, as acknowledged by Congress in the special immigrant religious worker classification.[790] Congress, however, did not exempt these workers from the public charge ground of inadmissibility and therefore, DHS will not exempt them in this rule. The public charge bond provides a way for individuals who would otherwise be inadmissible due to likelihood of becoming a public charge to overcome that finding. While DHS will take into account the totality of the circumstances regarding all applicants, and will adjudicate the applications of religious workers in light of the unique conditions under which many of them live and work, in those instances where a bond is offered it is already an extraordinary exercise of discretion to allow the alien to adjust status in the United States even when found inadmissible as likely to become a public charge. It is up to the applicant to determine whether it is in his or her best interests to accept the offered opportunity to post a public charge bond, and this rule does not require that the sponsor post the bond, rather this obligation is on the alien and the bond maybe posted by any entity or individual that can serve as an obligor under section 8 CFR 103.6 and 213.1. DHS declines to further modify this exercise of discretion based upon either the nature of the applicant's employment or the immigration classification in which the alien seeks to adjust status.

T. Effective Date(s)

Comment: Many commenters asked that the proposed rule be delayed as long as possible. One commenter noted that the verification requirements related to the Form I–944 would create new challenges and impose great burdens on State and local agencies. Another commenter requested that the rule be delayed as long as possible not only because of the impact on agencies but also because of the impact on the legal services community and ethnic community-based organizations who would bear the brunt of dealing with immigrants fearful about how the new requirements will affect them and their families. Another commenter said DHS should time the publication of the final rule so that the effective date falls within an ACA marketplace open enrollment period, so that those who are currently using Medicaid or CHIP and who may be affected by this rule, may discontinue that benefit and switch to an ACA marketplace plan without an interruption in health insurance coverage. A couple of commenters stated that the 60-day effective date may be insufficient and reasoned that DHS should delay the effective date of any final regulation until at least January 1, 2020, or one year after the publication of the final rule, which would minimize disruption to the markets, decrease consumer confusion of mid-year changes, and allow affected entities to adjust their outreach, messaging, and technology to accommodate the changes. A commenter asked that the proposed rule be delayed a minimum of three years to allow states to implement a comprehensive education program. Another commenter stated that if any changes are implemented public agencies will need far longer than 60 days to prepare, noting that contracts will need to be obtained with vendors in order to reprogram computer systems, all materials pertaining to immigrant eligibility will need to be reviewed, workers will need to be trained, and funding will need to be appropriated in order to do these things through a state's budget cycle. The commenter cited to the Medicaid expansion which, though passed in 2010, was not set to be implemented until January 2014; computer systems and other processes were not ready nearly 4 years later, causing adverse impacts on Californians. Another commenter detailed other impacts or administrative burdens the rule would place on benefit-granting agencies. These impacts include needing to provide aliens with documentation regarding benefit receipt, responding to inquiries from the public, updating communication materials, and increased caseload.

Response: DHS is retaining the 60-day effective date. Relatedly, DHS is also clarifying that DHS will apply the public charge final rule only to applications and petitions (in the context of extensions of stay or changes of status) postmarked (or if applicable, electronically submitted) on or after the effective date of the final rule. Applications and petitions pending with USCIS on the effective date of the rule, *i.e.* were postmarked before the effective date of the rule and were accepted by USCIS pursuant to 8 CFR 103.2(a)(1) and (a)(2)) will not be subject to the rule. For the purposes of determining whether a case was postmarked before the effective date of the rule, DHS will consider the postmark date for the application or petition currently before USCIS, not the postmark date for any previously-filed application or petition that USCIS rejected pursuant to 8 CFR 103.2(a)(7)(ii).

In addition, DHS will not consider the receipt of public benefits excluded under the 1999 Interim Field Guidance unless such benefits are received on or after the effective date of the final rule.

As DHS stated elsewhere in this rule, DHS is not imposing any requirements on benefit-granting agencies through this final rule or a requirement that these agencies specifically verify the information provided on the Form I–944. While the Form I–944 includes a Federal Agency Disclosure and Authorization, that part of the form will only become relevant after DHS enters into information sharing agreements with specific agencies to obtain verification of the information supplied by applicants. DHS expects that this process will take time and will likely be in effect at some point in the future after the final rule becomes effective. In addition, any such information sharing will depend on the ability of the relevant agencies to share such information with DHS. Because this aspect of the rule's implementation will necessarily involve inter-agency collaboration, DHS does not believe that delaying the effective date of the final rule beyond 60 days will be necessary to address the agencies' concerns related to the verification of information on Form I–944.

DHS is also not altering an alien's eligibility for public benefits, and therefore does not believe that agencies would have to change their guidance in that regard. The rule specifies what public benefits will be considered in the public charge inadmissibility determination. DHS encourages agencies to update their web pages and guidance to direct recipients of public benefits to DHS guidance related to this final rule rather than repeat or explain what receipt of public benefits may make a person a public charge. While aliens may choose to disenroll from benefits to ensure the public benefit threshold is not triggered, DHS is moving to a duration-only threshold, aliens will have more time to adjust

[789] *See* INA section 213, 8 U.S.C. 1183.

[790] For example, special immigrant religious workers under section 101(a)(27)(C), 8 U.S.C. 1101(a)(27)(C) qualify for adjustment of status under INA section 245(a), notwithstanding certain bars under INA section 245(c).

their conduct in response to this rule. Therefore any potential increase in agencies' caseloads will likely be spread over a longer period of time which would eliminate the need to further extend the effective date of the final rule.

Finally, DHS is also not requiring that benefit-granting agencies develop new documentation of benefits provided, but will accept documentation already provided in the normal course of benefit administration. Such documentation should be adequate given that DHS is simplifying the threshold standard to focus exclusively on the duration of receipt and not the amount. DHS notes that examples of implementation of the Medicaid expansion program are not apt for comparison to the implementation of this rule for the reasons explained above, namely, that this rule imposes no direct obligations on benefit-granting/administering agencies, and it does not modify eligibility criteria for the benefits covered by this rule.

With respect to comments requesting time so aliens can move from Medicaid to obtaining private health insurance through the ACA marketplaces, DHS notes that it believes aliens will have sufficient time to obtain private health insurance through the ACA marketplaces. Additionally, Medicaid benefits included in the definition of public benefit will only be a heavily weighted negative factor in the totality of the circumstances if the alien receives Medicaid for more than 12 months in the aggregate, beginning 36 months before the alien filed for adjustment of status. The open enrollment period for 2020 will run from November 1, 2019 to December 15, 2019.[791] Because USCIS will only consider benefits covered under this final rule if received on or after the effective date of the final rule, and given that this rule published on August 14, 2019, aliens will have sufficient time to disenroll from Medicaid and enroll in private health insurance through the ACA marketplaces without incurring a heavily weighted negative factor for purposes of the public charge inadmissibility determination. Therefore, DHS will implement the rule within 60 days from the date of publication.

Comment: A commenter stated that DHS does not provide sufficient notice to noncitizen benefit recipients of TANF, SSI, or general assistance about the impact of benefits received prior to the effective date of the rule. The commenter requested that DHS use the ''primarily dependent'' standard for TANF, SSI, and general assistance benefits received prior to the effective date of the rule.

Response: DHS disagrees that it has given recipients of public benefits inadequate time to make decisions about receiving public benefits before the effective date of this rule. Through the NPRM, DHS provided advance notice to the public that DHS was changing which public benefits would be considered in public charge inadmissibility determinations. The NPRM's provisions, coupled with the 60-day effective date of the final rule, provided adequate notice to the regulated public with respect to the possible consequences associated with the receipt of public benefits.[792]

DHS notes that in this final rule, DHS will not consider public benefits listed in 8 CFR 212.21(b) that were previously excluded under the 1999 Interim Field Guidance if received before the effective date of this final rule. DHS will continue to consider benefits listed in 8 CFR 212.21(b) that were previously considered under the 1999 Interim Field Guidance if received before the effective date of the final rule.[793] The receipt of such benefits would not be considered as a heavily weighted negative factor. In addition, DHS is clarifying that this final rule will not apply to any applications or petitions postmarked before the effective date and accepted by USCIS pursuant to 8 CFR 103.2(a)(7)(ii), and are pending on the effective date of the final rule, but only to applications or petitions postmarked (or if applicable, electronically submitted) on or after the effective date of the final rule.

Comment: A commenter stated that the proposed rule should be applied to applications filed on or after the effective date. Pending applications would be affected by the new rule and would place a strain on DHS to re-interview and re-adjudicate applications that are already pending. In contrast, one commenter stated the rule, if implemented, needs to apply retroactively at some point in order to remove green cards from individuals who may have already received them and who could be deemed public charges under the proposed rule.

Response: DHS agrees that the rule will not be applied to applications pending on the effective date of the rule, *i.e.* were postmarked (or if applicable, electronically submitted) and were accepted by USCIS pursuant to 8 CFR 103.2(a)(1) and (a)(2) the effective date of the rule and were accepted by USCIS pursuant to 8 CFR 103.2(a)(1) and (a)(2). As discussed above, DHS will continue to review such cases under the 1999 Interim Field Guidance. For the purposes of determining whether a case was postmarked before the effective date of the rule, DHS will consider the postmark date for the application or petition currently before USCIS, not the postmark date for any previously-filed application or petition that USCIS rejected pursuant to 8 CFR 103.2(a)(7)(ii).

DHS will only apply this final rule to applications for admission or applications or petitions for immigration benefits postmarked (or if applicable, electronically submitted) on or after the effective date of the rule. DHS does not anticipate a strain on USCIS resources due to the effective date of this final rule. By applying the public charge rule to applications postmarked on or after the effective date, DHS ensures a smooth implementation and ample notice to applicants and petitioners.

Benefits Received Before Effective Date and Previously Excluded Benefits

Comment: Several commenters generally opposed the consideration of benefits received before the effective date of the rule, and that the 1999 Interim Field Guidance should be applied to any receipt of benefits prior to the effective date of the final rule. Some commenters disagreed with this portion of the rule, stating it runs counter to the original purpose of the

[791] *https://www.healthcare.gov/quick-guide/dates-and-deadlines/* (last visited May 1, 2019).

[792] *See, e.g., Alcaraz* v. *Block,* 746 F.2d 593, 611 (9th Cir. 1984) (''In addition to the pre-promulgation procedures, 5 U.S.C. 553(d) provides for a 30-day lag time between the rule's publication and its effective date. This post-adoption delay in effectiveness affords parties affected by the regulations reasonable time in which to adjust their conduct or take other measures.'') (citations omitted).

[793] Under the 1999 Interim Field Guidance, DHS would consider the current receipt of cash benefits for income maintenance or long-term institutionalization at government expense in the totality of the circumstances. *See* Field Guidance on Deportability and Inadmissibility on Public Charge Grounds, 64 FR 28689, 28690 (May 26, 1999) (''If at the time of application for admission or adjustment an alien is receiving a cash public assistance for income maintenance or is institutionalized for long-term care (as discussed in section 6, below), that benefit should be taken into account under the totality of the circumstances test, along with the other statutory factors under section 212(a)(4)(B)(i) and any [adjustment of status].''). DHS would also consider past receipt of cash benefits for income maintenance or long-term institutionalization at government expense in the totality of the circumstances. *See* Field Guidance on Deportability and Inadmissibility on Public Charge Grounds, 64 FR 28689, 28690 (May 26, 1999) (''[P]ast receipt of cash income-maintenance benefits does not automatically make an alien inadmissible as likely to become a public charge, nor does past institutionalization for long-term care at government expense. Rather this history would be one of many factors to be considered in applying the totality of the circumstances test.'').

public charge test and the 1999 Interim Field Guidance standard by which individuals are becoming a public charge. A commenter expressed disapproval of this section of the rule because it would impact family members who rely on cash benefits.

Another commenter stated that the proposed rule could be retroactively applied so that immigrants' receipt of benefits prior to the effective date of the rule would be considered in a public charge determination. The commenter provided readings of the proposed regulatory text against the 1999 Interim Field Guidance, arguing that SNAP, specifically, could ''fall through the cracks.'' Other commenters stated that this part of the rule lacked clear guidance and proved difficult to implement, providing examples and saying this section will be unfair and unworkable. A commenter requested that DHS use the ''primarily dependent'' standard for TANF, SSI, and general assistance benefits received prior to the effective date of the rule. A commenter said this portion of the rule is in contrast with what many social workers have advised their clients on in the past.

Response: DHS acknowledges that the public charge inadmissibility standard in this final rule is a departure from the 1999 Interim Field Guidance. However, this final rule as it pertains to public charge inadmissibility will only apply to applications for admission or adjustment of status postmarked (or if applicable, electronically submitted) on or after the effective date of the rule. For any application for admission or adjustment of status postmarked (or if applicable, electronically submitted) and pending before the effective date of the rule, USCIS will apply the 1999 Interim Field Guidance. For the purposes of determining whether a case was postmarked before the effective date of the rule, DHS will consider the postmark date for the application or petition currently before USCIS, not the postmark date for any previously-filed application or petition that USCIS rejected pursuant to 8 CFR 103.2(a)(7)(ii).

Additionally, for any application for admission or adjustment of status postmarked (or if applicable, electronically submitted) on or after the effective date of the rule, if the alien received any included public benefit listed in the 1999 Interim Field Guidance (cash assistance for income maintenance, including SSI, TANF, and general assistance) before the effective date of the rule, DHS will consider those benefits as they would have been considered under the 1999 Interim Field Guidance. In other words, for adjustment of status applications filed on or after the effective date of the rule, an applicant's receipt of any of the benefits listed in the 1999 Interim Field Guidance prior to the effective date of the rule will be treated as a negative factor in the totality of the circumstances, as they were in the 1999 Interim Field Guidance. Public benefits that were not considered in the 1999 Interim Guidance, such as SNAP, would not be considered at all in the public charge inadmissibility determination; they would only be considered if received on or after the effective date of the rule. However, regardless of the length of time such benefits were received before the effective date of this rule, or the monetary amount of such benefits, DHS will not treat the receipt of these benefits as a heavily weighted negative factor, as set forth in 8 CFR 212.22(d).

DHS believes that it has minimized any adverse effects on applicants as a result of having received benefits that were listed in the 1999 Interim Field Guidance before the effective date of this rule. DHS believes that recipients of public benefits listed in the 1999 Interim Field Guidance are being given adequate time to make decisions about receiving public benefits on or after the effective date of this rule. The NPRM's discussion of how DHS would treat past receipt of benefits listed in the 1999 Interim Field Guidance, this rule's explanation of how such benefits will be treated, and the proposed 60-day effective date of the final rule, provide aliens an opportunity to discontinue the receipt of any public benefits before filing an application for admission or adjustment of status and provides an opportunity for public benefit-granting agencies to communicate the consequences of receiving public benefits, to the extent such agencies deem appropriate.

With respect to the public benefit condition for extension of stay and change of status, DHS will not consider any receipt of public benefits that occurred before the effective date of this final rule.

Comment: A commenter proposed that a 3-year grace period be applied for the consideration of previously excluded benefits. The commenter indicated that, in some cases, the receipt of benefits for up to 3 years prior to the proposed rule's enactment could count against immigrants, and that such an outcome would be absurd in light of the standard 3-year cycle process for benefits. The commenter indicated that people should not be punished for following the standard 3-year cycle process for receiving benefits which are currently excluded from the public charge determination, or for not being able to obtain a termination letter quickly enough.

Response: DHS appreciates the suggestion but declines to incorporate a 3-year grace period for previously received benefits. As previously indicated, the rule will only consider all benefits as listed in 8 CFR 212.21(b) if the application was filed on or after the effective date. For benefits received before the effective date and were also considered under the 1999 Interim Field Guidance, USCIS will only consider the benefits as they would have been considered under the 1999 Interim Field Guidance. The rule will become effective within 60 days, which DHS believes is sufficient time for aliens to terminate any currently received public benefits that may be reviewed in the public charge inadmissibility determination.

Comment: Commenters stated that such a rule should not be applied to immigrants already in the United States who are on a pathway to ''legalization'' (who are ''in line'').

Response: DHS disagrees with the comment that the rule will be applied to applicants with applications pending on the day the rule goes into effect. This rule only applies to applications for admission or adjustment of status postmarked (or if applicable, electronically submitted) on or after the effective date of the rule. Individuals who have applications pending with DHS on the effective date of the rule will not be subject to this rule; USCIS will adjudicate such applications under the terms of the 1999 Interim Field Guidance.

Comment: A commenter argued that past acceptance of legally-obtained Federal assistance programs or public benefits should not count against immigrants already in the country, as it is often U.S. born children who have qualified for and are receiving assistance because their immigrant parents are struggling. Neither the parents nor the children should be penalized for accepting public benefits that were legally available for assistance.

Response: As noted elsewhere in this preamble, benefits received by or on behalf of a U.S. citizen child are not considered in the public charge inadmissibility determination.

Comment: A commenter requested that DHS use the ''primarily dependent'' standard for TANF, SSI, and general assistance benefits received prior to the effective date of the rule.

Response: As noted, under this rule, USCIS will continue to apply the

criteria set forth in the 1999 Interim Field Guidance to applications postmarked (or if applicable, electronically submitted) before, and pending on, the effective date of this rule, and therefore, the receipt of previously-included benefits in those applications will be considered pursuant to the ''primary dependence'' standard. However, for applications postmarked (or if applicable, electronically submitted) on or after the effective date of this rule in which the applicant received previously-included benefits before the effective date of the rule, DHS will consider the receipt of those benefits as a negative factor in the totality of the circumstances, but such receipt will not be considered a heavily weighted negative factor.

U. Other Comments

Comment: A commenter indicated that DHS did not affirmatively address whether it consulted with Federal benefit-granting agencies such as HHS, USDA, and HUD in developing its proposed definition of ''public charge'' as ''an alien who receives one or more public benefit[s]'' and abandoning the current ''primarily reliant'' standard. Although the commenter acknowledged that the NPRM indicated that DHS consulted these benefit-granting agencies on other, tangential issues such as methodologies for considering and quantifying an immigrant's receipt of non-cash, non-monetizable benefits, the commenter was requesting that DHS address, in the next public action, whether or not it formally consulted Federal benefit-granting agencies such as HHS, USDA, and HUD in developing its proposed definition of ''public charge,'' and if so, that DHS publicly disclose copies of any written feedback it received from these agencies.

Response: Interagency discussions are a part of the internal deliberative process associated with the rulemaking.

Comment: Another commenter indicated that the rule would arbitrarily prevent immigrants from obtaining or maintaining lawful immigration status, which data shows improves immigrants' hourly wages.

Response: DHS disagrees that the rule will impermissibly prevent immigrants from obtaining or maintaining lawful immigration status. This rule only addresses one ground of inadmissibility and does not otherwise affect eligibility for public benefits. As discussed elsewhere in this rule, DHS's objective in promulgating this rule is to better ensure that aliens seeking admission, adjustment of status, extension of stay, and change of status, rely on their own resources and capabilities and the not government to meet their needs. DHS also intends that this rule provide a clear regulatory framework for assessing the factors Congress established as mandatory considerations with respect to the public charge ground of inadmissibility.

Comment: An individual commenter proposed creating a ''self-sufficiency program'' in place of the proposed rule. The commenter suggested the program be modeled after the ORR's Voluntary Agencies Matching Grant Program that provides intensive case management, English language and vocational training, and a variety employment services. A commenter suggested creating classes or having resources available to aliens to help them understand the importance of self-sufficiency and methods to obtain that ideal goal. The commenter indicated that those kinds of programs would provide more incentive to the aliens to avoid public assistance than revoking or denying their citizenship status just because they needed some help or might need it in the future.

Response: DHS appreciates the suggestion. However, this rule establishes guidelines for the inadmissibility of aliens based on the public charge ground of inadmissibility as established by Congress. The rule provides for the initial determination of admissibility; other immigration related benefits or activities fall beyond the scope of the rule. The programs offered to refugees are designated to assist people who are not subject to the public charge inadmissibility ground. Further, neither the statute nor this final rule permit revocation or denial of citizenship status based on inadmissibility on public charge grounds.

Comment: A commenter asked that a public information campaign be implemented that is targeted towards the general public to explain the rule changes.

Response: DHS will provide additional information and communication materials on the rule and its provisions as part of the implementation of the final rule.

Comment: Some commenters provided general comments and recommendations on and other aspects of the immigration system. Multiple commenters opposed the separation of families at the southwest border. Several commenters stated that asylum seekers and refugees are unfairly treated. Several commenters stated their support for suspension of all immigration via section 212(f) of the Act, 8 U.S.C. 1182(f). Commenters expressed concern regarding the lack of support provided to Iraqi translators in the search for asylum.

Response: DHS appreciates the comments. However, these comments are outside of the scope of DHS's rulemaking. Through this rulemaking, DHS is exercising its authority to regulations implementing the public charge ground of inadmissibility and the public charge bond framework. DHS is also setting a public benefit condition related to extension of stay and change of status.

Comment: Some commenters stated that all individuals should be treated with dignity, compassion, and kindness.

Response: DHS believes that this rule implements the public charge ground of inadmissibility consistent with those values, as well as other values prioritized by Congress.

Comment: One commenter suggested that DHS should issue work authorization cards to all aliens subject to the public charge ground of inadmissibility and that USCIS should amend the rule to include a work authorization category for all pending applications. Another commenter suggested that USCIS amend the rule to include a work authorization category for all pending applications.

Response: These comments are outside of the scope of DHS's rulemaking. DHS will not offer employment authorization to all aliens subject to the public charge ground of admissibility. DHS notes that aliens with pending adjustment of status application may apply for employment authorization under 8 CFR 274a.12(c)(9).

Comment: One commenter requested that DHS affirmatively review and incorporate into the administrative record for this rulemaking the supporting evidence and authority cited in the approximately 300 footnotes contained in the commenter's submission. The commenter also submitted to the docket 22 additional documents, which included some but not all of the commenter's supporting evidence and authority.

Response: DHS has fulfilled its obligation to meaningfully consider and respond to the public comments. With respect to the commenter's additional request regarding the administrative record, the APA does not require DHS to conduct the exercise requested by the commenter, and DHS respectfully declines to do so.

Comment: A commenter recommended that the proposed rule include the ''protective effect of secure immigration status against abuse and exploitation, as well as the bolstering effects on family stability.'' The

commenter indicated that as recognized under VAWA, admission to the United States or adjustment of status can help victims access employment and increase their ability to escape the violence or overcome the trauma they've suffered. The commenter further stated that a stable immigration status helps individuals obtain secure better paying jobs, reducing the stress associated with exploitative working conditions, leading to better short-term and long-term outcomes for their families. The commenter provided information on research conducted among immigrant victims across the United States that indicated 65 percent of immigrant victims reported that their violent partner had used some form of a threat of deportation after arrival in the United States as a form of abuse. The commenter suggested that DHS should consider the supportive and protective effects of stable immigration status to victims. The commenter indicated that such a consideration would support the purpose and guidance of the important protections that Congress has afforded for victims in various Federal laws, even if they are not seeking admission under an exempt victim-specific category.

Response: DHS understands the concerns and emphasizes that VAWA, T and U applicant categories are generally not subject to the public charge inadmissibility determinations. Further DHS has provided that if a person receives a public benefit during a status exempt from public charge inadmissibility, and later applies for an immigration benefit under a different status where admissibility is required, such public benefit receipt would not be considered in the public charge inadmissibility determination.

Comment: A commenter expressed concern about restricting the possibility of filing Request for Fee Waiver (Form I–912), stating that many applicants have an income below the Federal Tax Filling Requirement Threshold, do not file tax returns, and will lack the evidence to submit this request. The commenter went on to say that forcing applicants to submit evidence through IRS tax filing will increase the amount of tax return moneys that low-income tax payers are eligible to obtain, thus canceling out any additional income received by DHS if these applicants are unable to qualify for the fee waiver.

Response: This rule not change the eligibility or evidentiary requirements of Form I–912. This comment seems misdirected as it appears to relate to a routine revision of Form I–912 and not this rule. Therefore, this comment is out of scope of this rule.

Comment: Some commenters provided general comments and recommendations on public benefits and the welfare system in the United States. For example, multiple commenters stated that immigrants are putting a burden on public services and U.S. taxpayers. One commenter summarized potential methods for saving money within the public welfare system in the United States, as an alternative to changing how the Government implements the public charge ground of inadmissibility. An individual commenter in support of the rule provided information and views regarding fraud and abuse in the U.S. public welfare system, along with brief recommendations on how to address such issues.

Response: DHS appreciates these comments. However, DHS's public charge inadmissibility rule is not intended to address public benefit fraud and abuse specifically. Rather, this rule is intended to align the self-sufficiency goals set forth by Congress with the public charge ground of inadmissibility.

Comment: One commenter requested that USCIS ensure employers are paying living wages to immigrants. The commenter stated that SNAP participants are either employed or seeking jobs, or are children or elderly. Similarly, another commenter asserted that, unless DHS is willing to compel employers in agriculture and in other industries to provide a living wage and health benefits, it is cruel and unjust to punish hard-working immigrants who rely on public benefits but who also benefit the United States.

Response: The vast majority of workers who enter the United States on employment-based nonimmigrant and immigrant visas, including temporary agricultural workers, enter based on the terms and the conditions that have been certified by DOL.[794] For a temporary agricultural worker (H–2A nonimmigrant),[795] the employer must offer the appropriate wage rate [796] and comply with other requirements as set by law and regulations.[797] As such, DOL deemed the financial aspect and conditions of the employment itself sufficient for purpose of the alien's status.

With this rulemaking, DHS prevent individuals from receiving public benefits for which they are eligible. DHS understands that individuals may be hesitant to apply for or receive public benefits in light of this rulemaking. DHS, however, is implementing the congressional mandate provided in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4) to assess, as part of an alien's application for admission or adjustment of status, whether the alien is likely at any time to become a public charge.

Comment: Commenters referenced DOS's January 2018, changes to public charge in the FAM. One commenter stated that if DOS adopted a standard similar to the proposed rule, it would result in significant increases of visa denials.

Response: This rule only pertains to aliens who seek admission into the United States as a nonimmigrant, or as an immigrant, or seek an adjustment of status or a change of status or extension of stay. Although the standards set forth in the rule pertain to DHS's determinations as a whole, the rule's cost analysis focuses on the impact to USCIS adjudications, as the rule most directly impacts USCIS adjudication of applications for adjustment of status, as well as applications for extension of stay and change of status. DHS did not include an analysis of the costs and benefits associated with public charge inadmissibility determinations made by the DOS in the immigrant and nonimmigrant visa context. DHS defers to DOS on any information related to the application of the public charge inadmissibility determination as part of the immigrant and nonimmigrant visa process.

Comment: A commenter urged DHS to defer to the DOS's public charge determination. Another commenter stated that DOS could further modify its own public charge guidance in response to the proposed rule from DHS. The commenters stated that this would cause more than one million individuals that seek visas from DOS annually to be subjected to arbitrary standards and potentially shut out of the country.

Response: DHS is collaborating with other departments and agencies with regard to the regulatory changes promulgated by this final rules. DHS is working, and will continue to work, with DOS to ensure consistent application of the public charge ground of inadmissibility. As noted in the NPRM, DHS expects that DOS will make any necessary amendments to the FAM in order to harmonize its approach to public charge inadmissibility

[794] *See* 20 CFR parts 655 and 656.

[795] *See* INA section 101(a)(15)(H)(ii)(a), 218, 8 U.S.C. 1101(a)(15)(H)(ii)(a), 1188.

[796] *See* 20 CFR 655.120(l). Employers must pay H–2A workers and workers in corresponding employment, unless otherwise excepted by the regulations, at least the highest of the Adverse Effect Wage Rate (AEWR), the prevailing hourly wage rate, the prevailing piece rate, the agreed-upon collective bargaining wage (if applicable), or the Federal or State minimum wage in effect at the time the work is performed.

[797] *See* 20 CFR 655.100–185.

determinations with the approach taken in this final rule.[798]

Comment: A commenter discussed the rule's impact on consular processing. A commenter stated that DOS is likely to adopt public charge rules consistent with DHS's rules, thus exasperating and extending costs to applicants to many types of visa programs. Multiple commenters stated the rule would result in increased administrative burdens to other organizations such as DOS, as the proposed rule would require every adjudicator to be trained to apply the proposed rule, which is already subjective and unclear.

Response: This rule provides a standard for determining whether an alien who seeks admission into the United States as a nonimmigrant or as an immigrant, or seeks adjustment of status, is likely at any time in the future to become a public charge under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). DHS defers to DOS as to the procedure and timing for adopting changes consistent with the policy articulated in this final rule, as well as on the impact of any changes to visa processing times and costs incurred as a result of any such changes.

Comment: A commenter stated that DHS should consider the implications of defining the inadmissibility ground at section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), on the public charge deportability ground at section 237(a)(5) of the Act, 8 U.S.C. 1227(a)(5). The commenter stated that DHS should consider the impact and reasonableness of the proposed NPRM definition in the deportability context and how the definition ''might further heighten fear and anxiety related to deportation among lawful permanent residents and others.'' The commenter that the Administration ''will likely act quickly to adopt it for deportation purposes.''

Response: DHS does not believe it is essential to consider the impact on the public charge deportability ground. The rule is limited to the ground of inadmissibility. Additionally, as explained in the NPRM, standards applicable to DOJ continue to govern the standard regarding the public charge deportability ground.[799] While the forward-looking inadmissibility ground and the past-looking deportability grounds both use the phrase ''become a public charge,'' the two provisions are significantly different. Most notably, the deportability ground requires a two-step determination absent in the inadmissibility ground. Specifically, the public charge ground of deportability applies to an alien who (1) within five years after the date of entry, has become a public charge (2) from causes not affirmatively shown to have arisen since entry.[800] Whereas, the public ground charge of inadmissibility is prospective and requires an analysis to determine whether there is a likelihood that an alien will become a public charge at any time in the future. In the event there are any regulatory changes to the interpretation of the public charge deportability ground, such changes will necessarily comply with the APA and other statutory and regulatory requirements.

Comment: A commenter discussed the rule's impact on immigration courts. The commenter indicated that although immigration judges are not bound by DHS rules, DOJ is in the process of creating a public charge rule that is likely to parallel the DHS proposed rule. However, until a DOJ rule is finalized, the DHS proposed rule is likely to be used as persuasive authority by immigration judges tasked with making public charge assessments. The commenter pointed out that this will occur in at least three scenarios: (1) Individuals without lawful status seeking to adjust status in removal proceedings; (2) returning lawful permanent residents who are treated as applicants for admission under section 101(a)(13)(C) of the Act, 8 U.S.C. 1101(a)(13)(C); and (3) lawful permanent residents placed in removal proceedings who are seeking to re-adjust status with a waiver under section 212(h) of the Act, 8 U.S.C. 1182(h). Additionally, the commenter stated that the adjudication of adjustment of status applications in immigration courts will likely increase due to a 2018 policy change at USCIS, under which NTAs are issued in any case in which USCIS issues a denial, leaving the applicant with no legal status upon denial of the adjustment application. This, according to the commenter, will result in an increase of adjustment of status applications in front of an immigration judge, increasing the frequency of cases requiring a public charge adjudication. Until a DOJ rule is promulgated, ICE trial attorneys, who are bound by DHS regulations, will likely argue that immigration judges should apply the proposed rule's heightened standards. Lacking any binding precedent on the interpretation of section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), some immigration judges will agree and will rely on the proposed rule as a guide, while other immigration judges will not. The commenter stated that this will create inconsistencies in adjudication, and increase administrative inefficiencies through additional appeals and motions; will take significantly more court time for those cases already in front of the judge due to the heightened evidentiary requirements; and need additional and more detailed testimony. These heightened evidentiary requirements will also impact ICE attorneys, who will be required to review that evidence and prepare a response, as well as the respondent and his or her counsel, if represented. With an immigration court backlog that is already above 750,000 cases, the public charge rule would further exacerbate an already record high case volume. Additionally, increased evidentiary requirements, heightened scrutiny, and uncertainty as to what standard to apply will delay adjudications, add to the backlog, and result in inconsistent court adjudications.

Response: Comments regarding the manner in which EOIR will assess public charge inadmissibility are beyond the scope of DHS's rule. DHS's rule pertains to DHS's public charge inadmissibility determinations for applicants seeking admission to the United States and for applicants seeking adjustment of status. If DHS denies an adjustment of status application and places the applicant into removal proceedings, the alien may renew the adjustment of status application before an immigration judge unless the immigration judge does not have jurisdiction over the adjustment application.[801] DHS has no authority over EOIR's inadmissibility determinations.

DHS notes that all inadmissibility determinations are made on a case-by-case basis and depend on the facts and circumstances, as well as the available evidence, in each case. As such, it is impossible to anticipate the arguments that might be made or the evidence that might be submitted in support of a charge of inadmissibility. However, as noted above, under section 291 of the Act, 8 U.S.C. 1361, the burden of proof is on an applicant for admission to establish that he or she is not inadmissible to the United States under any provision of the Act. Similarly, under section 240(c)(2)(A) of the Act, 8 U.S.C. 1229a(c)(2)(A), an applicant for admission in removal proceedings has the burden of establishing that he or she is clearly and beyond doubt entitled to

[798] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51135 (proposed Oct. 10, 2018).

[799] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51134 (proposed Oct. 10, 2018).

[800] *See* INA section 237(a)(5), 8 U.S.C. 1227(a)(5).

[801] 8 CFR 245.2(a)(5)(ii) and 8 CFR 1245.2(a)(1).

be admitted and is not inadmissible under section 212 of the Act, 8 U.S.C. 1182. As noted above, DHS believes that concerns about DOJ's adjudication of cases pending before immigration courts, including immigration court backlogs, are more appropriately addressed by DOJ in the context of their public charge rulemaking.

V. Public Comments and Responses to the NPRM's Statutory and Regulatory Requirements Section

1. Comments on Costs and Benefits

a. Population Seeking Extension of Stay or Change of Status

Comment: Commenters stated the rule will have a disproportionate impact on South Asian immigrants seeking an extension of stay or change of status, stating that more than 550,000 from South Asian countries lawfully reside in the United States. Particularly, a commenter states that the rule will have a detrimental impact because it requires applicants for an extension or a change of status completing the Form I–129 or Form I–539 to complete an additional Form I–944.

Response: DHS appreciates the commenters' concerns regarding the impact this rule will have specifically on South Asian immigrants. DHS does not believe that the rule would impact all of the 550,000 aliens from South Asian countries that the commenter references, as it is unclear that all aliens from these countries would apply for an extension of stay or change of status. In addition, after reviewing the comments, DHS removed the requirement that individuals must establish that they are not likely to receive public benefits by submitting Form I–944. Under the revised standard, aliens seeking to change or extend their nonimmigrant status will have to demonstrate that they have not received any public benefit since obtaining the nonimmigrant status the alien is seeking to extend or change, as defined in 8 CFR 212.21, for more than 12 months, in the aggregate, within a 36-month period.

However, to the extent that South Asians may seek extension of stay or change of status in large numbers given their percentage of total foreign nationals present in the United States, the public benefit condition does not have a disparate impact that is ''unexplainable on grounds other than'' national origin.[802] Rather, under this rule, all applicants for extension of stay and change of status, regardless of national origin, will be required to demonstrate that they have not received, since obtaining the nonimmigrant status they are seeking to extend or change, any public benefit, as defined in 8 CFR 212.21(b), for more than 12 months, in the aggregate, within a 36-month period. Although this rule may impact aliens from South Asian countries to a larger extent solely because they account for a larger percentage of foreign nationals who may apply for an extension of stay or change of status, DHS did not add the public benefits condition to extension of stay and change of status applications in order to specifically target aliens from South Asian countries or for any other discriminatory purpose. Instead, in including the public benefits condition, DHS is seeking to ensure that aliens present in the United States do not depend on public benefits to meet their needs.

b. Other Comments on Affected Population

Comment: Multiple commenters stated that if the rule is finalized it could negatively impact between 24 and 26 million immigrants and their family members. Commenters stated that this estimate was based on a study that determined the number of aliens and their family members with incomes below 250 percent of FPG. Another commenter stated that between 22.2 and 41.1 million noncitizens and their family members could be impacted by the rule, and that out of this population, an estimated 4.9 million legal immigrants would lose healthcare coverage. Other commenters estimated that nearly 40 percent of individuals who sought adjustment of status last year (380,000 of 1.1 million, according to the commenters) would be subject to a public charge determination.

A few commenters stated that the rule could increase the number of immigrants that would be considered a public charge from the current three percent to 47 percent. Other commenters argued the rule could reduce naturalization overall because immigrants would be deterred from adjusting status. Another commenter stated that DHS has not indicated an estimate of the number of noncitizens that will be denied admissibility under the rule.

Response: DHS appreciates the comments regarding the potential negative effects of the rule and the number of individuals who may be affected. The study the commenters cited estimated that 24 million to 26 million aliens and their family members would be affected by the rule's potential chilling effect, *i.e.,* a circumstance under which the rule results in fear and confusion among aliens, who therefore voluntarily disenroll from or forgo enrollment in public benefits.[803] However, the study notes that most of the individuals who may experience a chilling effect are those who will not be subject to a public charge inadmissibility determination. DHS acknowledges that some individuals may disenroll or forego enrollment in public benefits programs even though they are not directly regulated by this rule. DHS has provided an estimate of the number of individuals that may choose to disenroll or forego enrollment due to the final rule, but it is unclear how long such individuals would remain disenrolled or forego enrollment.

As shown in the economic analysis of this rule, DHS estimates that the total population seeking to adjust status that will be subject to a public charge review for inadmissibility is about 382,264 annually. Further, DHS estimates that about 324,438 individuals who are members of households with foreign-born non-citizens and about 9,632 households with at least one foreign-born non-citizen will choose to disenroll from or forego enrollment in a public benefits program, based on a 2.5 percent rate of disenrollment or foregone enrollment.

Moreover, DHS notes that this rule does not force individuals who are eligible for public benefits to disenroll or forego enrollment in such benefits programs and acknowledges that those who choose to disenroll may need to rely on other means of support within their family or community. Nonetheless, through this rule, DHS seeks to better ensure that applicants for admission to the United States and applicants for adjustment of status who are subject to the public charge ground of inadmissibility are self-sufficient, *i.e.,* do not depend on public resources to meet their needs, but rely on their own capabilities and the resources of their family, sponsor, and private organizations.

Comment: Numerous commenters focused on the rule's impact on children, with some providing estimates of the number of impacted children. These include estimates that one in four children have at least one foreign-born parent, between nine and 10 million children who are U.S. citizens born of immigrant parents would be impacted by the rule, and that approximately 18.4 million children live in immigrant families and approximately 16 million

[802] *Vill. of Arlington Heights* v. *Metro. Hous. Dev. Corp.,* 429 U.S. 252, 266 (1977).

[803] *See* Fiscal Policy Institute, ''How a Trump Rule's Chilling Effect Will Harm the U.S.'' Oct. 10, 2018. Available at *http://fiscalpolicy.org/wp-content/uploads/2018/10/US-Impact-of-Public-Charge.pdf,* (last visited May 21, 2019).

of those children were born in the United States. Other commenters noted estimates that approximately 90 percent of the children of foreign-born parents in the United States are citizens of the United States. Many commenters estimated that 45 percent of children who recently became permanent residents of the United States could have multiple negative factors that could prevent adjustment of status. Some commenters noted that approximately 14 million children enrolled in CHIP live in a household with at least one immigrant parent. Many commenters noted the support that public benefits programs, including Medicaid and other health services as well as nutrition assistance, provide for individuals and families, often pointing to the support these programs provide to children. Some commenters stated the rule would have negative consequences on families and ''grand families,'' including family separation.

Response: DHS refers the reader to DHS's response regarding Potential Disenrollment Impacts in section III.D.5 of this preamble. With respect to comments that specifically referenced DHS's initial regulatory impact analysis, DHS notes that in consideration of the comments, it has revised the analysis for this final rule to include a range of potential disenrollment impacts.

Comment: Many commenters stated the rule would have a negative effect on low-wage workers with some stating it would reduce economic mobility and reduce the ability to support families. Commenters noted workers in specific industries, such as healthcare, construction, hospitality, agriculture, and recreation, would be negatively affected by the rule, as would those who benefit from these industries.

Response: DHS reiterates that the goal of this regulation is to ensure that aliens who are admitted to the United States, adjust status, or obtain extension of stay or change of status, are self-sufficient and do not depend on public benefits. This rule does not aim to reduce economic mobility or the ability to support families, but rather aims to do the opposite, by ensuring that those families who enter or remain in the United States are self-sufficient.

Comment: A commenter states the projected annual average of adjustment applicants subject to public charge review is underestimated. The commenter suggested using the publicly available USCIS datasets titled ''Data Set: All USCIS Application and Petition Form Types,'' ''All USCIS Application and Petition Form Types,'' and ''Number of Service-wide Forms by Fiscal Year To-Date, Quarter, and Form Status,'' rather than using internal data or data from approvals.

Response: DHS does not have historical data to serve as a basis of how many applicants currently are subject to a negative public charge determination or how many are ultimately denied admission due to negative factors. Additionally, DHS notes that we use data from internal and external sources as appropriate, and ensures that all data are current, valid, reliable, and accurate. For this economic analysis, DHS used publicly available data in various years of DHS statistical reports, ''Yearbook of Immigration Statistics,'' which are thoroughly vetted through the agency.[804] DHS used these data not only because of their quality, but because they provide the detailed classifications of those adjusting status to determine those who are exempt from inadmissibility based on the public charge ground and those who are not. Additionally, the USCIS data that the commenter cites does not provide enough detail to show the visa classifications of applicants for admission and adjustment of status. The information is necessary for DHS to tailor the analysis to those who are subject to the inadmissibility based on the public charge ground. The data cited only provide aggregate receipt totals whereby it is not possible to remove individuals from the population count who are exempt from a public charge review of inadmissibility. As the data used for the analysis considers all applicants who obtained lawful permanent resident status, the estimated number of individuals who disenroll or forego enrollment due to the rule is likely overestimated.

DHS notes that in the data cited by the commenter, there were approximately 567,640 applications for adjustment of status annually and about 532,887 approvals annually, based on the 5-year average number of application received during the period fiscal year 2012 to 2016.[805] The data the commenter cites only presents data in the broad categories of adjustments, including family-based, employment-based, asylum, and refugee, among others. In general, applicants in family-based and employment-based classifications will be subject to a public charge review of inadmissibility, while applicants in asylum, refugee, and other classifications that are exempt from a public charge review. After removing the categories that are exempt from the data the commenter cited, there were approximately 417,390 applications for adjustment of status annually and about 388,724 approvals annually.

By contrast, the total population in the dataset DHS uses in its economic analysis (including those who are exempt from public charge) is about 544,246 lawful permanent resident approvals annually. After removing the classifications that are exempt from a public charge review of inadmissibility, DHS estimates approximately 382,264 law approvals annually. Thus, the difference between the data cited by the commenter that uses receipts with general categories of applicants that are exempt from a public charge review of inadmissibility and the approvals data DHS used in its analysis is approximately 35,126 applicants annually.

Comment: A commenter indicated that the NPRM fails to provide data regarding the specific impact it might have on the individual, beyond the opportunity cost of time taken to familiarize oneself with the changes in policies and the time taken to accurately fill out new forms.

Response: DHS provides the direct costs of this rule for individuals, which include the familiarization costs of the rule and the costs associated with filling out forms as well as any new or adjusted form fees. The commenter did not provide DHS with any specific data or additional costs for consideration. Additionally, the economic analysis of this final rule discusses several indirect impacts that are likely to occur because of the final regulatory changes in order to provide a more thorough overview of the costs of this rule. However, indirect costs are less certain and more variable, therefore making it more difficult to reliably estimate what those costs may be. The long term impacts are not known at this time.

c. Determination of Inadmissibility Based on Public Charge Grounds

Comment: A commenter noted that the cost estimates of filing Form I–485, Form I–693, and Form I–912 should not be considered as new and additional costs.

Response: DHS presents these forms and costs to establish the baseline for this analysis. The Office of Management and Budget (OMB) Circular A–4 directs agencies to include differences from the baseline as costs, benefits, or transfers in the analysis of the rule. DHS also provides estimates of the additional

[804] *See* Dept. of Homeland Security. *Yearbook of Immigration Statistics.* Available at: *https://www.dhs.gov/immigration-statistics/yearbook* (last visited July 26, 2019).

[805] DHS notes that using the 5-year average over the period fiscal year 2012 to 2016 is consistent with the economic analysis that accompanies this rule, which can be found in the rule docket at *www.regulations.gov.*

costs associated with the rule's changes to some of these forms.

d. Other Comments on Baseline Estimates

Comment: A commenter stated that the rule incorrectly implies there is rampant abuse of public benefits by immigrants. The commenter cites the PRWORA and a Cato Institute working paper to note which immigrants have access to Federal public benefit programs, those who are not eligible for these programs, and who is likely to use certain public benefit programs compared to native born or naturalized citizens.

Response: DHS did not intentionally use language that would imply abuse of public benefits. DHS acknowledges the provisions in PRWORA that limit public assistance to eligible classes of aliens and confirms that this regulation is consistent with PRWORA. The Cato Institute working paper, which is based on Census data (and the Medical Expenditure Panel Survey), concludes that low-income non-citizen immigrants are less likely to receive public benefits than low-income native-born citizens and that the value of benefits received per recipient is less for immigrant groups.[806] These findings are not inconsistent with this final rule.

e. Costs to Applicants To Adjust Status

Comment: Many commenters remarked the impact the rule would have on applicants who may apply to adjust status. One individual commenter stated that, given the overall objectives of this rule, the estimated increased cost to immigrants seeking to adjust their status and economic loss which might represent a significant barrier to filing the application. The commenter stated that such a barrier might in fact suit the agency's goals and therefore represent a benefit. The commenter stated that greater concern are the costs borne by existing resident aliens, with some existing status, who are not the target of the rule and yet stand to be affected by it significantly. The commenter suggested a careful review should be conducted to ensure that this impact on a non-target group of people is warranted, or weigh whether this group should be forced to file all or some of the new forms.

Response: DHS agrees that there are benefits to this rule that justify the new costs it will impose. DHS does not consider the estimated opportunity cost of time for filling out the Form I–944 to be a ''benefit'' of the rule. DHS estimated the costs of this rule on those seeking to adjust status, or pursuing extension of stay or change of status. DHS also notes that costs and/or benefits of a rule are generally estimated from the perspective of what the societal costs and/or benefits of the rule will be. We have reviewed the data provided by commenters and where possible quantified the indirect impacts of the rule. Where quantification was not possible, the economic analysis provides a qualitative discussion of indirect impacts that might result due to this rule. To be clear, aliens who are already lawful permanent residents of the United States are not applying for adjustment of status, extension of stay, or change of status, and therefore generally, will not be directly affected by the rule. Elsewhere in this preamble, DHS addresses the suggestion that DHS apply the rule differently to those who are already in the United States, as compared to those who seek admission from abroad. The Form I–944 is intended to apply to all aliens who are subject to the public charge ground of inadmissibility and who apply for adjustment of status before USCIS.

Comment: One commenter stated that the rule changes are intended to prevent legal immigrants from applying to adjust status to lawful permanent resident as the fee increases are enormous and the bureaucratic hurdles outrageous.

Response: DHS disagrees the rule is intended to prevent eligible individuals from adjusting status to that of a lawful permanent resident. Rather, the rule is intended to better ensure that individuals seeking admission or adjustment of status are able to demonstrate that they are self-sufficient. DHS believes that the benefits to this rule justify the new costs it will impose. Where possible, DHS quantified the cost of completing the new forms.

f. Lack of Clarity

Comment: Multiple commenters noted costs related to a lack of clarity and certainty around strongly positive and negative factors. One commenter noted this lack of clarity would make estimating compliance costs difficult. Another commenter wrote that the form is highly confusing, because it conflates negative consideration of non-monetary benefits if received for more than two months in the aggregate within a 36-month period, and lacks questions seeking to elicit factors that would provide a basis for a positive finding.

Response: DHS agrees that it is unable to quantify the full compliance costs of this rule at this time. The Form I–944 is meant for the alien to provide information about the factors, which an immigration officer would then review to determine whether the alien is likely to become a public charge at any time in the future. The form has been updated for clarity.

Comment: Several commenters noted that applicants may incur additional costs as a result of having to pay for a credit report, an appraisal for a home, and retaining an attorney or accredited representative, and that applicants will need to expend time and effort to gather all documentation and estimate debts and assets from a variety of sources.

Response: DHS notes that applicants may incur additional costs associated with fulfilling the requirements of completing Form I–944 such as obtaining a credit report or appraisal for a home and includes theses costs in the economic analysis, where possible. The economic analysis that accompanies this rule can be found in the rule docket at *www.regulations.gov*. Completion of Form I–944, which includes gathering all necessary evidence, does entail time and cost burdens. DHS reported estimated time and cost burdens in the NPRM and in this final rule in compliance with the PRA.

Comment: A commenter stated that employers will likely not be able to prepare Form I–944 on their employees' behalf like more general immigration forms due to sensitive financial data requested.

Response: DHS has revised the public benefit condition for extension of stay and change of status, such that officer will not issue an RFE for the Form I–944 in that context. No employers will be required to complete the Form I–944.

Comment: One commenter stated the rule may discourage nonimmigrants from coming to or remaining in the United States, regardless of their financial status, and that the rule will reinforce the view that the United States has become an undesirable destination, damaging the nation's status as a welcoming country, and could deprive the U.S. economy of a substantial amount of tourism.

Response: The commenter did not provide evidence or sources to support the claim that the rule will discourage nonimmigrants from visiting, studying, or working in the United States. As stated above, this rule is intended to better ensure that aliens inside the United States ''do not depend on public resources to meet their needs, but rather rely on their own capabilities and the

[806] The Use of Public Assistance Benefits by Citizens and Non-Citizen Immigrants in the United States, Cato Institute Working Paper; Leighton Ku and Brian Bruen, February 19, 2013. *https://object.cato.org/sites/cato.org/files/pubs/pdf/workingpaper-13__1.pdf* (last visited July 26, 2019).

resources of their families, their sponsors, and private organizations.'' [807]

Comment: A commenter stated that an immigration service provider would need to develop expertise in all public benefit programs applicants may have used in any state where the applicant resided, that it will be virtually impossible for people to obtain proof that they did not trigger a negative factor for public charge test, and that their group will likely invest $500,000 to $1 million in trainings to assist the legal and service provider sector to understand this change, although the commenter stated that it still would not be able to advise with any certainty.

Response: The commenter did not explain how it developed the estimated training costs of $500,000 to $1 million. As discussed above, DHS will train and provide internal guidance to USCIS officials processing these forms so they can accurately adjudicate cases. DHS also notes that it considered the costs presented by commenters and provided estimates for additional indirect costs that might result from this rule in the RIA.

Comment: One commenter indicated there was no justification for imposing compliance costs on every alien seeking to adjust status, or on substantial numbers of nonimmigrants seeking routine extensions of status, even where nothing in that person's background or circumstances suggests the prospect that the public charge ground of inadmissibility might be an issue.

Response: DHS believes that the questions posed in the I–944 are relevant and necessary for the public charge inadmissibility determination and allows the alien an opportunity to provide all information regarding the factors as discussed in the rule. DHS reiterates that the public charge inadmissibility ground does not apply to those seeking a change of status or extension of stay. Additionally, DHS has decided against asking nonimmigrants seeking to extend or change such status to submit Form I–944. DHS notes that those categories of aliens exempt from the public charge inadmissibility ground by statute face no additional compliance costs as a result of this rule.

g. Other Comments on Costs to Applicants

Comment: One commenter stated that the agency acknowledges that most individuals this rule applies to would be making close to the Federal minimum wage of $7.25 an hour. The commenter stated that the agency's decision to base its estimates of opportunity cost of time on the mean average for all occupations ($24.35 per hour) instead of the mean national minimum wage ($10.66 per hour) suggests ''a desire to minimize the negative impact of the proposed rule by offsetting the negative impact with what appears to be a net positive, despite the analyzed wage applying to only a small segment of the population that this proposed rule seeks to reach.'' Another commenter stated that USCIS should consider using a more varied rate for calculated opportunity costs. The commenter further stated that the RIA uses $10.66 an hour, but many individuals affected by the rule may have a higher hourly rate.

Response: DHS does not understand the commenter's arguments regarding minimizing the negative impact of the proposed rule. Where appropriate and based on the population of focus, DHS uses various wage rates to estimate opportunity costs of time. DHS uses the average hourly wage for all occupations ($24.34 per hour plus benefits) to estimate the opportunity cost of time for some, not all, populations in the economic analysis. Populations for which this hourly wage is applicable include those submitting an affidavit of support for an immigrant seeking to adjust status and those requesting extension of stay or change of status. For these populations, DHS assumes that individuals are dispersed throughout the various occupational groups and industry sectors of the U.S. economy. Therefore, DHS calculates the average total rate of compensation as $35.78 per hour, where the mean hourly wage is $24.34 per hour worked and average benefits are $11.46 per hour.[808] [809] As noted in the economic analysis of the rule, DHS generally uses $10.66 per hour ($7.25 Federal minimum wage base plus $3.41 weighted average benefits) as a reasonable proxy of time valuation to estimate the opportunity costs of time for individuals who are applying for adjustment of status and must be reviewed for determination of inadmissibility based on public charge grounds.[810] DHS also uses $10.66 per hour to estimate the opportunity cost of time for individuals who cannot, or choose not to, participate in the labor market as these individuals incur opportunity costs and/or assign valuation in deciding how to allocate their time. Moreover, this analysis uses the Federal minimum wage rate since approximately 80 percent of the total number of individuals who obtained lawful permanent resident status were in a class of admission under family-sponsored preferences and other non-employment-based classifications such as diversity, refugees and asylees, and parolees.[811] Moreover, approximately 70 percent of the total number of individuals who obtained lawful permanent resident status were in a class of admission that were also subject to the public charge inadmissibility determination. Therefore, DHS assumes many of these applicants hold positions in occupations that are likely to pay around the Federal minimum wage.

Comment: There were a number of other general comments on costs and potential burdens to applicants:

- One commenter stated that the costs and fees imposed on applicants could burden non-citizens and require them to turn to public assistance programs as a result.
- Another commenter stated that USCIS did not consider ''departure costs'' such as plane tickets or broken leases/contracts for individuals that will need to leave the country due to the NPRM's provisions.
- A commenter stated that the NPRM places a significant burden on community organizations, requiring them to become experts on requirements to explain them to the community.
- Another commenter stated that NPRM would lead to a substantial increase in general legal costs related to applications citing a figure of $40 million for every 100,000 adjustments of status or immigrant visa applications.

Response: DHS appreciates comments regarding costs to applicants and the potential burdens that this rule may impose on those seeking immigration benefits. DHS notes that the purpose of this rule is to better ensure that aliens subject to the public charge inadmissibility ground are self-sufficient, *i.e.,* do not depend on public resources to meet their needs, and rely on their own capabilities, as well as the resources of family members, sponsors,

[807] 8 U.S.C. 1601(2)(A).

[808] The national mean hourly wage across all occupations is reported to be $24.34. *See* Occupational Employment and Wage Estimates United States. May 2017. Department of Labor, BLS, Occupational Employment Statistics program; *available at https://www.bls.gov/oes/2017/may/oes_nat.htm* (last visited July 26, 2019).

[809] The calculation of the weighted mean hourly wage for applicants: $24.34 per hour * 1.47 = $35.779 = $35.78 (rounded) per hour.

[810] *See* 29 U.S.C. 206. *See also* U.S. Department of Labor, Wage and Hour Division. The minimum wage in effect as of May 24, 2018. Available at *https://www.dol.gov/general/topic/wages/minimumwage* (last visited July 26, 2019).

[811] *See* United States Department of Homeland Security. Yearbook of Immigration Statistics: 2016, Table 7. Washington, DC, U.S. Department of Homeland Security, Office of Immigration Statistics, 2017. Available at *https://www.dhs.gov/immigration-statistics/yearbook/2016* (last visited July 26, 2019).

and private organizations.[812] Moreover, DHS sets the fees associated with requesting immigration benefits as necessary to recover the full operating costs associated with administering the nation's lawful immigration system, safeguarding its integrity, and efficiently and fairly adjudicating immigration benefit requests.

DHS appreciates receiving comments regarding the additional burden this rule imposes on community organizations, requiring them to become experts on the requirements in the rule to explain them to the community. DHS acknowledges that the final rule will add new direct and indirect impacts on various entities and individuals associated with regulatory familiarization with the provisions of the rule. Familiarization costs involve the time spent reading the details of a rule to understand its changes. To the extent that an individual or entity directly regulated by the rule incurs familiarization costs, those familiarization costs are a direct cost of the rule. In addition to those individuals or entities the rule directly regulates, a wide variety of other entities would likely choose to read and understand the rule and, therefore, would incur familiarization costs. For example, immigration lawyers, immigration advocacy groups, health care providers of all types, non-profit organizations, non-governmental organizations, and religious organizations, among others, may need or want to become familiar with the provisions of this final rule. DHS believes such non-profit organizations and other advocacy groups might choose to read the rule in order to provide information to those foreign-born non-citizens that might be affected by a reduction in Federal and state transfer payments. Familiarization costs incurred by those not directly regulated are indirect costs such as those listed. DHS estimates the time that would be necessary to read this final rule would be approximately 16 to 20 hours per person, resulting in opportunity costs of time. Additionally, an entity, such as a non-profit or advocacy group, may have more than one person that reads the rule.

With regard to USCIS' consideration of ''departure costs'' for individuals who must leave the United States as a consequence of a public charge inadmissibility determination, DHS agrees that some people may be required to depart the United States due to the requirements of this rule. However, DHS is unable to quantify the departure costs listed by the commenter as we do not have enough information on the number of immigrants who would incur departure costs nor the amount that each immigrant would incur.

DHS appreciates comments asserting that the rule would lead to a substantial increase in general legal costs related to applications of around $40 million per 100,000 adjustment of status or immigrant visa applications. DHS notes that the estimated costs of this rule are based on the estimated populations for relevant forms and the requirements for filing those forms, including any applicable filing fees, opportunity costs of time, travel costs for fulfilling a filing requirement such as submitting biometrics information, among other requirements. DHS has updated the economic analysis to account for additional legal costs as some applicants may retain a lawyer for help in filling out and filing the forms.

With respect to the comment that this rule will also impact legal costs associated with filing applications for immigrant visas, as noted above, DHS has estimated the costs for the populations that are directly regulated by this rule—applicants for adjustment of status, and those seeking change of status or extension of stay. DHS is unable to estimate costs and benefits associated with applicants for immigrant visas filed with DOS.

Comment: An individual commenter wrote that if USCIS took on credit score reporting costs from the beginning of the process it would lower the cost burden for applicants.

Response: It appears that this commenter misunderstands the credit report and score requirement in this rule and believes that DHS will reimburse the cost of obtaining a credit score and/or report associated with the public charge inadmissibility determination. However, under this rule, DHS will not reimburse applicants for costs incurred as a result of obtaining a credit score and/or report to individuals. Aliens seeking immigration benefits who are subject to public charge inadmissibility will bear the cost of obtaining a credit score and/or report solely, as described in the final rule and economic analysis. DHS notes that an applicant may obtain a credit report for free, but in its estimates DHS assumed that applicants would pay for the report.

h. Costs Related to Public Charge Bond

Comment: One commenter noted that the public charge bond provision in the NPRM would increase the overall costs for applicants, and that USCIS has not provided sufficient evidence that public charge bonds will achieve the administration's objective of ensuring immigrants remain self-sufficient.

The commenter indicated that USCIS has failed to adequately document and justify the costs related to how many people will secure public charge bonds; costs of bond for those using them to overcome the public charge definition; costs imposed on families; cost imposed on families that fall on hard times with a public charge bond; upfront and ongoing fees, bond cancellation fees, and fees related to ending a bond; benefits to bond surety companies; and costs to state and localities related to bonds.

A commenter wrote that the bond-related fees will never compensate for the additional administrative costs incurred by operation of the program, and these fees themselves will make the program cost prohibitive for many applicants and their families. Similarly, a commenter wrote that USCIS anticipates that the $25 filing fee for Forms I–945 and I–356 would cover the necessary administrative costs, but then later in the analysis suggests the fee would not fully recover intake costs. Another commenter wrote that the public bond cost should be subtracted from gross costs of the rule as it does not qualify as a marginal benefit.

Response: Although DHS agrees that there may be a cost associated a bond an alien choose to submit (if eligible), as described in the economic analysis, DHS disagrees that the amount of the bond was not properly justified. DHS had generally based the amount on the original regulatory amount adjusted for inflation. However, in order to more precisely match the effect of prior regulations, DHS has decided to have the minimum amount of the bond to be the exact amount as adjusted for inflation. The current *8 CFR 213.1* refers to a bond amount of at least $1,000. *8 CFR 213.1* was promulgated in July of 1964. This provision has not been updated and inflation has never been accounted to represent present dollar values. Simply adjusting the amount for inflation using CPI–U would bring the bond floor in June 2018 to about $8,100.[813]

Once the alien has been determined to likely to become a public charge, and provided the opportunity to submit a bond, the bond acts a deterrent and penalty if the bond is breach. Whether the public charge bonds will achieve the administration's objective of ensuring immigrants remain self-sufficient is not

[812] *See* 8 U.S.C. 1601(1), (2)(A).

[813] Calculation: Annual average for 1st half of 2018 (250.089)/annual average for 1964 (31) = 8.1; CPI–U adjusted present dollar amount = $1,000 * 8.1 = $8,100.

a necessary consideration as DHS would have already determine that the alien is likely to become a public charge and would be giving the alien the opportunity to be admitted with the condition that he or she not receive public benefits. Further, the bond provides was establish by Congress and therefore a requirement for DHS to consider affording the alien an opportunity to provide a bond even though he or she may be likely to become a public charge.[814]

When posting a surety bond, an individual generally would pay between 1 to 15 percent of the bond amount for a surety company to post a bond.[815] The percentage that an individual must pay may be dependent on the individual's credit score where those with higher credit scores would be required to pay a lower percentage of the bond to be posted. DHS notes that an individual may be allowed to submit cash or cash equivalent, such as a cashier's check or money order as another possible option for securing a public charge bond.

DHS will charge a filing fee of $25.00 to submit a public charge bond using Form I–945 and $25.00 to request cancellation of a public charge bond fee using Form I–356, which would cover the estimated administrative costs of processing these forms. Where possible, DHS sets fees at levels sufficient to cover the full cost of the corresponding services associated with fairly and efficiently adjudicating immigration benefit requests.[816] Congress has provided that USCIS may set fees for providing adjudication and naturalization services at a level that will ensure recovery of the full costs of providing all such services, including the costs of similar services provided without charge to asylum applicants or other immigrants.[817] Moreover, USCIS conducts biennial reviews of the fee amounts charged for each immigration and naturalization benefit request. Fees are collected from individuals and entities filing immigration benefit requests and are deposited into IEFA. Those funds then are used to cost of adjudicating immigration benefit requests, including those provided without charge to refugee, asylum, and certain other applicants. The primary objective of the fee review is to determine whether current immigration and naturalization benefit fees will generate sufficient revenue to fund the anticipated operating costs associated with administering the nation's legal immigration system. Therefore, if the results of this review indicate that current fee levels are insufficient to recover the full cost of operations, DHS may propose to adjust USCIS fees. For the forms used in the newly established public charge bond process, should DHS determine that the fees set for these forms are not sufficient to cover the full cost of the associated services adjudicating these immigration benefit requests, the agency will propose to adjust these form fees.

A legal requirement to provide a monetized total cost estimate for this rule does not exist. The public charge bond process is newly established and, therefore, historical data is not available. DHS explained in the NPRM the many factors that were not within the control of DHS that would influence total costs. To the extent possible DHS quantified the costs of the bond provision, for example DHS estimates that approximately 960 aliens will be eligible to file for a public charge bond annually using Form I–945 and approximately 25 aliens will request to cancel a public charge bond annually using Form I–356. DHS does not have enough information to estimate the costs imposed on families that fall on hard times with a public charge bond, upfront and ongoing fees, benefits to bond surety companies, and costs to state and localities related to bonds.

With regard to the comment that the public bond cost should be subtracted from gross costs of the rule as it does not qualify as a marginal benefit, DHS notes that the public charge bond process is being newly established and, therefore, any costs associated with the bond process are considered to be new costs to the public. Additionally, should DHS determine that the fees set for the relevant forms related to the public charge review process, including those for the bond process, are not sufficient to cover the full cost of the associated services adjudicating immigration benefit requests, the agency will propose to adjust these form fees in a subsequent fee rule. DHS sets the fees associated with requesting immigration benefits as necessary to recover the full operating costs associated with administering the nation's lawful immigration system, safeguarding its integrity, and efficiently and fairly adjudicating immigration benefit requests. DHS also notes that the new costs estimated for the public charge bond process are considered costs, not benefits. As shown in the economic analysis, which can be found in the Public Charge final rule docket at *www.regulations.gov*, DHS estimates the baseline cost of the rule and then estimates the costs and benefits of the policy changes that the final rule will implement. The difference between the estimated current baseline costs and benefits and the estimated costs and benefits of the policy changes are considered to be, and presented as, the new costs and benefits of the final rule.

j. Costs to U.S. Employers

Comment: Many commenters stated that the rule would impose significant compliance costs and administrative burdens on employers that would interfere with hiring and staff retention. Commenters also stated that search costs would increase for employers by reducing the supply of low-wage workers and skilled workers. The commenter indicated that the supply of skilled workers could be reduced as non-citizen residents reduce investments in human capital and skilled non-citizens are denied entry or discouraged from seeking entry into the United States. A commenter stated that the analysis does not include the effect on legal immigration to the United States, including how many applicants would be issued RFEs or estimating a potential denial rate. Several commenters stated that the RFE provision could cause potential delays and backlogs causing increased costs to employers. Many commenters stated that the rule change would make it harder for employers to extend H–1B visas or change students from F–1 to H–1B visas. A commenter stated the rule

[814] *See* INA section 213, 8 U.S.C. 1183.

[815] *See also* Surety Bond Authority, Frequently Asked Questions about Surety Bonds, *https://suretybondauthority.com/frequently-asked-questions/* (last visited May 8, 2019) and Surety Bond Authority, Learn More, *https://suretybondauthority.com/learn-more/* (last visited May 8, 2019). DHS notes that the company cited is for informational purposes only.

[816] *See* INA section 286(m), 8 U.S.C. 1356(m), provides broader fee-setting authority and is an exception from the stricter costs-for-services-rendered requirements of the Independent Offices Appropriations Act, 1952, 31 U.S.C. 9701(c) (IOAA). *See Seafarers Int'l Union of N. Am.* v. *U.S. Coast Guard,* 81 F.3d 179 (DC Cir. 1996) (IOAA provides that expenses incurred by agency to serve some independent public interest cannot be included in cost basis for a user fee, although agency is not prohibited from charging applicant full cost of services rendered to applicant which also results in some incidental public benefits). Congress initially enacted immigration fee authority under the IOAA. *See Ayuda, Inc.* v. *Attorney General,* 848 F.2d 1297 (DC Cir. 1988). Congress thereafter amended the relevant provision of law to require deposit of the receipts into the separate Immigration Examinations Fee Account of the Treasury as offsetting receipts to fund operations, and broadened the fee-setting authority. Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1991, Public Law 101–515, section 210(d), 104 Stat. 2101, 2111 (Nov. 5, 1990). Additional values are considered in setting Immigration Examinations Fee Account fees that would not be considered in setting fees under the IOAA. *See* 72 FR at 29866–7.

[817] *See* INA section 286(m), 8 U.S.C. 1356(m).

could lead employers to make their own public charge determinations. Multiple commenters wrote that a broad list of industries would experience a reduction in immigrant labor force or face challenges meeting their labor demand as a result of the rule.

Response: DHS disagrees with these commenters concerning the impact on the supply of labor to employers. This rule is not intended to change the composition of the labor market. Employers will still be permitted to seek extensions of stay and change of status for eligible nonimmigrants. Additionally, this rule is not intended to discourage nonimmigrants from seeking to extend their nonimmigrant stays or changing to another nonimmigrant status. Employers will still be permitted to file immigrant visa petitions for potential alien employees, who would still be able to file for adjustment of status. Instead, this rule as it pertains to extension of stay and change of status sets additional conditions, which are intended to better ensure that aliens present in the United States continue to remain self-sufficient for the duration of their nonimmigrant stay. DHS notes that aliens seeking extension of stay and change of status are not subject to the public charge ground of inadmissibility. Instead they are subject only to the condition that the applicant has not received public benefits since obtaining the nonimmigrant status from which he or she seeks to change, as described in 8 CFR 212.21(b) for more than 12 months, in the aggregate, within a 36-month period.

i. Costs Related to Program Changes and Public Inquiries

Comment: Several commenters noted that states, localities, universities, and healthcare providers will face the enormous task of reprogramming computer software, redesigning application forms and processes, and other aspects pertaining to benefit programs processes. As an example, a commenter stated that online application portals for public benefits often highlight disclaimers that applying for assistance will not affect immigration status. One commenter stated that in some states like Pennsylvania, individuals can submit an application for healthcare coverage and simultaneously be eligible for Medicaid, CHIP, or SNAP; however the rule will require local authorities to provide new systems to shield applicants from public charge risk. In addition, multiple commenters stated that ''churn'' is associated with higher administrative costs, increased clinic time spent on paperwork and certification process, and worsened healthcare outcomes.

Response: DHS appreciates receiving comments regarding administrative changes that will be needed in response to the rule regarding, for example, reprogramming computer software and redesigning application forms and processing. DHS agrees that some entities may incur costs related to the changes commenters identified and describes these costs in the economic analysis based on the data provided by commenters. However, DHS is unable to determine the entities that will choose to make administrative changes to their business processes.

Comment: Many organizations said that states, localities, and healthcare providers will incur increased costs in many unprecedented ways, including handling general inquiries related to the rule, creating public awareness campaigns, providing notice to current participants, retraining and educating staff, hiring additional response staff, and providing aid to partner programs.

Other commenters said that states, localities, healthcare providers, and housing providers will be bombarded with requests from current and former program participants for official documentation verifying that they have not received public benefits during a specific time frame, requiring significant resources in gathering this historical data and responding to these requests while also obeying privacy restrictions and other technical constraints. According to a commenter, many agencies will not have older documentation available in their records, or records will be incomplete or inaccessible. According to a commenter, state and local officials will likely see a significant volume of communication related to questions about eligibility for certain programs and the impact on immigration status.

Response: DHS acknowledges that the final rule will add new direct and indirect impacts on various entities and individuals associated with the provisions of the rule. However, in response to the commenters' concerns about the availability of older documentation related to receipt of public benefits, DHS does not agree that the new requirements associated with public charge inadmissibility determinations would pose an unnecessary administrative burden, as DHS has determined that it is necessary to establish a public charge inadmissibility rule. While age and availability of record of public benefits receipts may vary among Federal and State agencies, it is the responsibility of the individual seeking immigration benefits to provide the required documents and information. Beyond the indirect costs and other economic effects described in the economic analysis of this rule, it is unclear the effect that this rule will have on the entities mentioned by the commenters.

j. Costs Related to States and Local Governments, and Public Benefit-Granting Agencies

Comment: A commenter stated that most states have already established their budgets based on expected enrollment in programs such as SNAP and Medicaid. Another commenter wrote that resources for programs such as the USDA Community Eligibility Provision program are allocated based on direct certification data, which is based on SNAP enrollment, and that non-citizens in the program who disenroll based on public charge provisions will cause additional administrative work for the localities to adjust and compensate. Another commenter stated that local governments have already adjusted and planned services based on the location and living situations of immigrant communities that this rule could greatly affect. A commenter wrote that their state's housing investments could be destabilized by the rule.

Response: DHS appreciates the comments regarding the effects of the rule on State and local budgets. As discussed above, DHS agrees that some entities, such as State and local governments or other businesses and organizations, would incur costs related to the changes commenters identified. DHS considers these costs qualitatively in the final rule since it is unclear how many entities will choose to make administrative changes to their business processes and what the cost of making such changes will be. DHS notes that, in the economic analysis accompanying this rule, which can be found in the rule docket at *www.regulations.gov*, we estimate the reduction in transfer payments from federal and state governments to certain individuals who receive public benefits and discusses certain indirect impacts that are likely to occur because of the final regulatory changes. These indirect impacts are borne by entities that are not specifically regulated by this final rule, but may incur costs due to changes in behavior caused by this final rule. The primary sources of the reduction in transfer payments from the federal government are the disenrollment or foregone enrollment of individuals in public benefits programs. The primary sources of the consequences and indirect impacts of the final rule are

costs to various entities that the final rule does not directly regulate, such as hospital systems, state agencies, and other organizations that provide public assistance to aliens and their households. Indirect costs associated with this rule include familiarization with the rule for those entities that are not directly regulated but still want to understand the final rule.

The commenter's statement that the rule could destabilize the state's housing investments is unclear. This rule does not directly regulate the availability of Federal housing benefits and how states choose to allocate those funds. Rather, the rule directly regulates only aliens who, at the time of application for admission or adjustment of status, are subject to the public charge inadmissibility ground, as well as aliens seeking extension of stay or change of status who are subject to the public benefits condition on eligibility. DHS is prescribing how it will determine whether an alien is inadmissible because he or she is likely at any time in the future to become a public charge and identifying the types of public benefits that will be considered in the public charge determinations. An alien applying for admission or adjustment of status generally must establish that he or she is not likely at any time in the future to become a public charge.

k. Regulatory Familiarization Costs

Comment: Many commenters expressed concerns that NPRM was very complex and therefore would cause confusion, stress, and fear among those directly and indirectly affected by it, including the immigrant community, lawyers, government agencies, educational and social service providers, and community and charitable organizations. Other commenters noted that familiarization costs would be particularly burdensome for applicants with multiple jobs or limited English proficiency, small and medium sized businesses, as well as large complex healthcare providers, groups assisting applicants including advocacy groups and state and local agencies. Some commenters argue that the complexity of the rule would result in almost all applicants needing legal assistance. Other commenters noted that the complexity of the rule, and the resulting confusion, could lead immigrants to face discrimination, receive incorrect legal advice, or forego public benefits even if they are not affected by this rule. Many commenters believe substantial training and administrative work would be needed in order to provide accurate guidance to immigrant applicants and their families, specifically mentioned were issues related to education and employment. A commenter stated that state and local officials will incur costs related to not just familiarizing officials with the rule, but also in understanding recommendations, policies, and procedures with the general public. Some commenters said the rule would discourage workforce professionals, such as healthcare professionals and social workers, from providing advice to clients because of the risk of increased liability caused by providing advice beyond these workforce professionals' expertise. Some commenters wrote that USCIS would incur familiarization costs associated with the rule as well as understanding State laws and procedures associated with programs such as Medicaid eligibility. Research organizations suggested that the familiarization costs of eight to 10 hours is an underestimate and should be increased because of time spent on translation, public outreach, training, research, legal consultation, fielding questions, and dealing with the ''chilling effect.''

Response: DHS increased the expected familiarization burden to range between 16 to 20 hours after reviewing the time estimates in response to comments we received. DHS does not quantify the potential population that may incur familiarization costs associated with the rule due to the uncertainty surrounding the estimated number of people that will familiarize themselves with this rule. The net effect this rule will have on the population seeking an adjustment of status in terms of additional assistance sought is not known. However, to the extent possible DHS has incorporated the costs provided by commenters into the economic analysis.

As discussed above, USCIS has a robust stakeholder communication and engagement program that covers all aspects of the agency's operations. This program will engage stakeholders when this rule becomes final to help ensure that applicants for immigration benefits and their representatives fully understand the new rule. With respect to comments about healthcare professionals and social workers being concerned about liability and not providing advice, DHS notes that these professionals can provide information and disseminate that guidance that USCIS will issue to assist individuals understand and comply with this rule, but should not be providing legal advice without being licensed to practice law in the state.

l. Costs to the Federal Government

Comment: Several commenters discussed the costs of the rule to the Federal Government. Many commenters said the rule will add new adjudication costs to the Government while increasing the already overstretched and delayed processing and regulatory burden. Many commenters stated that the rule would impose an immense administrative burden on USCIS and require USCIS to conduct individualized public charge determinations and adjudications of Form I–944 for hundreds of thousands of applicants with increased evidentiary requirements, heightened scrutiny, and uncertainty as to what standards will apply. Multiple commenters highlighted the increased administrative burdens to USCIS and other organizations such as DOS, as the rule will require every adjudicator to be trained to apply rules which are already subjective and unclear.

According to a commenter, the increased complexity of applying the public charge definition would lead to increased work for USCIS related to adjudicating appeals. An individual commenter suggested USCIS would face additional costs related to removal proceedings as a result of the rule by requiring it to issue more NTAs. A couple of commenters said public charge assessments of individuals making requests to extend or change nonimmigrant status creates additional and unnecessary administrative burden on USCIS.

Response: DHS believes that the burdens associated with improved administration of the public charge ground of inadmissibility, including the expanded information collection, are justified. Adjudicators will be appropriately trained on Form I–944 and will make their determinations in as timely a manner as possible. In addition, DHS does not agree that the new requirements associated with public charge inadmissibility determinations would waste resources and be an unnecessary administrative burden, as DHS has determined that it is necessary to establish a public charge inadmissibility rule. Should DHS determine that the fees set for the relevant forms related to the public charge review process are not sufficient to cover the full cost of the associated services adjudicating immigration benefit requests, the agency will propose to adjust these form fees in a subsequent fee rule. DHS sets the fees associated with requesting immigration benefits as necessary to recover the full operating costs associated with

administering the nation's lawful immigration system, safeguarding its integrity, and efficiently and fairly adjudicating immigration benefit requests. DHS does not believe the costs of additional NTAs will be significant. As discussed above, while the rule may increase USCIS processing times, such is the burden of robust enforcement of the law.

m. Costs to Non-Citizens and Their Communities

Comment: A number of commenters highlighted the impact the proposed rule would have on non-citizens and their communities. Commenters stated that the rule holds non-citizen workers responsible for the low wages offered by employers utilizing visa programs, when instead the costs of the public charge determination should be placed on employers.

Response: DHS appreciates the comments concerning the impact on noncitizens and their communities. DHS does not agree that this rule holds noncitizen workers responsible for low wages offered by employers using visa programs. DHS also does not agree that employers should incur the costs of the public charge determination. As the alien has the burden of proof of establishing admissibility into the United States, the cost burden is appropriately on the individual seeking the immigration benefit in the United States.

n. Healthcare-Related Costs

Comment: A commenter wrote that the rule would increase costs related to general administrative burdens having to manage disenrollment, reenrollment, and inquiries related to the rule. A commenter stated that Medicaid coverage is heavily linked to the economic health of hospitals and, as a result, hospitals could realize significant costs due to the rule. Similarly, a commenter wrote that the rule could see administrative costs and uncompensated care significantly increase. Finally, another commenter wrote about concerns regarding costs related to the privacy of patient data and security as the rule may require USCIS to seize health records.

Response: As discussed elsewhere, this rule furthers the Government's interest, as set forth in PRWORA, to minimize the incentive of aliens to attempt to immigrate to the United States due to the availability of public benefits, as well as promote the self-sufficiency of aliens within the United States.[818] DHS addresses the rule's potential ''chilling effect,'' as well as the eligibility of affected aliens for the designated benefits, elsewhere in the preamble.

DHS appreciates concerns expressed about increasing healthcare costs, worse health outcomes, increased use of emergency rooms, and the economic health of hospitals. As explained in greater detail elsewhere in this rule, DHS has made a number of changes in the final rule itself. DHS has excluded the Medicare Part D LIS, receipt of public benefits by children eligible for acquisition of citizenship, and Medicaid receipt by aliens under the age of 18 from the definition of public benefit in the public charge determination. In addition, DHS is not including CHIP in the public benefit definition. DHS also adopted a simplified, uniform duration standard for public charge determinations for assessing the use of public benefits.

Finally, DHS does not agree that USCIS will ''seize'' health records of patients. Most adjustment of status applicants are already required to undergo an immigration medical examination and submit Form I–693 with their adjustment application. As noted previously, DHS will rely on the medical information provided by civil surgeons on the Form I–693, or report of a panel physician, to assess whether the alien has been diagnosed with a medical condition that is likely to require extensive medical treatment or institutionalization, or that will interfere with the alien's ability to provide and care for himself or herself, to attend school, or to work upon admission or adjustment of status. The data collected on Form I–693 is collected and kept in an alien's administrative record consistent with the Privacy Act and SORN. DHS must comply with the Privacy Act in safeguarding information in the applicable systems of records. As noted on the instructions to Form I–693, consistent with the Privacy Act, DHS may share the information an alien and the civil surgeon provide on Form I–693 with Federal, State, local, and foreign government agencies, and authorized organizations for law enforcement purposes, or in the interest of national security. The civil surgeon may share the results of the immigration medical examination with public health authorities.

o. Housing and Homelessness-Related Costs

Comment: Some commenters cited various studies regarding the costs of housing, homelessness, and healthcare. Another commenter referenced research showing that providing access to public housing to those with serious mental illness would reduce healthcare costs by 24 percent, arguing that housing is pivotal to healthcare. Low-income households with children that pay more than half of their monthly income on rent spend considerably less on other basic necessities—they spend $200 less per month on food, nearly $100 less on transportation, and about $80 less on healthcare. An individual commenter stated that a homeless person on the street may cost more to public service providers and healthcare facilities, such as ambulances, city street clean-up, law enforcement, etc., than the annual cost of providing them housing. The commenter stated that housing is a basic need that provides stability for all things needed to be contributing members of society and that without quality affordable housing, families are forced to pay for unsafe and unsanitary living conditions, which results in negative consequences for society.

A commenter cited studies where more students may experience homelessness under this rule. Commenters stated there is an affordable housing and homelessness crisis across the country that would be exacerbated by this rule, including overcrowding, long wait lists and inundated housing authorities, and make public housing more necessary for immigrants and citizens. A commenter stated that the Government failed to consider a potential increased cost of homelessness to local governments and cited a cost benefit analysis. Commenters stated that they use HCV as additional funding to cover costs and support permanent public housing, arguing that this rule would add to their overall costs. Another commenter stated that even with access to food assistance, 57 percent of households that face food-insecurity are forced to choose between buying enough food and paying for housing. The commenter further stated that due in large part to California's booming economy, there is a significant need for affordable housing in the state. Renters struggle to find affordable housing, particularly in California cities, where the cost of living is higher than the national average (nearly one-third of renter households in California spend at least half of their income on rent). The commenter stated that of the approximately 491,000 low-income households in California that use Federal housing rental assistance, 90 percent include children, the elderly, or the disabled who would be disproportionately impacted by the rule.

Response: DHS appreciates the comments regarding the potential effects and costs the rule may have regarding

[818] *See* 8 U.S.C. 1601.

housing, homelessness, and healthcare and the citation to various studies that address and estimate these issues. However, in most cases, the studies that commenters reference are not the focus of the NPRM and its economic analysis, but instead look at different populations of interest (*e.g.,* specific metropolitan areas or very low-income individuals/households), and/or are not generalizable. For example, the commenter who referenced research showing that providing access to public housing to those with serious mental illness would reduce healthcare costs by 24 percent cited a case study that examines the Mercy Maricopa Integrated Care contract for the Phoenix, Arizona area, which is highly localized and not generalizable to the wider U.S. population.

Regarding the effect of this rule on homelessness, this rule does not directly regulate eligibility for Federal housing benefits or other public benefits that individuals who are homeless, or at risk of being homeless, may rely upon. Rather, the rule directly regulates only aliens who, at the time of application for admission or adjustment of status, are subject to the public charge inadmissibility ground, as well as aliens seeking extension of stay or change of status who are subject to the public benefits condition on eligibility.[819] Moreover, this rule does not eliminate funding for public benefits programs. As a result, DHS only estimated the potential effect on individuals who choose to disenroll or forego enrollment in a public benefits program. DHS provides estimates of the amount of the reduction in transfer payments from the Federal and State governments to certain individuals who receive public benefits in the RIA, which can be found in the public docket of this final rule.

Comment: A commenter stated that any disenrollment or return of housing assistance will not result in any cost savings to public housing authorities (PHA) or federal programs because the demand for such assistance far outstrips the available assistance. The commenter stated that PHAs will be faced with increased administrative costs given the anticipated disenrollment/new enrollment turnover. As a result, PHAs will have to proceed with processing the next individual on the waiting list, as well as closing out the family that is exiting the program.

Another commenter stated that the DHS estimates of reduce housing assistance payments by $71 million per year is highly problematic. That commenter takes issue with the assertion of federal savings in housing programs, because HUD rental assistance programs are discretionary programs, not entitlements, and are provided with a fixed amount of funding that falls very far below what is needed to serve all eligible households. The commenter stated that therefore, net transfer payments for housing assistance would remain roughly the same as a result of the proposed rule and would yield no net savings for the Federal Government.

Response: DHS appreciates the comment regarding the effect the rule may have on PHAs. The commenter mischaracterizes ''cost savings'' in their comment to DHS. As DHS shows in the economic analysis of the rule, the effect of disenrollment or foregone enrollment by individuals in public benefits programs are likely to result in a reduction in transfer payments from Federal and State governments to certain individuals who receive public benefits, not a cost savings. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. The reduction in transfer payments are quantified in the transfer payments section of the economic analysis of this rule in accordance with OMB's Circular A–4. However, DHS notes that there is great uncertainty regarding the effects that changes in transfer payments will have on the broader economy and estimating those effects are beyond the scope of this rule.

Additionally, with regard to administrative costs that PHAs may incur due to the rule, DHS agrees that some entities may incur costs, but these costs are considered to be indirect costs of the rule since this rule does not directly regulate these entities and does not require them to make changes to their business processes. DHS considers these indirect costs as qualitative, unquantified effects of the final rule since it is unclear how many entities will choose to make administrative changes to their business processes and the cost of making such changes.

p. Economic Costs

Comment: A number of commenters had broad concerns about costs the rule would have on the economy as well as innovation and growth. Commenters wrote that the rule is essentially an unfunded mandate to businesses, nonprofits, and educational organizations with substantial compliance costs. A commenter wrote that the rule would stifle economic risk taking and the entrepreneurial spirit in immigrants, thus costing the American economy over the long term. One commenter stated that the rule would reduce immigration and hurt the country's economic future given the need for immigrant workers to replenish an increasingly aging population. Similarly, a commenter stated that demographic shifts mean that immigrant communities represented the future of their state, and the rule would significantly harm those communities. A commenter wrote that approximately 20 percent of their local businesses are run by foreign-born individuals and, therefore, the rule would hurt not just non-citizen families, but also local communities.

Response: DHS appreciates the comments regarding the potential effect of the rule on the economy, innovation, and growth. Beyond the indirect costs and other economic effects described in the economic analysis of this rule, DHS is unable to determine the effect this rule will have on every economic entity mentioned or all aspects of future economic growth. DHS agrees that there may be effects on the U.S. economy and on individuals seeking immigration benefits. DHS describes the potential economic effects in the economic analysis of this rule, which can be found in the rule docket at *www.regulations.gov.*

However, this rule does not directly regulate businesses, nonprofits, or educational organizations. DHS notes that this rule directly regulates only aliens who, at the time of application for admission, or adjustment of status, are deemed likely at any time in the future to become a public charge or who are seeking extension of stay or change of status.[820] DHS is prescribing how it will determine whether an alien is inadmissible because he or she is likely at any time to become a public charge and identify the types of public benefits that will be considered in the public charge determination or the public benefit condition.

Comment: Commenters stated that the number of noncitizens who will be forced to avoid benefits will have a significant impact on the U.S. economy. Commenters quoted cost estimates associated with the rule, including some estimates as high as $164.4 billion. Several commenters quoted an economic impact of $33.8 billion and a loss of 230,000 jobs. Similarly, one commenter stated that the annual income of workers potentially impacted by the rule is $96 billion, and losing these workers would have a $68 billion impact on the economy with $168 billion in damages total. A commenter wrote that the rule would have national

[819] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[820] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

effects across a number of sectors and industries in the economy. A commenter wrote that effects of the rule could total between $453 million and $1.3 billion due to various effects of increased poverty, reduced productivity, etc. Another commenter wrote that the rule would result in an increase in healthcare costs for their city of at least $45 million annually.

Response: DHS appreciates the comments regarding the impact of the rule on the U.S. economy. DHS does not agree that noncitizens will be forced to avoid benefits. Although individuals may choose to disenroll from or forego enrollment in public benefits programs for which they are eligible, this rule does not, and cannot, require individuals to do so and does not change the eligibility requirements for public benefits. Under the rule, DHS will conduct a public charge inadmissibility determination when an alien seeks an adjustment of status, by evaluating an alien's particular circumstances, including an alien's age; health; family status; assets, resources, and financial status; education and skills; required affidavit of support; and any other factor or circumstance that may warrant consideration in the public charge inadmissibility determination.[821] In addition, DHS will only consider the applicant's own receipt of public benefits.

DHS also appreciates the comments that included cost estimates and the potential effects of the rule on the U.S. economy. DHS agrees that there may be some effects on the U.S. economy and on individuals seeking immigration benefits from the United States. In the economic analysis of this rule, which can be found in the rule docket at *www.regulations.gov*, DHS estimates the direct and indirect costs according to the methodology presented using the best available data; DHS also estimates the amount of the reduction in transfer payments from the Federal Government to individuals who may choose to disenroll from or forego enrollment in a public benefits program.

In response to the commenter stating that the rule will cost as much as $164.4 billion dollars, DHS notes that this estimate is not comparable to the estimates DHS presents in the economic analysis that accompanies this rule, which can be found in the rule docket at *www.regulations.gov*. The $164.4 billion estimated cost of the rule the commenter cites comes from an analysis from New American Economy and is comprised of the total annual income of workers who could be affected by this rule.[822] In addition, the analysis estimates that there would be about $68 billion in indirect economic effects as part of the estimated $164.4 billion total cost. However, the validity and reliability of the analysis cited by the commenter is unclear as the calculations of the analysis are not presented, which makes it difficult to assess comparability with DHS's economic analysis.

The final rule, under section 3(f)(1) of E.O. 12866, is designated a ''significant regulatory action'' that is economically significant since it is estimated that the final rule would have an annual effect on the economy of $100 million or more (annualized costs are estimated to range from about $89.8 million to $144.4 million). In addition, DHS estimates approximately $2.47 billion for a reduction in transfer payments from the Federal Government and State governments to public benefits recipients who are members of households that include foreign-born non-citizens, which includes the estimated federal- and state-level shares of transfer payments to foreign-born non-citizens. While the commenters mentioned above provided estimates of the costs of the rule, DHS will maintain the cost and transfer payments estimates we presented in the economic analysis of the rule, which can be found in the rule docket at *www.regulations.gov*. Where possible, DHS discusses the costs presented by commenters and provides a range of additional costs that states, cities, businesses and people could incur because of this rule. However, DHS was unable to determine the number of entities and people that would be affected.

Comment: Some commenters noted the economic costs the rule would impose on aliens who have low income. One commenter stated that the most significant costs of the rule will be concentrated on the poorest communities in cities with large numbers of immigrants. A commenter wrote that if the Federal Government reduces transfer payments, the costs will be passed onto other entities such as food banks, pantries, religious organizations, etc. According to another commenter, the rule will incur costs to housing providers who will need to be prepared to answer inquiries from tenants and others related to the rule, and possibly provide materials on request.

Response: DHS does not intend the rule to disproportionately affect poor communities. As described elsewhere, the purpose of the rule is to ensure the self-sufficiency of aliens who are subject to the public charge ground of inadmissibility. As described in the economic analysis accompanying this rule, which can be found in the rule docket at *www.regulations.gov*, some may incur indirect costs of the rule. Additionally, the final rule does not force individuals who are eligible for public benefits to disenroll or forego enrolling in public benefits programs and acknowledges that those who choose to disenroll may need to rely on other means of support within their family or community. Individuals may choose to disenroll from or forego enrollment in public benefits programs for which they are eligible, but this rule does not, and cannot, require individuals to do so and does not change the eligibility requirements for public benefits. As such, the Federal Government is not intentionally reducing transfer payments for public benefits programs through this rule, but DHS estimates there is likely to be a reduction in transfer payments from individuals to federal and state governments because a number of individuals may choose to disenroll from or forego enrollment in public benefits program for which they are eligible.

Comment: A number of commenters provided input on the cost analysis of the rule provided by USCIS. A commenter wrote that the rule does not attempt to engage with strategies for avoiding the costs imposed by the rule's changes to the public charge inadmissibility determination. A commenter wrote that USCIS did not accurately estimate of the number of people who will disenroll from or forego enrollment in public benefits programs as a result of the rule. The commenter also noted that DHS did not did not monetize the costs of this disenrollment and foregone enrollment; did not account for the costs to the U.S. economy of deeming a greater number of foreign-born noncitizens inadmissible to the country; did not account for the non-financial costs of adverse public charge determinations for affected foreign-born noncitizens; and did not provide any evidence for its low estimate of the rule's familiarization costs. One commenter wrote that the rule acknowledges effects of changes on communities that could be harmful, but it fails to quantify this effect.

[821] *See* 8 CFR 212.22.

[822] *See* New American Economy Research Fund, ''*How Proposed Rule Change Could Impact Immigrants and U.S. Economy.*'' Oct. 31, 2018. Available at: *https://research.newamericaneconomy.org/report/economic-impact-of-proposed-rule-change-inadmissibility-on-public-charge-grounds/* (last visited July 26, 2019).

Response: DHS appreciates receiving comments regarding aspects of the cost-benefit analysis of this rule. The purpose of the economic analysis is not to provide suggestions for avoiding costs that regulated entities may impose. Instead, the purpose of the economic analysis is to estimate the costs and benefits of policy changes the agency is implementing through a regulation compared to current practices. Elsewhere in this preamble, DHS addresses specific alternatives and cost-saving recommendations submitted by commenters.

The final rule will affect individuals who are present in the United States and are seeking an adjustment of status to that of a lawful permanent resident and who are not expressly exempted, and individuals seeking extension of stay or change of status. DHS estimated the effect of the rule on foreign-born non-citizens as accurately as possible given the requirements that are being implemented for aliens to submit to a review for a public charge determination. However, due to serious data limitations, DHS is not able to estimate the effect of being deemed inadmissible as a public charge.

Comment: Commenters wrote that the inability to submit forms related to the rule electronically increases costs.

Response: DHS does not agree that not having the option to submit forms related to the rule electronically increases costs. Submitting forms via mail to USCIS is current practice, which is not changing with this final rule, and therefore estimated costs are expected to remain the same. However, USCIS is taking steps towards implementing a system for electronic filing of all immigration forms in the future, including the forms affected by this rule, which is expected to reduce costs to the agency and ultimately those who file forms with USCIS to request immigration benefits.

Comment: One commenter stated that DHS has disregarded the costs associated with the proposed age standard.

Response: DHS is unable to estimate the specific cost to individuals, society, or the Government, that a single factor considered as part of public charge reviews for inadmissibility may have because the public charge inadmissibility determination will be conducted based on an individual's ''totality of the circumstances.''

r. Economic Impact and Job Loss

Comment: Commenters cited studies pointing to the substantial impact on local economies and healthcare systems due to a significant drop in enrollment from public benefit programs, such as Medicaid and SNAP. Several commenters stated that this rule would pose substantial costs to New York City, which is home to a large number of immigrants and children with foreign-born parents. Other commenters provided data detailing the rule's economic impact to Los Angeles County, CA; Austin, TX; Minneapolis, MN; San Jose, CA; Philadelphia, PA; St. Paul, MN; Boston, MA; and Dallas, TX.

One commenter stated that the rule will undermine our nation's global competitiveness because a highly-educated workforce spurs economic growth and strengthens state and local economies. Similarly, a commenter noted that the rule will undermine our competitive advantage and allow other countries permitting natural immigration flows to take the United States' place on the global economic stage. The same commenter continued by writing that innovation carried out by immigrants has the potential to increase the productivity of native-born Americans, likely raising economic growth per capita. This commenter also cited a report finding that immigration has positive effects, with little to no negative effects, on wages and employment for native-born Americans.

Additionally, at the state level, several commenters noted that in California (the 5th largest economy in the world if it were a country), studies project a $718 million to $1.67 billion reduction in public benefits would lead to 7,600 to 17,700 lost jobs, $1.2 to 2.8 billion in lost economic output, and $65 to $151 million in lost State and local tax revenue. Several commenters cited a study concluding that reduced participation in California's Medicaid program, Medi-Cal, and California's SNAP program, CalFresh, could result in tens of thousands of jobs lost in California, as well as billions of dollars in lost federal funding and more than $150 million in lost tax revenue in California. Some commenters provided data relating to the rule's economic impact on specific states, such as Michigan, Oregon, New York, Washington, Pennsylvania, Rhode Island, Colorado, Florida, Ohio, Kentucky, Massachusetts, Illinois, Pennsylvania, Wisconsin, Maine, Georgia, Maryland, and North Carolina.

Response: DHS appreciates the comments concerning immigration and U.S. economic competitiveness. The final rule does not limit the number of individuals who may seek immigration benefits or restrict the existing categories of immigrants and nonimmigrants. Additionally, DHS does not agree that this final rule will have a negative effect on U.S. competitiveness or economic growth. Rather, through this final rule DHS seeks to better ensure that applicants for admission to the United States and applicants for adjustment of status who are subject to the public charge ground of inadmissibility, as well as applicants for extension of stay and change of status, are self-sufficient, *i.e.,* do not depend on public resources to meet their needs, but rely on their own capabilities and the resources of their family, sponsor, and private organizations.[823]

Comment: Several commenters stated that DHS's assessment of the downstream economic impacts of the rule is insufficient. A commenter said DHS provides no basis for its assertion that the state share of the total transfer impact of the rule would be 50 percent of the federal share, concluding that evaluation of the rule's impact on states should be part of any sound justification for the rule. A commenter similarly referenced DHS's statement that half of the savings will be from lower transfers from State and local governments and stated that, should DHS accept the commenter's recommendations to end various additional exemptions from the list of public charge-related benefits, these transfer payment savings would increase significantly. This commenter also stated that the cost-benefit ratio as proposed would thus be very favorable, between $14 to $37 in taxpayer saving for every dollar expended by the agency and the applicant to prepare and review documentation for a public charge determination.

Response: DHS appreciates the comments regarding downstream economic effects of the rule as well as DHS's estimate for the amount of transfer payments at the state-level. DHS notes there is not a legal requirement to provide a monetized total cost estimate for this rule. DHS explained in the proposed rule the many factors that were not within the control of DHS that would influence total costs. As previously explained, DHS described and monetized, where possible, the types of costs that would result from this rule and has added many additional costs that were provided by the commenters. For those costs and benefits that DHS was not able to quantify and monetize to calculate a total cost, the economic analysis includes a description of those costs and benefits and a reasoned discussion about why they could not be quantified or monetized.

[823] *See* 8 U.S.C. 1601(2).

DHS addressed its assumption that the state-level share of transfer payments is 59 percent of the estimated amount of Federal transfer payments. Because state participation in these programs may vary depending on the type of benefit provided, DHS is only able to estimate the impact of state transfers. For example, the Federal Government funds all SNAP food expenses, but only 59 percent of allowable administrative costs for regular operating expenses.[824] Similarly, Federal Medical Assistance Percentages (FMAP) in some HHS programs, like Medicaid, can vary from between 50 percent to an enhanced rate of 100 percent in some cases.[825] However, upon consideration of the commenter's point and further review of the published FMAPs for each state and territory of the United States, DHS has revised its estimates of the state share of transfer payments from 50 percent to 59 percent, which is the national average FMAP.

Comment: Commenters said the strength of America's economic future is dependent on the well-being and success of children, who are our future workforce and tax base, and the rule could jeopardize our country's economic future by causing tax-paying individuals who are legally eligible for support to forego it.

Response: DHS appreciates the comments regarding children and the economic future of the United States. DHS agrees that children are part of what will continue to make the U.S. economy strong into the future. However, DHS does not agree that this rule will jeopardize the economic future of the United States. While DHS acknowledges the potential disenrollment (or foregone enrollment) from public benefits by aliens based on the final rule, the final rule does not force individuals who are legally eligible for public benefits to disenroll or forego enrolling in such benefits programs. Instead, through this final rule DHS seeks to better ensure that applicants for admission to the United States and applicants for adjustment to lawful permanent resident status who are subject to the public charge ground of inadmissibility, as well as aliens seeking extension of stay or change of status, are self-sufficient, *i.e.,* do not depend on public resources to meet their needs, but rely on their own capabilities and the resources of their family, sponsor, and private organizations.[826]

s. Economic Impact on Healthcare System

Comment: Some commenters stated that the rule will result in decreased tax revenue and lower productivity for individuals who delay primary care.

Response: DHS appreciates the comment regarding decreased tax revenue and lower productivity for individuals who delay primary care. DHS agrees that working age individuals who fall ill would have lower productivity at their jobs and possibly cause decreased tax revenue if such individuals are forced to take unpaid sick leave or must quit working altogether. However, DHS does not agree that this rule would be the cause of such unfortunate events. DHS reiterates that the main purpose of the rule is to provide guidance on the public charge inadmissibility ground statutory provision for those seeking admission or adjusting status in establishing that the person is not likely at any time in the future to become a public charge.

Comment: Multiple commenters stated that the rule would cause reductions in reimbursement, patient use, and collectability, which would have substantial negative financial impacts on hospitals and health centers, with many citing supporting data on potentially lost revenue. Some commenters pointed to a study showing that enrollees affected by the rule account for $68 billion in Medicaid and CHIP healthcare services. One commenter calculated the amount of hospital Medicaid payments at risk for 13 million beneficiaries who are likely to experience a chilling effect from this rule, finding that hospitals could lose up to $17 billion annually in payments from these programs.

Many commenters stated that the rule would negatively impact the healthcare workforce, particularly direct care workers. Commenters cited data indicating that the rule will impact health and long-term care agencies' ability to hire and retain their health care workers, as approximately 25 percent of healthcare support workers, such as nursing and home health aides, are immigrants, many of whom are paid low wages and rely on public assistance who would either leave the profession or forego health coverage and put their health at risk. Some commenters emphasized that this obstacle to expanding the workforce would be particularly impactful at a time when the need for home care workers is growing rapidly due to an aging U.S. population. Commenters state that an exacerbated direct care workforce shortage would particularly impact people with disabilities since many direct care workers are immigrants who often rely on publicly-funded programs due to low wages. Some commenters stated that if home health care workers are unable to continue working, vulnerable populations may be forced to leave their homes and receive more expensive care in nursing homes. Commenters stated that this would not only put these vulnerable populations at risk, but also would destroy decades of federal and state efforts, including millions of federal dollars spent, to reduce the number of individuals residing in nursing homes. Some commenters said the costs to hospitals and the public health system would amount to more than any cost-savings from lower enrollment in public programs.

Response: DHS agrees that some entities such as hospitals would incur costs related to the rule such as rule familiarization costs and various administrative costs. DHS considers these costs as qualitative, unquantified effects of the final rule since it is unclear how many entities will choose to make administrative changes to their business processes and the cost of making such changes.

Additionally, in response to commenters' concern that this rule will cause a direct care worker shortage, DHS is unable to quantify or confirm these effects because DHS does not know how aliens will change their behavior in response to this rule. DHS reiterates that the intent of this rule is not to prevent individuals such as these from working, but to provide guidance on determining whether an alien seeking admission or adjustment of status is likely at any time in the future to become a public charge.

Comment: One commenter stated that, without the contributions made by immigrants to the healthcare system, health insurance premiums could be expected to rise for Americans who rely on that coverage, concluding that the rule neither mentions nor considers these costs to U.S. citizens in its economic analysis. This commenter also said DHS should take into account that

[824] Per section 16(a) of the Food and Nutrition Act of 2008. *See also* USDA, FNS Handbook 901, p. 41 available at: *https://fns-prod.azureedge.net/sites/default/files/apd/FNS_HB901_v2.2_internet_Ready_Format.pdf* (last visited July 26, 2019).

[825] *See* Dept. of Health and Human Services, ''Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2016 through September 30, 2017.'' ASPE FMAP 2017 Report. Dec. 29, 2015. Available at *https://aspe.hhs.gov/basic-report/fy2017-federal-medical-assistance-percentages* (last visited July 26, 2019).

[826] *See* 8 U.S.C. 1601(2).

the rule would actually increase Federal Medicaid expenditures for HHS. The commenters points to three factors that were included in the proposed rule, or could be included in the final rule, that would exacerbate their concern. The commenters recommended not including them as part of the final rule. The concerns were: (1) Including Medicaid or Medicare Part D LIS as negative factors in public charge determinations; (2) including the Children's Health Insurance Program (CHIP) in public charge determinations; and (3) considering premium tax credits for purchasing individual market coverage in a public charge determination.

Response: The commenter states that health insurance premiums could rise and Federal Medicaid expenditures will increase as an effect of the rule. DHS notes that the Public Charge final rule no longer includes Medicare Part D LIS as a public benefits program considered in public charge determinations, nor does it include CHIP or Medicaid for aliens under the age of 21 or pregnant women. In addition, the final rule does not consider premium tax credits in public charge determinations. Therefore, these changes to the final rule is responsive to a number of the commenters' concerns.

Comment: Several commenters stated that, in the long-run, some of the uncompensated care incurred by hospitals will be reimbursed by the Federal Government in the form of Medicare and Medicaid disproportionate share hospital payments, which is another instance of unaccounted for cost shifting that the rule will cause. One commenter requested that USCIS systematically research the increased costs that this rule will cost our healthcare system. An individual commenter cited DHS's reference to the decrease in particular healthcare providers' revenues, but asserted that there is no reference to findings showing either an increased or a decreased percentage of uncompensated care. To determine if including both non-monetary and monetary public benefits is a positive, the commenter said there must be some information on the amount of uncompensated care that healthcare providers provide to non-citizen aliens.

Response: DHS acknowledges in the economic analysis accompanying this rule that various entities may incur indirect costs associated with the rule. Additionally, in the economic analysis that accompanies this rule, which can be found in the rule docket at *www.regulations.gov,* DHS notes there are a number of consequences that could occur because of follow-on effects of the reduction in transfer payments identified in the final rule. DHS is provides a list of the primary non-monetized potential consequences of the final rule where disenrollment or foregoing enrollment in public benefits programs by aliens who are otherwise eligible could lead to issues such as increases in uncompensated care in which a treatment or service is not paid for by an insurer or patient. However, DHS notes that it is not able to estimate such costs at this time.

t. Impact on U.S. Workforce

Comment: Some commenters pointed to a study indicating that over 91 percent of all adults active in the labor force who would be affected by the public charge rule are employed in critical industries, such as farming, construction, mining, hospitality, manufacturing, and professional and business services. A commenter provided data indicating the rule's destabilizing impact on multiple sectors of the California workforce that are comprised of a large number of low-wage immigrants, including agriculture, construction, child care and early education, and students. Some commenters provided data regarding the rule's impact on the workforce in Massachusetts, particularly in the construction field. A commenter wrote about the rule's potential impact on the immigrants in the construction industry who have been helping to rebuild Houston after Hurricane Harvey and who contribute billions each year in state and local taxes. The commenter notes that this rule would prevent immigrants from partaking in benefits that their tax dollars help support and will cause confusion in the immigrant community for using benefits that lead to a better life. Another commenter stated that Maine faces extraordinary demands to replace an aging and retiring workforce.

Two commenters described the rule's impact on the workforce in areas such as agriculture, ranching, hotels, and restaurants. Two other individual commenters provided input on the rule's impact on the horse industry, stating that putting immigrants in situations where they are working in physically demanding jobs with no access to healthcare could be ''disastrous'' for all involved. Another individual commenter stated that, because the disenrollment and foregone enrollment figures are unclear or uncalculated, it is impossible to know what the immediate economic impact will be in agriculture, healthcare, retail, and rental markets.

After asserting that the rule will cause job losses and economic decline, a commenter said restricting the number of immigrants to the United States could leave the nation at a vulnerable position given the current national employment boom.

Response: DHS appreciates the comments regarding the impact on the U.S. workforce, particularly the effect that the rule will have on specific industries. DHS does not anticipate that this rule will have a strong or extensive effect on the U.S. workforce overall or across specific industries as discussed in the economic analysis that accompanies this rule, which can be found in the rule docket at *www.regulations.gov*, and the Final Regulatory Flexibility Analysis. DHS estimates the potential impacts to businesses, states and small entities using the data provided by commenters. Small entities that could be impacted by this final rule are those who file Form I–129 or Form I–129CW as petitioners on behalf of beneficiaries requesting an extension of stay or change of status as well as obligors that would request a cancellation of a public charge bond.

u. Economic Impacts Related to Nutrition Programs

Comment: Some commenters said a significant drop in use of food stamps and other food programs will negatively affect farmers, local growers, and grocery sales at retailers and farmers markets. A commenter said reduced enrollment in SNAP will shift the burden to local communities and food banks that are already stretched to meet demand. A commenter stated that in 2017 more than $22.4 million in SNAP benefits were spent at farmers markets. The commenter also asserted that many small farmers, farm workers, and their families are beneficiaries of SNAP, which the commenter concluded meant that they would be hit doubly hard by the proposed rule. Similarly, an academic commenter stated that limiting the ability of immigrants to use SNAP would hurt the American farming community and destabilize the American food system, reasoning that the revenues of farmers would be reduced and some farmworkers would lose access to SNAP benefits.

A commenter said the rule would withdraw nearly $200 million in Federal SNAP funding, amounting to approximately $358 million in lost economic activity when taking the economic multiplier into account. A couple of commenters stated that SNAP is an economic driver in local economies, especially rural communities. Commenters stated that

lower participation in SNAP means less federal funding to support local economies and lower worker productivity. Other commenters provided estimates for the amount of economic activity that would be lost in certain states as a result of immigrants foregoing critical nutritional benefits.

Response: DHS appreciates the comments regarding the economic effects of disenrollment or foregone enrollment in the SNAP benefits program. As noted in the NPRM, DHS recognizes that reductions in federal and state transfers under Federal benefit programs may have downstream impacts on state and local economies, large and small businesses, and individuals. However, DHS is generally not able to quantify these impacts due to uncertainty and availability of data. DHS estimated these impacts or discussed them qualitatively to the extent possible in the economic analysis for this final rule. For example, the rule might result in reduced revenues for grocery retailers participating in SNAP, agricultural producers who grow foods that are eligible for purchase using SNAP benefits, or landlords participating in federally funded housing programs. DHS notes that the economic impact will result in a reduction in transfer payments from the Federal Government and State governments to individuals who may choose to disenroll from or forego enrollment in a public benefits program. However, the same amount of funding for public benefits programs, such as SNAP, will be available for qualified individuals. This final rule does not appropriate or disappropriate funding for public benefits programs, but ensures that applicants for admission to the United States and applicants for adjustment of status to lawful permanent resident who are subject to the public charge ground of inadmissibility, as well as aliens seeking extension of stay or change of status, are self-sufficient, *i.e.,* do not depend on public resources to meet their needs, but rely on their own capabilities and the resources of their family, sponsor, and private organizations.[827]

Comment: A commenter stated that a reduction in SNAP enrollment could also reduce school reimbursement for free and reduced lunches in states that have extended SNAP benefits above 130 percent of FPL. A commenter indicated an expectation to see a decline in families willing to complete the forms in the Child and Adult Care Food Program center-based child care programs, which would result in less federal nutrition funding to support healthy meals for children, the local retail and agriculture food economy, and revenue for child care businesses.

Response: DHS appreciates the comment regarding the effect of the final rule on enrollment in reduced and free school lunches. DHS does not believe the rule will reduce school reimbursement for reduced and free school lunches beyond the effect of individuals who may choose to disenroll from or forego enrollment in a public benefits program. Again, the final rule only regulates applicants for admission to the United States and applicants for adjustment of status to lawful permanent resident who are subject to the public charge ground of inadmissibility, as well as aliens seeking change of status or extension of stay.[828]

v. Other Economic Impacts

Comment: A commenter stated the rule will adversely impact colleges and universities, as even a slight decrease in international student enrollment has drastic impacts on higher education institutions because international students often receive little or no financial aid and pay higher out-of-state tuition at public universities. Similarly, a school said colleges across the country could see significant decrease in enrollment and increased burden on student health centers.

Response: DHS appreciates the comments regarding the effect of the rule on colleges and universities, including student health centers, as it relates to international student enrollment. However, this rule does not regulate international student enrollment in colleges and universities nor the amount of financial aid awards or the rate of tuition that colleges and universities charge. The final rule also does not regulate student health centers located at colleges and universities. Rather, the rule directly regulates aliens who, at the time of application for admission or adjustment of status, are deemed likely at any time in the future to become a public charge, as well as aliens seeking extension of stay or change of status.[829] DHS is prescribing how it will determine whether an alien is inadmissible because he or she is likely at any time in the future to become a public charge and identify the types of public benefits that will be considered in the public charge determinations. An alien applying for admission or adjustment of status generally must establish that he or she is not likely at any time in the future to become a public charge.

As explained in the preamble of the rule,[830] DHS believes that the government interest in ensuring the self-sufficiency and non-reliance on public benefits of aliens, including nonimmigrants, as articulated by Congress in PRWORA,[831] applies to all aliens within the United States, including to those whose stays are temporary. Moreover, although the extension of stay or change of status provisions in the INA and the regulations do not specifically reference an alien's self-sufficiency, consideration of an alien's self-sufficiency in these applications is consistent with the principles of PRWORA and aligns DHS's administration of the INA to those principles.[832]

w. DHS Estimates of Discounted Direct Costs and Reduced Transfer Payments

Comment: A commenter stated that USCIS characterization of reduced transfer payments as the primary benefit of the rule ignores long-standing principles of regulatory cost-benefit analysis distinguishing between benefits and transfers. This commenter suggests that the cost-benefit analysis should estimate the net effect that the reduced transfer payments would have on the larger economy. A commenter stated the exactness of the values used in our range of estimates leave little room for error as well as suggesting a more enhanced analysis given the broadness of the estimated range.

Another commenter questioned USCIS' approach in estimating costs and benefits of the rule stating that the reduction in transfer payments to non-citizens is itself a cost to those individuals per the guidelines of OMB Circular A–4 and should be defined as such in the regulatory impact analysis (RIA). A commenter also stated that cost savings of $2.27 billion will not be realized due to the effect on temporary visa applications and the potential that DOS starts applying public charge standards to applicants abroad. Another commenter said that the cost benefit analysis did not have sufficient documentation, and the rule's cost savings of $2.2 billion was chosen for its ''wow'' factor.

Finally, a commenter stated that USCIS highlights $23 billion in savings related to Medicaid, but fails to account for the beneficial impacts of the program

[827] *See id.*

[828] *See id.*

[829] *See* INA section 212(a)(4), 8 U.S.C. 1182(a)(4).

[830] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51135–36 (proposed Oct. 10, 2018).

[831] *See* 8 U.S.C. 1601.

[832] *See Southern S.S. Co.* v. *N.L.R.B.,* 316 U.S. 31, 47 (1942) (requiring ''careful accommodation of one statutory scheme to another. . . .'').

and the effects of losing Medicaid coverage.

Response: DHS appreciates the comments regarding transfer payments. DHS notes that the $2.27 billion in cost savings that a commenter refers to are actually the estimated transfer payments of the rule as shown in the economic analysis, which can be found in the rule docket at *www.regulations.gov*. The method and calculation of the estimated transfer payments is shown as clearly as possible in the economic analysis of the rule. As previously discussed, DHS estimates the reduction in transfer payments from the Federal and State governments to certain individuals who receive public benefits and discusses certain indirect impacts that are likely to occur because of the final regulatory changes. The primary sources of the reduction in transfer payments from the Federal and State governments of this final rule are the disenrollment or foregone enrollment of individuals in public benefits programs. DHS notes there is not a legal requirement to provide a monetized total cost estimate for this rule. As previously explained, DHS described and monetized where possible the types of costs that would result from this rule and has added many additional costs provided by the commenters. For those costs and benefits that DHS was not able to quantify and monetize to calculate a total cost, the economic analysis includes a description of those costs and benefits and a reasoned discussion about why they could not be quantified or monetized. DHS does not agree that it is not adhering to long-standing principles of regulatory cost-benefit analysis. The economic analysis for this final rule was conducted based on the guidelines set forth in OMB's Circular A–4, which provides guidance to agencies for conducting cost-benefit analyses and, in this case, a discussion on the distinction between cost and/or benefits and transfer payments.[833] As noted in OMB Circular A–4 (p. 38), ''[b]enefit and cost estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society.'' The reduction in transfer payments are quantified in the transfer payments section of the economic analysis of this rule, in accordance with OMB's Circular A–4. A reduction in transfer payments is not quantified in the benefits section of this rule. There is great uncertainty regarding the effects that changes in transfer payments will have on the broader economy and DHS is unable to estimate those effects.

x. Benefits of Proposed Regulatory Changes

Comment: A few commenters provided input on the benefits of the rule. A benefit noted by commenters is that the rule enforces the requirement that immigrants should be self-sufficient. One commenter provided scenarios and personal experiences as examples of fraudulent claims and behavior of immigrants. An educational institution said the rule ensures participation of immigrant families in federal or state-funded public benefit programs are monitored and limited. Two individual commenters provided comments, data, or studies relating to immigrants' dependence on public assistance programs causing continued decay on American culture. One commenter stated that the rule would save American taxpayers money. Another commenter noted the rule is non-discriminatory by creating a uniform process, and that the additional forms will allow better collection of information.

Response: DHS appreciates these comments. DHS's public charge inadmissibility rule is neither intended to address public benefit fraud and abuse nor ensure that alien access to public benefit programs is monitored and limited. As stated throughout this preamble, this rule is intended to align the self-sufficiency goals set forth in the PRWORA with the public charge ground of inadmissibility.

y. Cost Benefit Analysis Issues

Comment: Some commenters stated that DOS's January changes to public charge has led to improper denials, and that the rule may exacerbate that problem and lead to administrative inconsistency. Another commenter argued that DHS failed to adequately consider the costs of the rule on CBP application of the rule, citing studies.

Response: Although the standards set forth in the rule pertain both to whether an alien who seeks admission as a nonimmigrant or immigrant or seeks adjustment of status is inadmissible, the rule's economic analysis, which can be found in the rule docket at *www.regulations.gov*, focuses on the impact to USCIS adjudications, as the rule primarily impacts USCIS' adjudication of applications for adjustment of status, as well as applications for extension of stay and change of status. DHS is working closely with the Department of State to ensure that they are aware of the requirements of this rule and to prevent any administrative inconsistency. In addition, DHS did not include an analysis of costs and benefits associated with public charge inadmissibility determinations made by CBP in the admission context. This rule would potentially limit entries into the United States in that CBP officers would deny admission to aliens at the ports of entry on public charge grounds, but CBP is already responsible for administering the public charge ground of inadmissibility and we do not anticipate a meaningful change in the amount of time the determination would take.

Comment: A commenter remarked on USCIS' approach to estimating costs and benefits of the rule noting that USCIS states the rule will have no effect on wages or growth, but this is unlikely given the rule will cause a fundamental change in future working populations. The commenter cited research with data and suggested using it as a model for this rule's economic analysis.[834]

Response: DHS does not expect this rule to have a direct effect on wages or economic growth as this rule does not regulate hiring practices of employers in the United States. This final rule requires an individual seeking admission or adjusting status to establish that he or she is not likely at any time in the future to become a public charge, and that aliens seeking change of status or extension of stay meet the public benefits condition. Moreover, DHS notes that the research the commenter cites is not relevant to a discussion of wages or economic growth that may result from this rule.[835] The research cited primarily discusses the effects on applicants when they are reviewed for public charge based on the factors that will be considered in the ''totality of the circumstances.''

Comment: Several commenters provided suggestions on how the analysis could have been done differently overall. One commenter said that USCIS should consider a general equilibrium analysis to better analyze the holistic impacts of the rule throughout the entire economy. Another commenter said in order to develop an

[833] OMB Circular A–4 is *available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf* (last accessed July 26, 2019).

[834] *See* MPI, Gauging the Impact of DHS' Proposed Public-Charge Rule on U.S. Immigration (Nov. 2019), available at *https://www.migrationpolicy.org/sites/default/files/publications/MPI-PublicChargeImmigrationImpact_FinalWeb.pdf* (last visited April, 18, 2019).

[835] *See* Capps, et al. (2018). Gauging the Impact of DHS' Proposed Public-Charge Rule on U.S. Immigration. Washington, DC: Migration Policy Institute, available at *https://www.migrationpolicy.org/sites/default/files/publications/MPI-PublicChargeImmigrationImpact_FinalWeb.pdf* (last visited April, 18, 2019).

accurate portrayal of the rule's cost and benefits, USCIS must use actual benefit receipt information to determine the affected population rather than DHS summary statistics.

Response: DHS appreciates the commenters' suggestions. DHS did not consider a general equilibrium analysis to be appropriate here. We do not have enough data to build a general equilibrium model that would be able to estimate the impact of this rule. In addition, due to the complexity of potential benefits, issues of confidentiality, and data limitations, it was not possible to use actual benefit receipt information for the analysis.

Comment: A commenter stated that USCIS has not made any attempt to detail costs related to processing delays and noted that public charge determinations will inevitably slow down federal agency processing times, for which DHS did not estimate the opportunity cost of such delays.

Response: DHS appreciates the comment. DHS was unable to quantify such costs at this time. DHS notes that delays in processing various forms may occur, but that every effort is taken to avoid such delays whenever possible. DHS does not agree that the new requirements associated with public charge inadmissibility determinations would waste resources and be an unnecessary administrative burden, as DHS has determined that it is necessary to establish a public charge inadmissibility rule. Should DHS determine that the fees set for the relevant forms related to the public charge review process are not sufficient to cover the full cost of the associated services adjudicating immigration benefit requests, the agency will propose to adjust these form fees in a subsequent fee rule. DHS sets the fees associated with requesting immigration benefits as necessary to recover the full operating costs associated with administering the nation's lawful immigration system, safeguarding its integrity, and efficiently and fairly adjudicating immigration benefit requests. As discussed above, while the rule may increase USCIS processing times, such is the burden of robust enforcement of the law.

Comment: A commenter stated that USCIS fails to properly estimate the impact of effects such as immigrants foregoing noncash benefits and other reductions in transfer payments. Another commenter stated that the impact that a loss of public benefits would have on immigrant communities should be calculated in a more robust way by using actuarial models or models used in personal injury litigation that accurately capture the pain and suffering these individuals would undergo.

Response: DHS conducted its economic analysis to the best of its ability given the complexity of the analysis and the availability of data. DHS does not agree that the economic analysis should employ ''actuarial models or models used in personal injury litigation'' to estimate the economic effects of this rule. Actuarial models assess risk and probabilities utilizing a given set of parameters. Unfortunately, DHS does not have enough data on the usage of various subsidies nor the rate of disenrollment needed to create an accurate model. More specifically, in the case of actuarial models used in personal injury litigation, each person's situation is unique and DHS would need to know the specific impacts for each person in order to utilize that type of model. DHS reiterates that the main purpose of the rule is to provide guidance on the public charge inadmissibility ground statutory provision for those seeking admission or adjusting status in establishing that the person is not likely at any time in the future to become a public charge.

Comment: A commenter stated that the cost benefit analysis fails to consider the upward mobility of immigrant communities, the impact of lower levels of immigration on the economy, and other costs such as separation of families, businesses losing workers, and families going without needed assistance.

Response: Where possible, DHS has tried to quantify the indirect impacts of this rule, but DHS is unable to fully quantify the impact of lower immigration on the economy and other costs that could indirectly result from this rule.

Comment: A commenter stated that the cost benefit analysis details an increase in the number of denials for adjustment of status applications, but it does not provide a monetization of these impacts. A commenter stated that the proposed rule requires additional sensitivity analysis. Another commenter stated that USCIS fails to consider key impacts centered around increased denials for admission, change of status, or re-entry, and USCIS should complete a further literature review around these issues.

Response: DHS was able to detail an increase in the number of denials for adjustment of status applications, but did not have enough detailed information on specific aliens to monetize the impacts such denials may have on the economy. DHS disagrees that the rule requires additional sensitivity analysis.

Comment: A commenter stated that USCIS significantly overestimated the average cost of housing assistance per person in calculating costs and benefits.

Response: DHS used the publicly available HUD Federal Rental Assistance and HUD HCV programs report data on the household level in order to estimate the number of households that may be receiving housing benefits. The average annual benefit of $8,121.16 is the estimate DHS calculated per household. DHS recognizes that actual average annual benefits may be less due to the size and location of a particular household.

Comment: A commenter stated that USCIS failed to estimate the number of applicants who will be deemed inadmissible, and the associated effects.

Response: DHS is unable to estimate the number of applicants who will be deemed inadmissible due to this rule. The review for public charge inadmissibility will be based on the totality of the circumstances that considers many positive and negative factors that are specific to each applicant. Therefore, DHS is unable to estimate the number of individuals who may be deemed inadmissible based on public charge. However, DHS estimated the annual population that will be subject to a public charge review for inadmissibility in the economic analysis for this rule, which can be found in the rule docket at *www.regulations.gov.*

Comment: A commenter stated that USCIS should monetize the costs of reduced participation in public benefits programs.

Response: DHS appreciates the comment regarding monetizing the costs of reduced participation in public benefits programs. DHS monetized the effect of disenrollment in public benefits programs to the extent possible based on the best available data. While DHS provides estimates of the direct costs of the final rule in the economic analysis, we also provide estimates and detailed methodology of the reduction in transfer payments from the Federal and State governments to certain individuals who receive public benefits such as those individuals who choose to disenroll or forego future enrollment in public benefits programs due to fear or confusion. As noted in OMB Circular A–4 (p. 38), ''[b]enefit and cost estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society.'' The reduction in transfer payments are quantified in the transfer section of the economic analysis

of this rule, in accordance with OMB's Circular A–4. However, a reduction in transfer payments are not quantified in the benefits section of this rule. DHS notes that there is great uncertainty regarding the effects changes in transfer payments will have on the broader economy, and estimating those effects are beyond the scope of this rule.

Comment: A commenter stated that USCIS includes the removal of Form I–864W as a benefit, but does not present a primary, minimum, or maximum estimate of the benefits.

Response: As noted in the economic analysis, which can be found in the rule docket at *www.regulations.gov*, DHS is eliminating Form I–864W and instead individuals will be required to provide the information previously requested on the Form I–864W using Form I–485. Based on the information provided in the Form I–485, an adjudication officer can verify whether an immigrant is statutorily required to file an affidavit of support. DHS estimated the cost per petitioner for filing Form I–864W, but was unable to determine the number filings of Form I–864W and was unable to estimate the total annual cost savings of eliminating this form.

Comment: A commenter stated that the lack of a sufficient economic model showing the potential impact this could have on families and the economy should be grounds to reject the proposed rule.

Response: DHS does not agree that DHS did not conduct a sufficient economic analysis for this final rule. E.O. 12866 directs agencies subordinate to the President to assess costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). In implementing E.O. 12866, OMB has provided further internal guidance to agencies through OMB Circular A–4 (Sept. 17, 2003), found at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.* OMB Circular A–4 states that it ''is designed to assist analysts in the regulatory agencies by defining good regulatory analysis . . . and standardizing the way benefits and costs of Federal regulatory actions are measured and reported.'' OMB Circular A–4, at 3.

As previously explained, DHS described and monetized where possible the types of costs that would result from this rule and has added many additional costs provided by the commenters. For those costs and benefits that DHS was not able to quantify and monetize to calculate a total cost, the economic analysis includes a description of those costs and benefits and a reasoned discussion about why they could not be quantified or monetized.

Comment: One commenter submitted a detailed comment on the cost-benefit analysis accompanying the proposed rule stating that over half of foreign-born spouses eligible for green cards would be impacted by USCIS' rule.[836] The commenter also stated that USCIS has not provided sufficient analysis to determine how many temporary visitors to the United States would be impacted, that the number of individuals likely to be impacted by the proposed rule's Form I–944 requirement on an annual basis is 436,029 as opposed to 382,264, and that the opportunity costs model used by USCIS is flawed largely due to the use of a weighted minimum wage rather than the average prevailing wage. The commenter stated that the number of individuals impacted by the proposed rule who receive minimum wage is likely significantly lower than 28.5%, and the minimum wage is often higher in a number of states than the national average. The commenter stated that the cost of attorney fees to applicants will be significantly higher than DHS recognizes. When correcting for these effects, the proposed rule would incur total costs of $2,260,448,302, or about 17 times greater than USCIS' estimate. A commenter stated that the cost savings related to healthcare provisions were unworkable given the disjointed nature of exempting some health services such as immunizations but punishing use of Medicaid and CHIP. A commenter stated that the proposed rule would lead to significant increase in administrative costs to deal with public charge provisions.

Response: DHS appreciates these comments. The analysis used the Federal minimum wage rate since approximately 80 percent of the total number of individuals who obtained lawful permanent resident status were in a class of admission under family-sponsored preferences and other non-employment-based classifications such as diversity, refugees and asylees, and parolees.[837] Further, the benefits-to-wage multiplier raised the Federal minimum wage to $10.59, which could account for wages above $7.25 that do not receive non-wage benefits.[838] The cost savings presented in the analysis were based on the provisions of the proposed rule and have been updated in the final rule. Administrative costs were not calculated.

The analysis does not quantify potential effects on admissibility, as opposed to adjustment of status. Instead, the purpose of the rule is to determine whether an alien is inadmissible to the United States under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), because an alien is likely at any time in the future to become a public charge. Aliens who seek adjustment of status or a visa, or who are applicants for admission, must establish that they are not likely at any time to become a public charge, unless Congress has expressly exempted them from this ground of inadmissibility or has otherwise permitted them to seek a waiver of inadmissibility. Moreover, DHS will require all aliens seeking an extension of stay or change of status to demonstrate that they have not, since obtaining the nonimmigrant status they wish to extend or change, received public benefits, as defined in this rule, for more than 12 months in the aggregate within any 36-month period unless the nonimmigrant classification that they seek to extend, or to which they seek to change, is exempt from the public charge ground of inadmissibility.

In addition, DHS acknowledges the commenter's estimate of the population that would be affected by this rule's requirement to submit the new Form I–944. However, DHS notes that we use data from internal and external sources as appropriate, and ensures that all data are current, valid, reliable, and accurate. DHS declines use the commenter's population estimate in favor of the estimates we present in the economic analysis that accompanies this rule, which can be found in the rule docket at *www.regulations.gov*. The data DHS used for its estimates were necessary since it provides detailed information showing the classes of applicants for admission, adjustment of status, or registry according to statute or regulation that are exempt from

[836] *See* Looming Immigration Directive Could Separate Nearly 200,000 Married Couples Each Year, Boundless Immigration Inc. (Sept. 24, 2018),*https://www.boundless.com/blog/looming-immigration-directive-separate-nearly-200000-married-couples.* (last visited July 26, 2019).

[837] *See* United States Department of Homeland Security. Yearbook of Immigration Statistics: 2016, Table 7. Washington, DC, U.S. Department of Homeland Security, Office of Immigration Statistics, 2017. Available at *https://www.dhs.gov/immigration-statistics/yearbook/2016.* (last visited July 26, 2019).

[838] Note that the benefits-to-wage multiplier of 1.47 used in the proposed rule has been updated to 1.46 for the final rule based on an annual data update released by the Bureau of Labor Statistics. Therefore, DHS updated its wage estimate using the Federal minimum wage plus benefits from $10.66 per hour to $10.59 per hour.

inadmissibility based on the public charge ground. Other data that are available are informative, but only provide aggregate receipt totals whereby it is not possible to remove individuals from the population count who are exempt from a public charge review of inadmissibility.

Finally, based on comments received, DHS amended its economic analysis, where possible, to account for individuals who choose to hire an attorney for legal representation on their behalf.

Comment: A commenter noted that though the rule impacts only a small number of immigrants, its chilling effect impacts will outweigh its intentional impacts. This, the commenter and others commenters asserted, is an abdication of DHS's APA duties to consider costs and benefits. Further, a commenter stated that DHS failed to satisfactorily justify the prospective harm of the chilling effect of this rule. Another commenter stated that DHS's cost analysis is arbitrary, stating that its estimates appear in some cases to reflect a range based on simply moving decimal places rather than evidence. Elsewhere, the commenters say estimates are inconsistent, such as the Form I–944 cost estimates in the PRA analysis versus elsewhere in the proposed rule. A few commenters noted that the public charge definition is not supported by or tied to any benefit to ''health, well-being, businesses, economies, or communities.'' One commenter stated that the rule ''does not point to any expected benefits for individual or public health, for national, state or local economies, for businesses, for healthcare systems, or for our communities.''

Response: DHS disagrees with these comments. E.O. 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; the regulation is tailored to impose the least burden on society, consistent with achieving the regulatory objectives; and in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. E.O. 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

2. Federalism Comments

Comment: A commenter stated that DHS did not conduct an adequate analysis of the NPRM's federalism implications. The commenter further stated that because of the serious impact the NPRM will have on the States, it is improper for DHS to forego the federalism summary impact statement. The commenter also stated that E.O. 13132 requires DHS to produce a federalism summary impact statement. One commenter stated that DHS did not engage in adequate consultation with governors pursuant to E.O. 13132, and requested that DHS engage in a meaningful and formal way before taking further action on the public charge rule. The commenter noted that the rule would likely impose significant financial and administrative burdens on states, including costly and labor-intensive changes in how states implement their shared eligibility systems among human services and health programs.

Response: This final rule does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Although this rule defines public benefit to include certain cash and non-cash benefits, some of which may be fully or partially administered by states or local governments, DHS is not purporting to regulate which aliens may receive such benefits or how states and local governments administer such programs. DHS does not expect that this final rule will impose substantial direct compliance costs on State and local governments, or preempt State law. Accordingly, in accordance with section 6 of E.O. 13132, this rule requires no further agency action or analysis.

Comment: A commenter stated that this rule impinges on a state's right to provide healthcare services and increases federal intrusion into local issues.

Response: DHS disagrees that this rule impinges on state's rights to provide healthcare services and increases federal intrusion into local issues. This rule enforces a law that has been in place, in one form or another, since the late 19th century. The review of public charge inadmissibility, which is an immigration matter, is a matter of Federal jurisdiction alone, as indicated by the Supreme Court.[839]

Comment: A commenter indicated that as a matter of law and effective policy, USCIS must consult with States and localities about the impact of the public charge rule on state and local choice and policy. The need for this consultation was apparent because the formulation of the guidance document this regulation proposes to replace considered state and local public health concerns.

Response: DHS has considered the relevant public comments and engaged in many meetings with state and local entities as part of the E.O. 12866 process. Aliens entitled to public benefits under State or local law may elect to receive such benefits and this rule does not, and cannot, change that fact. However, DHS believes that the consideration of an alien's receipt of designated public benefits is consistent with congressional intent, as set forth in PRWORA, that the receipt of public benefits should not be an incentive to come to the United States, and aligns DHS's administration of the INA to those principles.[840]

Comment: Some commenters stated that the rule violates state's rights to provide benefits to children and immigrants experiencing short-term crises. Some commenters said this rule impinges on a state's right to provide healthcare services and increases federal intrusion into local issues. Commenters stated that some state statutes and constitutions, as well as DHS's own 1999 Interim Field Guidance, make it a state interest to provide certain benefits to non-citizens.

Several commenters stated that the proposed rule impermissibly overrides state authority. Others stated that the proposed rule would bar their states' from providing state-funded aid to their own residents, regardless of immigration status. A commenter stated that the proposed rule violates the 10th Amendment of the U.S. Constitution because it commandeers state resources by compelling agencies to implement the rule, especially in providing notice and information to applicants. Another commenter stated that the rule violates a federalism principle by imposing an unfunded mandate. One commenter stated that the proposed rule will impose substantial costs on State and local governments such that federalism concerns are implicated. Other commenters stated that the proposed rule would harm their states. A commenter stated that the proposed rule would undermine a state statute that was passed with bipartisan support in order to extend CHIP.

[839] *See, e.g., Hines* v. *Davidowitz,* 312 U.S. 52 (1941); *see also Arizona* v. *United States,* 567 U.S. 387, 394 (2012) (''The Government of the United States has broad, undoubted power over the subject of immigration and the status of aliens.'').

[840] *See Southern S.S. Co.* v. *N.L.R.B.,* 316 U.S. 31, 47 (1942) (requiring ''careful accommodation of one statutory scheme to another.'').

Another commenter asserted that, even if the proposed rule were passed in the form of a statute, it would violate Article I of the Spending Clause for coercively restricting state use of Federal grant money.

Response: DHS did not propose in the NPRM to, in any way, regulate or circumscribe the ability of states to offer public benefits to children and immigrants, or to require states to implement the DHS rule. Similarly, this final rule neither prohibits states from providing benefits to children and immigrants nor prohibits any category of immigrants from receiving any state or local benefits for which they are eligible. Furthermore, the rule's definition of public benefit does not include emergency aid, emergency medical assistance, or disaster relief. Likewise, the rule does not impact the Spending Clause since it does not restrict a state's ability to use Federal funds.

3. Family Assessment Comments

Comment: One commenter said that the rule violated Section 654 of the Treasury General Appropriations Act, 1999, Public Law 105–277, which requires agencies to assess their policies' impact on family stability, families' ability to function, and other indicators of family well-being. Another commenter stated that DHS's Family Policymaking Assessment failed to fully and meaningfully evaluate the rulemaking's effects on family well-being under section 654(c)(1) and did not address 654(c)(2)–(7) at all. Other commenters generally agreed that the family assessment in the proposed rule is insufficient.

Several commenters stated this rule will unnecessarily harm family unity, such as by making it difficult for some spouses of U.S. citizens to enter the United States or adjust status. A commenter generally stated that the proposed rule's definition of ''household,'' along with the asset and income standards, would pressure families to separate. The commenter also stated that the proposal to subject residents to public charge determinations upon reentering the United States would discourage immigrants from preserving contact with family outside of the United States. A commenter added that it would make it especially difficult for immigrants to let their parents join them in the United States. Another commenter cited an article noting that there are 9,000,000 mixed status families in the United States, and many would be faced with the threat of coerced separation.

Another commenter stated that this rule could result in the separation of at least 200,000 married couples annually. Another commenter provided data on the impact of the study on marriage-based permanent residency applications, saying the proposed rule would undermine family unity and stability. A commenter stated that the proposed rule would chill access to their state's Department of Children and Families and Juvenile Court, leading to children remaining dependent on state child welfare programs.

Many commenters said this rule would dramatically hurt and jeopardize families, as well as place undue burden on all family members. A commenter stated that the proposed rule fails to analyze the rule's effect on the well-being of families, especially its impact to family stability, and on the disposable income of families and children. Some commenters provided studies showing how children could be severely and irreversibly harmed, including children's health, by separation as part of a strategy to prevent immigrants from legalizing their status.

A commenter stated that the rule contravenes international and domestic policies that support children's best interests, citing the U.N. Convention on the Rights of the Child.

Response: Section 654 of the Treasury and General Government Appropriations Act, 1999[841] requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. Agencies must assess whether: (1) The action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and whether (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

As discussed in the NPRM,[842] DHS has determined that the rule may decrease disposable income and increase the poverty of certain families and children, including U.S. citizen children. And as discussed previously, DHS has modified some provisions in ways that will mitigate the impact on families, such as by exempting receipt of Medicaid by aliens under 21 and pregnant women. Ultimately, however, DHS continues to believe that the financial impact on the family is justified.

Additionally, because the final rule considers receipt of public benefits that were not considered under the 1999 Interim Field Guidance, DHS determined that the aliens found inadmissible under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), will likely increase. However, given the compelling legal and policy reasons associated with this rulemaking, including but not limited to, better ensuring self-sufficiency, DHS determined that this rulemaking's impact is justified and no further actions are required. DHS also determined that this final rule will not have any impact on the autonomy or integrity of the family as an institution.

Furthermore, with this rulemaking, DHS does not intend to separate families. DHS's intent is to implement Congress' mandate to assess whether an alien has met his or her burden to demonstrate that he or she is not likely at any time to become a public charge under section 212(a)(4)(A) of the Act, 8 U.S.C. 1182(a)(4), given the congressional policy to ensure that those coming to the United States should be self-sufficient and not rely on the government for assistance to meet their needs.[843]

DHS agrees that family unity is a significant tenet of the family-based immigration system. As indicated above, the rule does not alter eligibility criteria for a family-based immigrant petition, although it could have some impact on the ultimate outcome of such petitions. DHS has taken certain steps that mitigate the potential effects of this rule on families. For instance, DHS will not attribute U.S. citizen children's receipt of public benefits to their parents who are subject to the public charge inadmissibility ground. Like all other applicants for admission or adjustment of status who are subject to the public charge or any other ground of inadmissibility, aliens are not guaranteed admission or adjustment of status merely by virtue of their

[841] Public Law 105–277, 112 Stat. 2681 (Oct. 21, 1998).

[842] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51277 (proposed Oct. 10, 2018).

[843] *See* 8 U.S.C. 1601(1) and (2).

relationship to a U.S. citizen or lawful permanent resident.[844]

4. Paperwork Reduction Act Comments

Comment: A commenter stated that the newly proposed Form I–944 is duplicative and unnecessary in light of the Form I–864. Another commenter stated that DHS has not shown that there are not less burdensome ways of gaining the information from I–944 than the form requires.

Response: DHS disagrees that the Form I–944 duplicates information collected on Form I–864 and is therefore duplicative. However, DHS has updated the forms to remove the questions about employment that are also on the I–485. In addition, DHS added language to the forms, indicating to the applicant that if tax forms were submitted as part of Form I–485, Form I–864 or Form I–944, the same tax returns do not need to be submitted with the I–864. Any document that is submitted as part of another form related to the immigrant benefit does not need to be submitted multiple times. Form I–864 is an affidavit of support submitted by an intending immigrant's sponsor, as required for certain categories of aliens subject to the affidavit of support requirements under section 213A of the Act, 8 U.S.C. 1183a. Form I–864 is a contract between the sponsor and the U.S. Government in which the sponsor agrees to use his or her income, assets, and resources to support the intending immigrants named in Form I–864, if it becomes necessary. The sponsor completing and signing Form I–864 must show that he or she has enough income and/or assets to maintain the intending immigrants listed on the affidavit and the rest of the sponsor's household at 125 percent of the FPG. The sponsor, therefore, is largely submitting information regarding his or her financial situation.

However, Form I–944 is completed by the intending immigrant, *i.e.,* applicant for adjustment of status, and requests information on the relevant factors as established by section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and the final rule, which are distinct from the requirements of the affidavit of support.

Comment: A commenter suggested a simplification of the declaration of self-sufficiency that targets aliens that might trigger public charge concerns, rather than, for example, all aliens who seek to adjust status. Another commenter stated that Form I–944 imposes undue burdens and that DHS has failed to justify requiring it.

Response: DHS disagrees that the Form I–944 needs to be simplified and more carefully targeted or is overly burdensome. Form I–944 requests information about all the relevant factors as established by section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), and the rule to determine whether the alien is inadmissible based on public charge ground.

The Form I–944 instructions state that only applicants filing Form I–485 who are subject to the public charge ground of inadmissibility must file Form I–944. The Form I–944 instructions also explain that an alien who is exempt from the public charge ground of inadmissibility does not need to file Form I–944, and subsequently lists all categories of aliens that are exempt from the public charge ground of inadmissibility. Therefore, DHS believes the declaration of self-sufficiency is appropriately targeted to the aliens that might trigger public charge concerns.

Comment: A commenter noted that there was no way to specify the receipt of public benefits was for an emergency on the Form I–944, nor did the form indicate that such services were excluded.

Response: DHS appreciates the comment and has updated the form to include questions regarding the exemptions and updated the description of the designated public benefits to clarify the information being sought.

Comment: A commenter opposed requiring that employees provide employers with certain information, whether through Form I–129, Form I–539, or Form I–944. The commenter stated that requiring a nonimmigrant to provide such personal information to his or her employer or prospective employer to overcome the presumption that he or she is or could become a public charge, such as medical payments, tax return transcripts, W–2s, or documents for temporary housing needs, is an unfair and unreasonable imposition on any employee. The commenter stated the employer should not know such personal information, and that the requirement could potentially expose an employer to liability. The commenter stated further that it is unclear who would be responsible to pay for the Form I–944, especially in the context of H–1B-based change or extension of status petitions, where the employer is generally required to pay the fees associated with the filing.

Response: Employees seeking employment-based nonimmigrant visas and those seeking to extend of change to an employment-based nonimmigrant category, must provide certain biographical information to employers as part of the application process. Form I–129 and Form I–539/Form I–539A already provide for some information from both employers and employees when the benefit is related to employment-based immigration. As noted on the instructions for USCIS forms, the failure to provide requested information, or any other requested evidence, may delay adjudication or result in a denial of the benefit requested.

Comment: A commenter stated that DHS appears to be acting on the basis of either conflicting information or no information at all. For example, in the context of its PRA analysis, DHS estimates that 382,264 individuals will be required to fill out Form I–944, that the hour burden per response will be 4 hours, and that the monetary burden is $59,931,350. Those figures seem to directly conflict with DHS's earlier estimates that Form I–944 would take 4.5 hours to fill out and that the annual cost would be $25,963,371.[845] The commenter notes that the number of applicants is similarly in conflict. DHS also appears to assume that only applicants for adjustment will fill out Form I–944.[846] DHS overtly states, however, that at least some nonimmigrant visa applicants would have to fill out that form as well, and it provides statistics showing annual averages of those applicants over 200,000.[847] The commenter concludes from this information that DHS does not know how many people will have to fill out the form, how long it will take them, or how much it will cost on an annualized basis.

Response: DHS has corrected an error in the estimated time burden for Form I–944 from 4 hours to 4.5 hours. DHS uses historical data to estimate the populations and burdens reported. In some instances, DHS does not have historical data on a population and may need to derive these populations using statistical methods. For example, the 5-year average of those filing Form I–485 who are not exempt from the public charge inadmissibility determination is estimated at 382,264. DHS used this population for the Form I–944 estimate. Additionally, as part of the calculation of the 5-year average estimated population, DHS used the FY 2016 population of those who are not exempt

[844] *See Agyeman* v. *INS,* 296 F.3d 871, 879 (9th Cir. 2002) (''[A]pproval of the I–130 petition does not automatically entitle the alien to adjustment of status as an immediate relative of a United States citizen.'').

[845] 83 FR 51284–85, at 51254.

[846] 83 FR 51284–85, at 51240 (calculating that 382,769 adjustment applicants would be subject to public charge review).

[847] 83 FR 51284–85, at 51243–44.

from public charge review (382,769 filers), which is very close to the 5-year average estimate. In sum, the economic analysis used the 5-year average of those filing Form I–485 of 382,264 and the FY 2016 population of those not exempt from public charge review, to estimate the population that will be subject to public charge inadmissibility determination and, therefore, will have to submit Form I–944.

Finally, DHS is required to estimate cost burden in multiple ways: (1) The PRA requires estimating cost burden based on the average hourly wage of the respondent; (2) the PRA also requires estimating the annual cost burden based on expenses incurred to complete the information collection including but not limited to attorney's fees, shipping and handling, etc., and (3) E.O. 12866 requires estimating the benefits and costs of the regulation, including the opportunity cost of time, among other costs.

Comment: A commenter stated that the proposed rule would also impose unreasonable burdens and financial costs on immigration benefit applicants and petitioners, specifically mentioning Form I–944. The comment indicated that though DHS projects an average Form I–944 preparation time of 4 hours and 30 minutes, the evidentiary requirements associated with the form and the public charge assessment overall suggest that DHS has seriously underestimated the time commitment. For example, using a method of assessing ''household size'' that differs significantly from the long-accepted definition used to evaluate Form I–864, the proposed rule and Form I–944 instructions require individuals to submit extensive supporting documentation of the financial status of the applicant's household, including all sources of household income and all cash and non-cash assets that can be converted into cash within 12 months. For every such asset, an applicant must provide a description of the asset, along with the value, basis of the claim for the value, and proof of ownership. The net value of a home may be included as an asset, but only if accompanied by documentation of ownership, evidence of all secured loans or liens, and a recent appraisal completed by a licensed appraiser (estimated to cost an average of $300 to $400 for a single family home). The commenter indicated that these requirements alone could consume significant amounts of time beyond the DHS estimate. In addition, multiple commenters stated that the documentation and information applicants would be required to collect and present is extensive (the commenter stated that the Form I–944 would require the alien to list the name of every household member, amount of current assets and resources, recent Federal tax return history for the applicant and household members, credit score, proof of debts and liabilities, complete list of all public benefits applied for or received, and education and employment history), and that accurately completing the form and providing all required information with documentation would be a significant effort for non-citizens and their families.

Response: DHS acknowledges that the time that it would take each individual to complete Form I–944 could be more or less time than the reported estimated average time burden, depending on the applicant's individual facts and circumstances. For example, some applicants would be children who do not have extensive education, assets, and liabilities to report on the Form I–944. In contrast, an older applicant could have extensive education, assets, and liabilities to report on the Form I–944. Moreover, in estimating the time burden, DHS does not include the time burden already accounted for by other information collections subject to the PRA nor inactive time to obtain the necessary evidence required. DHS also notes that an alien does not always have to provide information about the net value of a home and the related evidence. In general, the alien would need to provide information regarding the home and its net value if aliens using the home as evidence of his or her assets or resources. DHS will maintain the estimated time burden at 4.5 hours.

Comment: One commenter detailed several issues with Form I–944 and its requirements, saying that it will disproportionately harm low-income applicants and their families, place an unreasonable burden on families especially those who apply with their minor children, impose costly administrative burdens on Federal, State, and local government agencies, generate a huge workload for social services agencies, and undermine privacy rights of applicants. The commenter also noted that the rule will likely make it more difficult for low-income and vulnerable immigrants to remain on the path to U.S. citizenship, will dissuade many potential applicants from pursuing adjustment due to the costs of the application process, create financial hardship for people, and result in processing delays and lengthy wait times. One commenter said that the Form I–944 requirement would require states and counties to develop new work processes, require system updates, and would likely result in hiring and specially training additional personnel. The commenter further indicated that counties will need to work with their respective states to develop standardized processes for receiving requests and providing information across the state that safeguards personal data. The commenter stated that this is not only a significant workload but also would include potentially major automation costs, given the level of detail required.

Response: The purpose of Form I–944 is to demonstrate that an adjustment of status applicant subject to the public charge ground of inadmissibility is not likely at any time in the future to become a public charge, as required by Congress in section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4). Form I–944 collects information relevant to the mandatory factors, such as age, family status, assets, resources, financial status, education, and skills. DHS is required to assess an applicant's assets and resources as part of the public charge inadmissibility determination, which entails a review of the alien's income. These factors are mandated by Congress in section 212(a)(4) of the Act, and DHS does not have the authority to disregard these factors. Additionally, the estimated burden on any alien submitting Form I–944 was provided in the NPRM.

DHS acknowledges in the economic analysis accompanying this rule that various government agencies may incur indirect costs associated with the rule such as, for example, the potential need to update administrative processes and provide additional training. However, Form I–944 imposes no requirements on Federal, State, or local government agencies. Instead, applicants required to submit Form I–944 must submit certain evidence from Federal, State, and local government agencies such as Federal income tax returns and documentation of receipt of public benefits. DHS has reviewed the data provided by commenters and updated the cost estimates to account for the indirect effects of this rule, where possible.

IV. Statutory and Regulatory Requirements

A. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 13771 directs agencies to reduce regulation and control regulatory costs.

The Office of Information and Regulatory Affairs has designated this final rule as a ''significant regulatory action'' that is economically significant since it is estimated that the final rule would have an annual effect on the economy of $100 million or more, under section 3(f)(1) of E.O. 12866. Accordingly, OMB has reviewed this final regulation.

This rule is a regulatory action under E.O. 13771.

1. Summary

As discussed above, DHS is modifying its regulations to add new regulatory provisions for inadmissibility determinations based on the public charge ground under the INA. DHS is prescribing how it will determine whether an alien is inadmissible because he or she is likely at any time in the future to become a public charge and is identifying the types of public benefits that will be considered in the public charge determinations. An alien applying for admission at the port of entry, or adjustment of status generally must establish that he or she is not likely at any time in the future to become a public charge. DHS will weigh certain factors positively or negatively, depending on how the factor impacts the immigrant's likelihood to become a public charge. DHS is also revising existing regulations to require all aliens seeking an extension of stay or change of status to demonstrate that they have not received public benefits, as defined in this rule unless the nonimmigrant classification that they seek to extend or to which they seek to change is exempt from the public charge ground of inadmissibility. Finally, DHS is revising its regulations governing the Secretary's discretion to accept a public charge bond or similar undertaking under section 213 of the Act, 8 U.S.C. 1183. Similar to a waiver, a public charge bond permits an alien deemed inadmissible on the public charge ground to obtain adjustment of status, if otherwise admissible.[848]

This final rule will impose new costs on the population applying to adjust status using Form I–485 that are subject to the public charge ground of inadmissibility who will now be required to file the new Form I–944 as part of the public charge inadmissibility determination. DHS will require any adjustment applicants subject to the public charge inadmissibility ground to submit Form I–944 with their Form I–485 to demonstrate they are not likely at any time in the future to become a public charge. The final rule will also impose additional costs for completing Forms I–485, I–129, I–129CW, and I–539 as the associated time burden estimate for completing each of these forms will increase. Moreover, the final rule will impose new costs associated with the new public charge bond process, including new costs for completing and filing Forms I–945 and I–356. DHS estimates that the additional total cost of the final rule will be approximately $35,202,698 annually to the population applying to adjust status who is also required to file Form I–944, for the opportunity cost of time associated with the increased time burden estimates for Forms I–485, I–129, I–129CW, and I–539, and for requesting or cancelling a public charge bond using Form I–945 and Form I–356, respectively.

Over the first 10 years of implementation, DHS estimates the total quantified new direct costs of the final rule will be about $352,026,980 (undiscounted). In addition, DHS estimates that the 10-year discounted total direct costs of this final rule will be about $300,286,154 at a 3 percent discount rate and about $247,249,020 at a 7 percent discount rate.

The final rule will also potentially impose new costs on obligors (individuals or companies) if an alien has been determined to be likely at any time in the future to become a public charge and will be permitted to submit a public charge bond, for which USCIS will use the new Form I–945. DHS estimates the total cost to file Form I–945 will be, at minimum, about $34,166 annually.[849]

Moreover, the final rule will potentially impose new costs on aliens or obligors who submit Form I–356 as part of a request to cancel the public charge bond. DHS estimates the total cost to file Form I–356 would be approximately $824 annually.[850]

The final rule will also result in a reduction in transfer payments from the Federal Government to individuals who may choose to disenroll from or forego enrollment in a public benefits program. Individuals who might choose to disenroll from or forego future enrollment in a public benefits program include foreign-born non-citizens as well as U.S. citizens who are members of mixed-status households,[851] who otherwise may be eligible for the public benefits. DHS estimates that the total reduction in transfer payments from the Federal and State governments will be approximately $2.47 billion annually due to disenrollment or foregone enrollment in public benefits programs by foreign-born non-citizens who may be receiving public benefits. DHS estimates that the 10-year discounted federal and state transfer payments reduction of this final rule will be approximately $21.0 billion at a 3 percent discount rate and about $17.3 billion at a 7 percent discount rate. However, DHS notes there may be additional reductions in transfer payments, or categories of transfers such as increases in uncompensated health care or greater reliance on food banks or other charities, that we are unable to quantify.

There also may be additional reductions in transfer payments from states to individuals who may choose to disenroll from or forego enrollment in a public benefits program. For example, the Federal Government funds all SNAP food expenses, but only 50 percent of allowable administrative costs for regular operating expenses.[852] Similarly, FMAP in some HHS programs, like Medicaid, can vary from between 50 percent to an enhanced rate of 100 percent in some cases.[853] Since the state

[848] There is no mention of ''waiver'' or ''waive'' in INA section 213, 8 U.S.C. 1183. However, the BIA has viewed that provision as functioning as a waiver of the public charge ground of inadmissibility. *See Matter of Ulloa,* 22 I&N Dec. 725, 726 (BIA 1999).

[849] Calculation: $35.59 (cost per obligor to file Form I–945) * 960 (estimated annual population who would file Form I–945) = $34,166.40 = $34,166 (rounded) annual total cost to file Form I–945.

[850] Calculation: $33.00 (cost per obligor to file Form I–356) * 25 (estimated annual population who would file Form I–356) = $825.00 annual total cost to file Form I–356.

[851] DHS uses the term ''foreign-born non-citizen'' since it is the term the U.S. Census Bureau uses. DHS generally interprets this term to mean alien in this analysis. In addition, DHS notes that the Census Bureau publishes much of the data used in this analysis.

[852] Per section 16(a) of the Food and Nutrition Act of 2008, Pub. L. 110–234, tit. IV, 122 Stat. 923, 1092 (May 22, 2008) (codified as amended at 7 U.S.C. 2025). *See also* USDA, FNS Handbook 901, at p. 41 (2017). Available at: *https://fns-prod.azureedge.net/sites/default/files/apd/FNS_HB901_v2.2_Internet_Ready_Format.pdf*, (last visited May 7, 2019).

[853] *See* Dept. of Health and Human Servs. Notice, Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons

Continued

share of FFP varies from state to state, DHS uses the average FMAP across all states and U.S. territories of 59 percent to estimate the amount of state transfer payments. Therefore, the estimated 10-year undiscounted amount of state transfer payments that could occur as a result of the provisions of this final rule is about $1.01 billion annually. The estimated 10-year discounted amount of state transfer payments of the provisions of this final rule would be approximately $8.63 billion at a 3 percent discount rate and about $7.12 billion at a 7 percent discount rate. Finally, DHS recognizes that reductions in federal and state transfers under Federal benefit programs may have downstream impacts on state and local economies, large and small businesses, and individuals. For example, the rule might result in reduced revenues for healthcare providers participating in Medicaid, companies that manufacture medical supplies or pharmaceuticals, grocery retailers participating in SNAP, agricultural producers who grow foods that are eligible for purchase using SNAP benefits, or landlords participating in federally funded housing programs.

Additionally, the final rule will have new direct and indirect impacts on various entities and individuals associated with regulatory familiarization with the provisions of the rule. Familiarization costs involve the time spent reading the details of a rule to understand its changes. A foreign-born non-citizen (such as those contemplating disenrollment or foregoing enrollment in a public benefits program) might review the rule to determine whether she or he is subject to its provisions and may incur familiarization costs. To the extent that an individual or entity directly regulated by the rule incurs familiarization costs, those familiarization costs are a direct cost of the rule. In addition to those individuals or entities the rule directly regulates, a wide variety of other entities would likely choose to read and understand the rule and, therefore, would incur familiarization costs. For example, immigration lawyers, immigration advocacy groups, health care providers of all types, non-profit organizations, non-governmental organizations, and religious organizations, among others, may need or want to become familiar with the provisions of this final rule. DHS believes such non-profit organizations and other advocacy groups might choose to read the rule in order to provide information to those foreign-born non-citizens that might be affected by a reduction in federal and state transfer payments. Familiarization costs incurred by those not directly regulated are indirect costs.

DHS estimates the time that would be necessary to read this final rule would be approximately 16 to 20 hours per person depending on an individual's average reading speed and level of review, resulting in opportunity costs of time. An entity, such as a non-profit or advocacy group, may have more than one person that reads the rule. Using the average total rate of compensation as $36.47 per hour for all occupations, DHS estimates that the opportunity cost of time will range from about $583.52 to $729.40 per individual who must read and review the final rule.

The final rule will produce some quantified benefits due to the regulatory changes DHS is making. The final rule will produce some benefits for T nonimmigrants applying for adjustment of status based on their T nonimmigrant status, as this population will no longer need to submit Form I–601 seeking a waiver on the public charge ground of inadmissibility. DHS estimates the total benefits for this population is $15,176 annually.[854]

The primary benefit of the final rule would be to better ensure that aliens who are admitted to the United States, seek extension of stay or change of status, or apply for adjustment of status are not likely to receive public benefits and will be self-sufficient, *i.e.,* individuals will rely on their own financial resources, as well as the financial resources of the family, sponsors, and private organizations.[855] DHS also anticipates that the final rule will produce some benefits from the elimination of Form I–864W. The elimination of this form will potentially reduce the number of forms USCIS would have to process. DHS estimates the amount of cost savings that will accrue from eliminating Form I–864W will be about $36.47 per petitioner.[856] However, DHS is unable to determine the annual number of filings of Form I–864W and, therefore, currently is unable to estimate the total annual cost savings of this change. Additionally, a public charge bond process will also provide benefits to applicants as they potentially will be given the opportunity for adjustment if otherwise admissible, at the discretion of DHS, after a determination that he or she is likely to become a public charge.

Table 2 provides a more detailed summary of the final provisions and their impacts.

TABLE 2—SUMMARY OF MAJOR PROVISIONS AND ECONOMIC IMPACTS OF THE FINAL RULE

Provision	Purpose	Expected impact of final rule
Revising 8 CFR 212.18. Application for Waivers of Inadmissibility in connection with an application for adjustment of status by T nonimmigrant status holders. Revising 8 CFR 245.23. Adjustment of aliens in T nonimmigrant classification.	To clarify that T nonimmigrants seeking adjustment of status are not subject to public charge ground of inadmissibility.	**Quantitative:** *Benefits:* • Benefits of $15,176 annually to T nonimmigrants applying for adjustment of status who will no longer need to submit Form I–601 seeking a waiver on public charge grounds of inadmissibility. *Costs:* • None.

for October 1, 2016 through September 30, 2017, 80 FR 73779 (Nov. 25, 2015).

[854] Calculation: $14,880 (Filing fees for Form I–601) + $296.48 (Opportunity cost of time for Form I–601) = $15,176.48 = $15,176 (rounded) total current estimated annual cost for filing T nonimmigrants filing Form I–601 seeking a waiver of grounds of inadmissibility. Therefore, the estimated total benefits of the final rule for T nonimmigrants applying for adjustment of status using Form I–601 seeking a waiver on grounds of inadmissibility will equal the current cost to file Form I–601 for this population.

[855] 8 U.S.C. 1601(2).

[856] Calculation of savings from opportunity cost of time for no longer having to complete and submit Form I–864W: ($36.47 per hour * 1.0 hours) = $36.47.

TABLE 2—SUMMARY OF MAJOR PROVISIONS AND ECONOMIC IMPACTS OF THE FINAL RULE—Continued

Provision	Purpose	Expected impact of final rule
Adding 8 CFR 212.20. Purpose and applicability of public charge inadmissibility. Adding 8 CFR 212.21. Definitions ..... Adding 8 CFR 212.22. Public charge determination.   <

TABLE 2—SUMMARY OF MAJOR PROVISIONS AND ECONOMIC IMPACTS OF THE FINAL RULE—Continued

Provision	Purpose	Expected impact of final rule
		• DHS anticipates a likely increase in the number of denials for adjustment of status applicants based on public charge inadmissibility determinations due to formalizing and standardizing the criteria and process for public charge determination. • Costs to various entities and individuals associated with regulatory familiarization with the provisions of the final rule. Costs will include the opportunity cost of time to read the final rule and subsequently determine applicability of the final rule's provisions. DHS estimates that the time to read this final rule in its entirety would be 16 to 20 hours per individual. DHS estimates that the opportunity cost of time will range from about $583.52 to $729.40 per individual who must read and review the final rule. However, DHS cannot determine the number of individuals who will read the final rule.
Public Charge Bond Provisions		
Amending 8 CFR 103.6. Public charge bonds.	To set forth the Secretary's discretion to approve bonds, cancellation, bond schedules, and breach of bond, and to move principles governing public charge bonds to final 8 CFR 213.1.	**Quantitative:** *Costs:* • $34,166 annually to obligors for submitting Public Charge Bond (Form I–945); and • $823.50 annually to filers for submitting Request for Cancellation of Public Charge Bond (Form I–356).
Amending 8 CFR 103.7. Fees	To add fees for new Form I–945, Public Charge Bond, and Form I–356, Request for Cancellation of Public Charge Bond.	• Fees paid to bond companies to secure public charge bonds. Fees could range from 1–15 percent of the public charge bond amount based on an individual's credit score.
Amending 8 CFR 213.1. Admission or adjustment of status of aliens on giving of a public charge bond.	In 8 CFR 213.1, to add specifics to the public charge bond provision for aliens who are seeking adjustment of status, including the discretionary availability and the minimum amount required for a public charge bond.	**Quantitative:** *Benefits:* • Potentially enable an alien who was found inadmissible only on the public charge ground to adjust his or her status by posting a public charge bond with DHS.

Source: USCIS analysis.

DHS has prepared a full analysis according to E.O.s 12866 and 13563, and can be found in the docket for this rulemaking or by searching for RIN 1615–AA22 on *www.regulations.gov*. In addition to the impacts summarized above and as required by OMB Circular A–4, Table 8 presents the prepared accounting statement showing the costs associated with this final regulation.[857]

TABLE 8—OMB A–4 ACCOUNTING STATEMENT

[$, 2018]

Category	Primary estimate	Minimum estimate	Maximum estimate	Source citation
BENEFITS:				
Monetized Benefits	The final rule will produce some benefits for T nonimmigrants applying for adjustment of status based on their T nonimmigrant status, as this population will no longer need to submit Form I–601 seeking a waiver on grounds of inadmissibility. DHS estimates the total benefits for this population is $15,176 annually. Form I–485 applicants will no longer have to file Form I–864W. Benefits to applicants will be approximately $36.47 per petition based on the opportunity cost of time.			RIA.
Annualized quantified, but un-monetized, benefits.	.....	.....	.....	RIA.
Unquantified Benefits	The primary benefit of the final rule is to ensure that aliens who are admitted to the United States or apply for adjustment of status will not use or receive one or more public benefits for which they are entitled to receive, and instead, will rely on their financial resources, and those of family members, sponsors, and private organizations.			RIA.

[857] OMB Circular A–4 is *available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.*

TABLE 8—OMB A–4 ACCOUNTING STATEMENT—Continued

[$, 2018]

Category	Primary estimate	Minimum estimate	Maximum estimate	Source citation
	Potential to improve the efficiency for USCIS in the review process for public charge inadmissibility.			
COSTS:				
Annualized monetized costs (discount rate in parenthesis).	(3%) $35,202,698 (7%) $35,202,698	N/A N/A	N/A N/A	RIA.
Annualized quantified, but un-monetized, costs.	N/A.			
Qualitative (unquantified) costs.	DHS anticipates a likely increase in the number of denials for adjustment of status applicants based on public charge inadmissibility determinations due to formalizing and standardizing the criteria and process for public charge determination. Costs to various entities and individuals associated with regulatory familiarization with the provisions of the rule. Costs will include the opportunity cost of time to read the final rule and subsequently determine applicability of the final rule's provisions. DHS estimates that the time to read this final rule in its entirety would be 16 to 20 hours per individual. DHS estimates that the opportunity cost of time will range from about $583.52 to $729.40 per individual who must read and review the final rule. However, DHS cannot determine the number of individuals who will read the final rule. Fees paid by aliens to obligors to secure public charge bond. Other qualitative, unquantified effects of the final rule could include: • Potential lost productivity, • Adverse health effects, • Additional medical expenses due to delayed health care treatment, and • Increased disability insurance claims • Administrative changes to business processes such as reprogramming computer software and redesigning application forms and processing.			RIA.
TRANSFERS:				
Annualized monetized transfers: "on budget".	($1,455,724,086)	N/A	N/A	RIA.
From whom to whom?	Reduction in transfer payments from the federal government to public benefits recipients who are members of households that include foreign-born non-citizens. This amount includes the estimated federal-level shares of transfer payments to members of households that include foreign-born non-citizens.			RIA.
Annualized monetized transfers: "off-budget".	($1,011,604,874)	N/A	N/A	
From whom to whom?	Reduction in transfer payments from state governments to public benefits recipients who are members of households that include foreign-born non-citizens. This amount includes the estimated state-level shares of transfer payments to members of households that include foreign-born non-citizens. DHS estimates that the state-level share of transfer payments is 59 percent of the estimated amount of federal transfer payments. DHS estimates the annual federal-level share would be about $1.46 billion and the annual state-level share of transfer payments would be about $1.01 billion.			
Miscellaneous analyses/category	Effects			Source citation
Effects on state, local, and/or tribal governments.	DHS believes that the rule may have indirect effects on state, local, and/or tribal government, but DHS does not know the full extent of the effect on state, local, and/or tribal governments. There may be costs to various entities associated with familiarization of and compliance with the provisions of the rule, including salaries and opportunity costs of time to monitor and understand regulation requirements, disseminate information, and develop or modify information technology (IT) systems as needed. It may be necessary for many government agencies to update guidance documents, forms, and webpages. It may be necessary to prepare training materials and retrain staff at each level of government, which will require additional staff time and will generate associated costs.			RIA.
Effects on small businesses	DHS believes there may be some impacts to those small entities that file Form I–129 or Form I–129CW for beneficiaries that extend stay or change status. These petitioners will have an increase in time burden for completing and filing Form I–129 or Form I–129CW and possibly have labor turnover costs if the Form I–129 or Form I–129CW EOS/COS request is denied and the beneficiary has to leave the United States or the Commonwealth of the Northern Mariana Islands (CNMI), respectively. DHS also believes that some surety companies that are small entities may be impacted by filing Form I–356. DHS estimates the total annual cost to file Form I–356 will be about $823.50.			RIA.

Miscellaneous analyses/category	Effects	Source citation
Effects on wages	None	None.
Effects on growth	None	None.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (March 29, 1996), imposes certain requirements on Federal agency rules that are subject to the notice and comment requirements of the APA, 5 U.S.C. 553(b), and are likely to have a significant economic impact on a substantial number of small entities. The RFA requires Federal agencies to consider the potential impact of regulations on small businesses, small governmental jurisdictions, and small organizations during the development of their rules. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, or governmental jurisdictions with populations of less than 50,000.[858] This final rule requires an individual seeking admission at the port of entry or adjusting status to establish that he or she is not likely at any time in the future to become a public charge. Most of this rule's regulatory changes do not fall under the RFA because they directly regulate individuals who are not, for purposes of the RFA, within the definition of small entities established by 5 U.S.C. 601(6). However, DHS recognizes that there may be some provisions of this final rule that would directly regulate small entities, and, therefore, DHS has examined the impact of this final rule on small entities.

This final rule would increase the time burden by an additional 30 minutes for petitioners who file Form I–129 or Form I–129CW on behalf of a beneficiary requesting an extension of stay or change of status, which would impose direct costs on these petitioners. Additionally, the provisions to establish a public charge bond process included in this final rule would allow for either an alien or an obligor (individual or an entity) to request a cancellation of a public bond. As a result, this final rule could have direct impacts on small entities that are obligors. DHS also recognizes that a Form I–129 or Form I–129CW beneficiary, for whom a Form I–129 or Form I–129CW petitioner (*i.e.,* the employer) sought either an extension of stay or a change of status, may have to leave the United States if the employer's request was denied. In these cases, the petitioner may lose the beneficiary as an employee and may incur labor turnover costs. DHS presents this Final Regulatory Flexibility Analysis (FRFA) to examine these impacts.

1. Final Regulatory Flexibility Analysis

The small entities that could be impacted by this final rule are those who file Form I–129 or Form I–129CW as petitioners on behalf of beneficiaries requesting an extension of stay or change of status as well as obligors that would request a cancellation of a public charge bond.

a. A Statement of the Need for, and Objectives of, the Rule

DHS seeks to better ensure that applicants for admission to the United States and applicants for adjustment of status to lawful permanent resident who are subject to the public charge ground of inadmissibility are self-sufficient, *i.e.,* they will rely on their own financial resources as well as the financial resources of their family, sponsors, and private organizations as necessary.[859] Under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), an alien is inadmissible if, at the time of an application for admission or adjustment of status, he or she is likely at any time to become a public charge. The statute requires DHS to consider the following minimum factors that reflect the likelihood that an alien will become a public charge: The alien's age; health; family status; assets, resources, and financial status; and education and skills. In addition, DHS may consider any affidavit of support submitted by the alien's sponsor and any other factors relevant to the likelihood of the alien becoming a public charge.

Separate from these requirements, as a condition for permitting extension of stay or change of status for certain nonimmigrant aliens, this rule requires such aliens (or their petitioning employer) to establish that they have not received certain public benefits above a particular threshold since obtaining the nonimmigrant status that they wish to extend or change. This ''public benefit condition'' serves the same policy goals as the rule generally.

b. A statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

Comment: Some commenters stated that the rule will negatively impact small businesses. An individual commenter stated that the rule would undercut small and mid-sized businesses' ability to manage their talent pipelines. The commenter stated that nearly 48 percent of private-sector workers in the United States are employed in these small and mid-sized businesses, and that small businesses rely on strategic partnerships and related tools to ensure a strong talent pipeline of workers who are equipped with the skills they need. The commenter stated that the rule would penalize individuals who often draw upon public benefits to support themselves or their families during their training period or even when they first begin work. The commenter stated that in view of currently low unemployment, employers need access to labor that is able to attend training while still relying on public benefits programs to provide for their families' basic needs.

A commenter stated that the RFA mandates that DHS consider more impacts than it has such as labor turnover costs, or reduced productivity and educational attainment.

Response: DHS appreciates the comments regarding the effect of the rule on small entities, including small business, and DHS's RFA analysis. The RFA analysis discusses and estimates the potential direct costs that small businesses could incur and explains the limitations for providing a more thorough quantification of the potential costs to small businesses. Additionally, the economic analysis that accompanies this rule, which can be found in the rule docket at *www.regulations.gov*, discusses the direct and indirect effects of the rule, including on small businesses. Most of this rule's regulatory effects, such as the effects described in the comment summary above, do not fall under the RFA because they directly

[858] A small business is defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act, 15 U.S.C. 632.

[859] *See* 8 U.S.C. 1601(2).

regulate individuals who are not, for purposes of the RFA, within the definition of small entities established by 5 U.S.C. 601(6). However, DHS recognizes that there may be some provisions of this final rule that would directly regulate small entities, and, therefore, DHS has examined the impact of this final rule on small entities.

The primary effect on small entities is that this rule will increase the time burden for petitioners who file Form I–129 or Form I–129CW on behalf of a beneficiary requesting an extension of stay or change of status, which would impose direct costs on these petitioners via opportunity costs of time. DHS also recognizes that a Form I–129 or Form I–129CW beneficiary, for whom a Form I–129 or Form I–129CW petitioner (*i.e.,* the employer) sought either an extension of stay or a change of status, may have to leave the United States if the employer's request was denied. In these cases, the petitioner may lose the beneficiary as an employee and may incur labor turnover costs. Additionally, this rule could have direct impacts on small entities as the provisions establish a public charge bond process included in this final rule would allow for either an alien or an obligor (individual or an entity) to request a cancellation of a public bond.

DHS believes it has considered all impacts that the RFA requires. The courts have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates them.[860] However, DHS notes that we have also considered other, indirect impacts in the economic analysis that accompanies this rule.

c. The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.

No comments were filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA).

d. A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available.

This final rule will increase the time burden by an additional 30 minutes for petitioners who file Form I–129 or Form I–129CW on behalf of a beneficiary requesting an extension of stay or change of status, which would impose direct costs on these petitioners and entities.[861] As previously discussed in the E.O. 12866 section of this final rule, DHS estimates an annual population of 336,335 beneficiaries seeking extension of stay or change of status through a petitioning employer using Form I–129. In addition, DHS estimates an annual population of 6,307 beneficiaries seeking extension of stay or change of status through a petitioning employer using Form I–129CW. DHS estimates that the 30-minute increase in the estimated time burden for these populations would increase the opportunity cost of time for completing and filing Form I–129 and Form I–129CW and would result in about $6.1 million and about $115,040 million in costs, respectively.

The provisions regarding the bond process included in this final rule will allow a surety company to become an obligor on a public charge bond (Form I–945) and, later, to request a cancellation of such a bond (Form I–356). Therefore, this final rule could have some impacts to surety companies, some of which are small entities. A request for cancellation of a public bond using Form I–356 includes a time burden of 15 minutes per request and a fee to DHS of $25.00. The number of surety bond companies that might complete and file Forms I–945 and I–356 is not known due to a lack of historical data and uncertainty in the number individuals that may be granted the opportunity to post a public charge bond. However, DHS estimates that the filing volume for Form I–945 might be about 960 and the filing volume for Form I–356 might be approximately 25. While DHS cannot predict the exact number of surety companies that might be impacted by this final rule, nine out of 273 Treasury-certified surety companies in fiscal year 2015 posted new immigration bonds with ICE.[862] DHS found that of the nine surety companies, four entities were considered ''small'' based on the number of employees or revenue being less than their respective SBA size standard.[863] Assuming these nine surety companies post public charge bonds with USCIS, we can assume that four surety companies may be considered as small entities. However, USCIS cannot predict the exact impact to these small entities at this time. We expect that obligors would be able to pass along the costs of this rulemaking to the aliens.

e. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

In addition to time burden costs discussed in Section 4 of this FRFA, DHS recognizes that a Form I–129 or Form I–129CW beneficiary, for whom a Form I–129 or Form I–129CW petitioner (*i.e.,* the employer) sought either an extension of stay or a change of status, may have to leave the United States if the employer's request is denied. In these cases, the petitioner may lose the beneficiary as an employee and may incur labor turnover costs. A 2012 report published by the Center for American Progress surveyed several dozen studies that considered both direct and indirect costs and determined that turnover costs per employee ranged from 10 to 30 percent of the salary for most salaried workers.[864] An employer paid an average of about 20 percent of the worker's salary in total labor turnover costs. Specifically, for workers earning $50,000 or less, and for workers earning $75,000 or less, the average turnover cost was about 20 percent for both earning levels. According to the study, these earning levels corresponded to the 75th and 90th percentiles of typical earnings, respectively. Assuming Form I–129 and Form I–129CW beneficiaries are employed, DHS believes it is reasonable to assume an annual mean wage of $50,620 across all occupations.[865] Assuming an average labor turnover cost of 20 percent of $50,620, on average, an employer could incur costs of approximately $10,124 per beneficiary

[860] *See* U.S. Small Business Administration, Office of Advocacy. *The RFA in a Nutshell: A Condensed Guide to the Regulatory Flexibility Act.* Oct. 2010. Available at: *https://www.sba.gov/advocacy/rfa-nutshell-condensed-guide-regulatory-flexibility-act* (Last visited July 25, 2019).

[861] In the context of Form I–129, a petitioner is typically an employer or the representative of an employer who files on behalf of a nonimmigrant worker (or beneficiary) to come to the United States temporarily to perform services or labor, or to receive training. See *https://www.uscis.gov/i-129.*

[862] *See* DHS, Procedures and Standards for Declining Surety Immigration Bonds and Administrative Appeal Requirement for Breaches NPRM, 83 FR 25951, 25962–25965 (June 5, 2018).

[863] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System (NAICS) Codes, October 1, 2017. *https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf* (Last visited July 26, 2019).

[864] *See* ''There Are Significant Business Costs to Replacing Employees,'' by Heather Boushey and Sarah Jane Glynn (2012), Center for American Progress, *available: https://www.americanprogress.org/issues/economy/reports/2012/11/16/44464/there-are-significant-business-costs-to-replacing-employees/* (last visited July 26, 2019).

[865] Bureau of Labor Statistics, May 2017 National Occupational Employment and Wage Estimates, All Occupations *https://www.bls.gov/oes/2017/may/oes_nat.htm* (last visited July 26, 2019).

that would be separated from employment as a result of a denied request for an extension of stay or change of status. However, DHS does not know the number of small entities within this population of petitioners that might incur labor turnover costs.

Additionally, DHS also recognizes that a Form I–129 or Form I–129CW beneficiary, for whom a Form I–129 or Form I–129CW petitioner (*i.e.,* the employer) sought either an extension of stay or a change of status and the request was denied, may still be able to get a visa and return to the U.S., including pursuant to other means.

DHS does not believe it would be necessary for Form I–129 or Form I–129CW petitioners, or for surety bond companies (obligors) to acquire additional types of professional skills as a result of this final rule. These petitioners and obligors should already possess the expertise to fill out the associated forms for this final rule. Additionally, these petitioners and obligors would be familiar with the final rule and such familiarization costs are accounted for the in the E.O. 12866 sections.

f. Description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

DHS considered a range of potential alternatives to the final rule. First, under a ''no action'' alternative, DHS would continue administering the public charge ground of inadmissibility under the 1999 Interim Field Guidance, and would not impose a public benefit condition for extension of stay and change of status. For reasons explained more fully elsewhere in the preamble to the final rule, DHS determined that this alternative would not adequately ensure the self-sufficiency of aliens subject to the public charge ground of inadmissibility. Second, DHS considered including a more expansive definition of ''public benefit,'' potentially to include a range of non-cash benefit programs falling in specific categories (such as other programs that provide assistance for basic food and nutrition, housing, and healthcare). For reasons explained more fully elsewhere in the preamble to the final rule, DHS chose the approach contained in this final rule—a more limited list of cash benefits for income maintenance and high-expenditure non-cash benefits. DHS expects that, as compared to the broader alternative, the approach DHS decided to pursue may reduce the overall effect of the rule on transfers, but enhance its administrability and predictability. Employers filing Forms I–129 and I–129CW, and surety companies will have a better understanding of the types of non-cash benefits that may be covered under this final rule than they would under the broader alternative, and may realize cost savings as a result. In addition, certain indirect effects of the rule may be different as a result of the decision to reject this alternative.

DHS has revised the final rule to eliminate the future-looking aspect of the public benefit condition, which will reduce burden on small entities.

C. Congressional Review Act

DHS has sent this final rule to the Congress and to the Comptroller General under the Congressional Review Act, 5 U.S.C. 801 *et seq.* The Administrator of the Office of Information and Regulatory Affairs has determined that this rule is a ''major rule'' within the meaning of the Congressional Review Act. The rule therefore requires at least a 60-day delayed effective date.

D. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of UMRA requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may directly result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector. The inflation-adjusted value of $100 million in 1995 is approximately $165 million in 2018 based on the Consumer Price Index for All Urban Consumers (CPI–U).[866]

This final rule does not contain such a mandate as it does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments; nor does it increase private sector expenditures by more than $165 million annually (inflation adjusted); nor does it significantly or uniquely affect small governments. Accordingly, the UMRA requires no further agency action or analysis.

E. Executive Order 13132 (Federalism)

This final rule does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, E.O. 13132, Federalism, requires no further agency action or analysis.

F. Executive Order 12988 (Civil Justice Reform)

This final rule was drafted and reviewed in accordance with E.O. 12988, Civil Justice Reform. This final rule was written to provide a clear legal standard for affected conduct and was carefully reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. DHS has determined that this final rule meets the applicable standards provided in section 3 of E.O. 12988.

G. Executive Order 13175 Consultation and Coordination With Indian Tribal Governments

This final rule does not have ''tribal implications'' because it does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, E.O. 13175, Consultation and Coordination with Indian Tribal Governments, requires no further agency action or analysis.

H. Family Assessment

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. Agencies must assess whether the regulatory action: (1) Impacts the stability or safety of the family, particularly in terms of marital commitment; (2) impacts the authority of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions; (4) affects disposable income or poverty of families and children; (5) if the regulatory action financially impacts families, are justified; (6) may be carried out by State or local government or by the family; and (7) establishes a policy

[866] U.S. Bureau of Labor Statistics, *Historical Consumer Price Index for All Urban Consumers (CPI–U): U.S. City Average, All Items, available at https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-201902.pdf* (last visited April 25, 2019).

concerning the relationship between the behavior and personal responsibility of youth and the norms of society. If the determination is affirmative, then the Agency must prepare an impact assessment to address criteria specified in the law. As discussed in the NPRM,[867] DHS has determined that the rule may decrease disposable income and increase the poverty of certain families and children, including U.S. citizen children. DHS continues to be of the opinion that the benefits of the action justify the financial impact on the family. Additionally, because the final rule considers public benefits for purposes of the inadmissibility determination that were not considered under the 1999 Interim Field Guidance, DHS determined that the aliens found inadmissible under section 212(a)(4) of the Act, 8 U.S.C. 1182(a)(4), will likely increase. However, given the compelling need for this rulemaking, including but not limited to ensuring self-sufficiency and minimizing the incentive to immigrate based on the U.S. social safety net, DHS determined that this rulemaking's impact is justified and no further actions are required. DHS also determined that this final rule will not have any impact on the autonomy or integrity of the family as an institution.

I. National Environmental Policy Act (NEPA)

DHS analyzes actions to determine whether NEPA applies to them and if so what degree of analysis is required. DHS Directive (Dir) 023–01 Rev. 01 and Instruction Manual (Inst.) 023–01–001 Rev. 01 establish the procedures that DHS and its components use to comply with NEPA and the Council on Environmental Quality (CEQ) regulations for implementing NEPA, 40 CFR parts 1500 through 1508. The CEQ regulations allow Federal agencies to establish, with CEQ review and concurrence, categories of actions (''categorical exclusions'') which experience has shown do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment (EA) or Environmental Impact Statement (EIS). 40 CFR 1507.3(b)(1)(iii), 1508.4. DHS Instruction 023–01–001 Rev. 01 establishes such Categorical Exclusions that DHS has found to have no such effect. Inst. 023–01–001 Rev. 01 Appendix A Table 1. For an action to be categorically excluded, DHS Inst. 023–01–001 Rev. 01 requires the action to satisfy each of the following three conditions:

(1) The entire action clearly fits within one or more of the Categorical Exclusions;

(2) the action is not a piece of a larger action; and

(3) no extraordinary circumstances exist that create the potential for a significant environmental effect. Inst. 023–01–001 Rev. 01 section V.B(1)–(3).

DHS has analyzed this action and has concluded that NEPA does not apply due to the excessively speculative nature of any effort to conduct an impact analysis. This final rule fits within the Categorical Exclusion found in DHS Inst. 023–01–001 Rev. 01, Appendix A, Table 1, number A3(d): ''Promulgation of rules . . . that interpret or amend an existing regulation without changing its environmental effect.'' This final rule is not part of a larger action. This final rule presents no extraordinary circumstances creating the potential for significant environmental effects. Therefore, this final rule is categorically excluded from further NEPA review.

This final rule applies to applicants for admission or adjustment of status, as long as the individual is applying for an immigration status that is subject to the public charge ground of inadmissibility. In addition, this final rule would potentially affect individuals applying for an extension of stay or change of status because these individuals would have to demonstrate that they have not received, since obtaining the nonimmigrant status they are seeking to extend or change, public benefits for a duration of more than 12 months in the aggregate within a 36-month period. As discussed in detail above, this final rule establishes a definition of public charge and expands the types of public benefits that DHS would consider as part of its public charge inadmissibility determinations. The final rule also proposes to establish a regulatory framework based on the statutory factors that must be considered in public charge determinations, including enhanced evidentiary requirements for public charge inadmissibility determinations by USCIS. Finally, the final rule revises the public charge bond process. Overall, the final rule requires an in-depth adjudication that may result in additional findings of inadmissibility, ineligibility for adjustment of status on public charge grounds, or denials of requests for extension of stay or change of status based on the public benefit condition.

DHS cannot estimate with any degree of certainty the extent to which any potentially increased findings of inadmissibility on public charge grounds would result in fewer individuals being admitted to the United States. DHS is similarly unable to estimate the extent to which there would be an increased denial of applications for extension of stay or change of status. Even if DHS could estimate any of these numerical effects, any assessment of derivative environmental effect at the national level would be unduly speculative. This final rule is not part of a larger action. This final rule presents no extraordinary circumstances creating the potential for significant environmental effects. Therefore, this final rule is categorically excluded from further NEPA review.

J. Paperwork Reduction Act

Under the PRA, all Departments are required to submit to OMB, for review and approval, any reporting requirements inherent in a rule. *See* Public Law 104–13, 109 Stat. 163 (May 22, 1995). Table 9 below is a listing of all forms impacted by this rule.

[867] *See* Inadmissibility on Public Charge Grounds, 83 FR 51114, 51277 (proposed Oct. 10, 2018).

TABLE 9—SUMMARY OF FORMS

Form	Form name	New or updated forms	General purpose of form	General categories filing	Applicability to public charge rule
I–944	Declaration of Self-Sufficiency.	New	This form is used to demonstrate that an alien is not likely to become a public charge.	Anyone who is subject to a public charge inadmissibility determination. See Tables 2–7 for a full list.	This form is the primary basis for determining whether an applicant is inadmissible on public charge grounds, as it asks questions about the factors considered.
I–356	Request for Cancellation of a Public Charge Bond.	Update—Previously discontinued.	This form is used to request cancellation of the bond that was submitted on Form I–945, Public Charge Bond, on behalf of an alien.	An obligor who posted Form I–945 on the alien's behalf or an alien who posted Form I–945 posted on his or her own behalf, and who seeks to cancel Form I–945 because the alien has permanently departed the United States, naturalized, or died; the obligor or the alien seeks cancellation of the bond following the alien's fifth anniversary of admission to the United States as a lawful permanent resident; or the alien, following the initial grant of lawful permanent resident status, obtains an immigration status that is exempt from the public charge ground of inadmissibility.	This form is used to seek cancellation of the Form I–945 the criteria as provided in the rule.
I–945	Public Charge Bond	New	This form is the bond contract between USCIS and the obligor.	For aliens inadmissible only based on public charge and who are permitted to post bond. The form is completed by the obligor, who posts the bond on the alien's behalf.	If an alien seeking adjustment of status has been found inadmissible he or she may be admitted to the United States upon the posting of a suitable and proper a bond at the discretion of DHS.
I–485	Application to Register Permanent Residence or Adjust Status.	Update—adds questions and instructions to clarify what categories need to file Form I–944 and Form I–864.	This form is used by aliens present in the United States to obtain lawful permanent resident status..	For aliens applying for adjustment of status including: Immediate relatives (spouses, children, and parents of U.S. citizens) Family-based immigrants (principal beneficiaries and their dependents) Employment-based immigrants (principal beneficiaries and their dependents) Those who entered as Ks (Fiance(e)s or certain spouses of U.S. citizens, and their children) who are seeking lawful permanent resident status based on the primary beneficiary's marriage to the U.S. citizen petitioner.	Adjustment of status applicants generally must be admissible, including with regard to the public charge inadmissibility ground.
I–864	Affidavit of Support Under Section 213A of the INA.	Update—reference to Form I–864W, which is being discontinued.	Statement/contract provided by a sponsor to show that the sponsor has adequate financial resources to support the alien.	Most family-based immigrants and some employment-based immigrants must have a sponsor submit this form. See additional Tables 2–7 for a full list.	The affidavit of support, when required, is part of the public charge inadmissibility determination.

TABLE 9—SUMMARY OF FORMS—Continued

Form	Form name	New or updated forms	General purpose of form	General categories filing	Applicability to public charge rule
I–864EZ ...	Affidavit of Support Under Section 213A of the Act.	Update—reference to Form I–864W, which is being discontinued.	Statement/contract provided by sponsor to show that the sponsor has adequate financial resources to support the alien. This is a simpler version of Form I–864.	The sponsor is the person who filed or is filing Form I–130, Petition for Alien Relative, for a relative being sponsored; the relative the sponsor is sponsoring is the only person listed on Form I–130; and the income the sponsor is using to qualify is based entirely on the sponsor's salary or pension and is shown on one or more Internal Revenue Service (IRS) Form W–2s provided by the sponsor's employers or former employers.	The affidavit of support, when required, is part of the public charge inadmissibility determination.
I–864W	Request for Exemption for Intending Immigrant's Affidavit of Support.	Discontinued—information incorporated into Form I–485.	Certain classes of immigrants are exempt from the affidavit of support, Form I–864, requirement and therefore must file Form I–864W instead.	Aliens who have earned 40 quarters of SSA coverage. Children who will become U.S. citizens upon entry or adjustment into the United States under INA 320. Self-Petitioning Widow(er) Form I–360, Petition for Amerasian, Widow(er) or Special Immigrant; Self-Petitioning bettered spouse or child.	Although some people may be exempt from the affidavit of support requirement, the person may still be subject to public charge.
I–129	Petition for Nonimmigrant Worker.	Update—adds questions and instructions about receipt of public benefits.	This form issued by an employer to petition USCIS for an alien beneficiary to come temporarily to the United States as a nonimmigrant to perform services or labor, or to receive training. This form is also used by certain nonimmigrants to apply for EOS or COS.	• E–2 CNMI—treaty investor exclusively in the Commonwealth of the Northern Mariana Islands (CNMI). • H–1B—specialty occupation worker; an alien coming to perform services of an exceptional nature that relate to a U.S. Department of Defense-administered project; or a fashion model of distinguished merit and ability. • H–2A—temporary agricultural worker • H–2B—temporary nonagricultural worker. • H–3—trainee • L–1—intracompany transferee • O–1—alien of extraordinary ability in arts, science, education, business, or athletics. • O–2—accompanying alien who is coming to the United States to assist in the artistic or athletic performance of an O–1 artist or athlete. • P–1—major league sports • P–1—internationally recognized athlete/entertainment group. • P–1S—essential support personnel for a P–1. • P–2—artist/entertainer in reciprocal exchange program. • P–2S—essential support personnel for a P–2. • P–3—artist/entertainer coming to the United States to perform, teach, or coach under a program that is culturally unique. • P–3S—essential support personnel for a P–3. • Q–1—alien coming temporarily to participate in an international cultural exchange program. Extension of Status. • E–1—treaty trader • E–2—treaty investor (not including E–2 CNMI treaty investors). • E–3—Free Trade Agreement professionals from Australia. Free Trade Nonimmigrants—H–1B1 specialty occupation workers from Chile or Singapore and TN professionals from Canada or Mexico. • R–1—religious worker	As a condition of granting extension of stay and change of status, the applicant must show that he or she has not received, since obtaining the nonimmigrant status he or she is seeking to extend or change public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate, within a 36-month period.

TABLE 9—SUMMARY OF FORMS—Continued

Form	Form name	New or updated forms	General purpose of form	General categories filing	Applicability to public charge rule
I–129CW	Petition for a CNMI-Only Nonimmigrant Transitional Worker.	Update—adds questions and instructions about receipt of public benefits.	.....	This form is used by an employer to request an extension of stay or change of status for a Commonwealth of the Northern Mariana Islands (CNMI) temporarily to perform services or labor as a CW–1, CNMI-Only Transitional Worker.	As a condition of granting extension of stay and change of status, the applicant must show that he or she has not received, since obtaining the nonimmigrant status he or she is seeking to extend or change public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within a 36-month period.
I–539	Application to Extend/Change Nonimmigrant Status.	Update—adds questions and instructions about receipt of public benefits for principal aliens.	This form is used by certain nonimmigrants (principal filers) to apply for an extension of stay or change of status. In certain circumstances, this form may be used as an initial nonimmigrant status, or reinstatement of F–1 or M–1 status (students).	CNMI residents applying for an initial grant of status; Student (F) and vocational students (M) applying for reinstatement; and Persons seeking V nonimmigrant status or an extension of stay as a V nonimmigrant (spouse or child of a lawful permanent resident who filed a petition on or before December 21, 2000).	As a condition of granting extension of stay and change of status, the applicant must show that he or she has not received since obtaining the nonimmigrant status he or she is seeking to extend or from which he or she is seeking to change public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within a 36-month period.
I–539A	.....	Update—adds questions and instructions about receipt of public benefits by co-applicants of I–539 applicants.	This form is used by certain nonimmigrants (co-applicants of the primary I–539 applicants) to apply for an extension of stay or change of status.	Co-Applicants of I–539 principal filers	As a condition of granting extension of stay and change of status, the co-applicant must show that he or she has not received, since obtaining the nonimmigrant status he or she is seeking to extend or from which he or she is seeking to change, public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within a 36-month period.

TABLE 9—SUMMARY OF FORMS—Continued

Form	Form name	New or updated forms	General purpose of form	General categories filing	Applicability to public charge rule
I–912	Request for Fee Waiver.	Update—provides a notice that a request for a fee waiver may be a factor in the public charge determination.	This form may be filed with certain USCIS applications, petitions, and requests in order to request a fee waiver.	Certain Form I–485 applicants, generally those who are not subject to the public charge ground of inadmissibility and those applying under certain humanitarian programs, may request a fee waiver on Form I–912. Applicants for E–2 CNMI investor nonimmigrant status under 8 CFR 214.2(e)(23) filing Form I–129 or Form I–539 may request a fee waiver..	A request of a fee waiver is a factor in the determination of Public Charge.
I–407	Record of Abandonment of Lawful Permanent Resident Status.	No changes	This form is used to record an alien's abandonment of status as a lawful permanent resident in the United States.	An alien who wants to record the voluntary abandonment of his or her lawful permanent resident status.	If a public charge bond has been posted on the alien's behalf, the obligor or the alien may request that the bond be cancelled because the alien permanently departed the United States. The alien shows that he or she voluntarily abandoned his or her status by submitting proof that he or she executed Form I–407 and that he or she physically departed the United States.
I–693	Report of Medical Examination and Vaccination Record.	No changes	This form is used to report results of an immigration medical examination performed by a civil surgeon to USCIS..	Generally, adjustment of status applicants are required to submit Form I–693. Nonimmigrants seeking a change or extension of status are generally not required to submit Form I–693, except for nonimmigrants seeking a change of status to spouse of legal permanent resident (V) status. See table in *https://www.uscis.gov/policymanual/HTML/PolicyManual-Volume8-PartB-Chapter3.html*.	Form I–693 is used as part of the health factor to identify medical conditions that will affect an applicant's ability to provide and care for himself or herself, to attend school or to work.

To conform with the requirements set forth by the PRA, on October 10, 2018, at 83 FR 51114, USCIS requested comments on the following information collection. USCIS did receive comments on some of these information collections after publishing that notice. USCIS responded to these comments above in Section III. At this time, the following forms are not open for comment.

USCIS Form I–944

(1) *Type of Information Collection Request:* New Collection.

(2) *Title of the Form/Collection:* Declaration of Self-Sufficiency.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–944; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. USCIS will require an individual applying to adjust status to lawful permanent residence (Form I–485) and who is subject to the public charge ground of inadmissibility to file Form I–944. The data collected on these forms will be used by USCIS to determine the likelihood of a declarant becoming a public charge based on the factors regarding age; health; family status; assets, resources, and financial status; and education and skills. The information collection serves the purpose of standardizing public charge evaluation metrics and ensures that declarants provide all essential information required for USCIS to assess self-sufficiency and adjudicate the declaration. If USCIS determines that a declarant is likely to become a public charge, the declarant may need to provide additional evidence to overcome this determination.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–944 is 382,264 and the estimated hour burden per response is 4.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,720,188 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $177,943,892.

USCIS Form I–356

(1) *Type of Information Collection Request:* New Collection.

(2) *Title of the Form/Collection:* Request for Cancellation of Public Charge Bond.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–356; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or household, business or other for profits. The alien (on whose behalf a public charge bond has been posted) or the obligor (surety) (who is the obligor who posted a bond on the alien's behalf). The form is used to request cancellation of the public charge bond because of the alien's naturalization, permanent departure, or death. The form is also used by the alien or the obligor to request cancellation of the public charge bond upon the fifth anniversary of the alien's admission to the United States as a lawful permanent resident.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–356 is 25 and the estimated hour burden per response is 0.75 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 19 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $6,250.

USCIS Form I–945

(1) *Type of Information Collection Request:* New Collection.

(2) *Title of the Form/Collection:* Public Charge Bond.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–945; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households, business or other for profit. In certain instances, a surety bond, or cash or any cash equivalent and contract to secure the bond, can be posted on behalf of the alien to guarantee a set of conditions set by the Government concerning an alien, *i.e.,* that the alien will not become a public charge as defined in 8 CFR 212.21 because he or she will not receive public benefits, as defined in the rule, after the alien's adjustment of status to that of a lawful permanent resident. An acceptable surety is generally any company listed on the Department of the Treasury's Listing of Approved Sureties (Department Circular 570) in effect on the date the bond is requested or an individual or an entity that deposits cash or a cash equivalent, such as a cashier's check or money order for the full value of the bond.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–945 is 960 and the estimated hour burden per response is one hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 960 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0.

USCIS Form I–485

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application to Register Permanent Residence or Adjust Status.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–485; Supplement A; and Supplement J; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information collected is used to determine eligibility to adjust status under section 245 of the INA.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–485 is 382,264 and the estimated hour burden per response is 6.42 hours. The estimated total number of respondents for the information collection Supplement A is 36,000 and the estimated hour burden per response is 1.25 hours. The estimated total number of respondents for the information collection Supplement J is 28,309 and the estimated hour burden per response is one hour. The estimated total number of respondents for the information collection of Biometrics is 305,811 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 2,885,243 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $131,116,552.

USCIS Forms I–864; I–864A; I–864EZ

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Affidavit of Support Under Section 213A of the INA; Contract Between Sponsor and Household Member; Affidavit of Support under Section 213 of the Act.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–864; Form I–864A; and Form I–864EZ; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–864: USCIS uses the data collected on Form I–864 to determine whether the sponsor has the ability to support the sponsored alien under section 213A of the INA. This form standardizes evaluation of a sponsor's ability to support the sponsored alien and ensures that basic information required to assess eligibility is provided by petitioners. The information collection required on Form I–864A is necessary for public benefit agencies to enforce the affidavit of support in the event the sponsor used income of his or her household members to reach the required income level and the public benefit agencies are requesting reimbursement from the sponsor. Form I–864A: Form I–864A is a contract between the sponsor and the sponsor's household members. It is only required if the sponsor used income of his or her household members to reach the required 125 percent of the FPG. The contract holds these household members jointly and severally liable for the support of the sponsored immigrant. The information collection required on Form I–864A is necessary for public benefit agencies to enforce the affidavit of support in the event the sponsor used income of his or her household members to reach the required income level and the public benefit agencies are requesting reimbursement from the sponsor. Form I–864EZ: USCIS uses Form I– 864EZ in exactly the same way as Form I–864; however, USCIS collects less information from the sponsors as

less information is needed from those who qualify in order to make an adjudication.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–864 is 453,345 and the estimated hour burden per response is 6 hours. The estimated total number of respondents for the information collection I–864A is 215,800 and the estimated hour burden per response is 1.75 hours. The estimated total number of respondents for the information collection I–864EZ is 100,000 and the estimated hour burden per response is 2.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 3,347,720 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $135,569,525.

USCIS Form I–129

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Nonimmigrant Worker.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–129; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. USCIS uses the data collected on this form to determine eligibility for the requested nonimmigrant petition and/or requests to extend or change nonimmigrant status. An employer (or agent, where applicable) uses this form to petition USCIS for an alien to temporarily enter as a nonimmigrant. An employer (or agent, where applicable) also uses this form to request an extension of stay or change of status on behalf of the alien worker. The form serves the purpose of standardizing requests for nonimmigrant workers, and ensuring that basic information required for assessing eligibility is provided by the petitioner while requesting that beneficiaries be classified under certain nonimmigrant employment categories. It also assists USCIS in compiling information required by Congress annually to assess effectiveness and utilization of certain nonimmigrant classifications.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–129 is 552,000 and the estimated hour burden per response is 2.84 hours. The estimated total number of respondents for the information collection I–129, E–1/E–2 Classification Supplement is 4,760 and the estimated hour burden per response is 0.67 hours. The estimated total number of respondents for the information collection I–129, Trade Agreement Supplement is 3,057 and the estimated hour burden per response is 0.67 hours. The estimated total number of respondents for the information collection I–129, H Classification Supplement is 255,872 and the estimated hour burden per response is two hours. The estimated total number of respondents for the information collection I–129, H–1B and H–1B1 Data Collection and Filing Fee Exemption Supplement is 243,965 and the estimated hour burden per response is one hour. The estimated total number of respondents for the information collection I–129, L Classification Supplement is 37,831 and the estimated hour burden per response is 1.34 hours. The estimated total number of respondents for the information collection I–129, O and P Classifications Supplement is 22,710 and the estimated hour burden per response is one hour. The estimated total number of respondents for the information collection I–129, Q–1 Classification Supplement is 155 and the estimated hour burden per response is 0.34 hours. The estimated total number of respondents for the information collection I–129, R–1 Classification is 6,635 and the estimated hour burden per response is 2.34 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 2,417,609 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $132,368,220.

USCIS Form I–129CW

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for a CNMI-Only Nonimmigrant Transitional Worker.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–129CW; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for profit. USCIS uses the data collected on this form to determine eligibility for the requested immigration benefits. An employer uses this form to petition USCIS for an alien to temporarily enter as a nonimmigrant into the CNMI to perform services or labor as a CNMI-Only Transitional Worker (CW–1). An employer also uses this form to request an extension of stay or change of status on behalf of the alien worker. The form serves the purpose of standardizing requests for these benefits, and ensuring that the basic information required to determine eligibility, is provided by the petitioners. USCIS collects biometrics from aliens present in the CNMI at the time of requesting initial grant of CW–1 status. The information is used to verify the alien's identity, background information and ultimately adjudicate their request for CW–1 status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–129CW is 3,749 and the estimated hour burden per response is 3.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 13,122 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $459,253.

USCIS Form I–539 and Form I–539A

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application to Extend/Change Nonimmigrant Status.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–539; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This form will be used for nonimmigrants to apply for an extension of stay, for a change to another nonimmigrant classification, or for obtaining V nonimmigrant classification.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to*

respond: The estimated total number of respondents for the information collection Form I–539 paper filers is 174,289 and the estimated hour burden per response is two hours. The estimated total number of respondents for the information collection Form I–539 e-filers is 74,696 and the estimated hour burden per response is 1.08 hours. The estimated total number of respondents for the information collection I–539A is 54,375 and the estimated hour burden per response is 0.5 hour. The estimated total number of respondents for the information collection of Biometrics is 248,985 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 747,974 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $56,121,219.

USCIS Form I–912

Under the PRA DHS is required to submit to OMB, for review and approval, covered reporting requirements inherent in a rule. This rule will require non-substantive edits to USCIS Form I–912, Request for Fee Waiver. These edits make clear to those who request fee waivers that an approved fee waiver can negatively impact eligibility for an immigration benefit that is subject to the public charge inadmissibility determination. Accordingly, USCIS has submitted a PRA Change Worksheet, Form OMB 83–C, and amended information collection instrument to OMB for review and approval in accordance with the PRA.

USCIS Form I–407

Under the PRA, DHS is required to submit to OMB, for review and approval, covered reporting requirements inherent in a rule. This rule requires the use of USCIS Form I–407 but does not require any changes to the form or instructions and does not impact the number of respondents, time or cost burden. This form is currently approved by OMB under the PRA. The OMB control number for this information collection is 1615–0130.

USCIS Form I–693

Under the PRA, DHS is required to submit to OMB, for review and approval, covered reporting requirements inherent in a rule. This rule requires the use of USCIS Form I–693 but does not require any changes to the form or instructions and does not impact the number of respondents, time or cost burden. This form is currently approved by OMB under the PRA. The OMB control number for this information collection is 1615–0033.

V. List of Subjects and Regulatory Amendments

List of Subjects

8 CFR Part 103

Administrative practice and procedure, Authority delegations (Government agencies), Freedom of information, Immigration, Privacy, Reporting and recordkeeping requirements, Surety bonds.

8 CFR Part 212

Administrative practice and procedure, Aliens, Immigration, Passports and visas, Reporting and recordkeeping requirements.

8 CFR Part 213

Immigration, Surety bonds.

8 CFR Part 214

Administrative practice and procedure, Aliens, Cultural exchange programs, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

8 CFR Part 245

Aliens, Immigration, Reporting and recordkeeping requirements.

8 CFR Part 248

Aliens, Reporting and recordkeeping requirements.

Accordingly, DHS amends chapter I of title 8 of the Code of Federal Regulations as follows:

PART 103—IMMIGRATION BENEFITS; BIOMETRIC REQUIREMENTS; AVAILABILITY OF RECORDS

■ 1. The authority citation for part 103 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1101, 1103, 1304, 1356, 1365b; 31 U.S.C. 9701; Public Law 107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*); E.O. 12356, 47 FR 14874, 15557, 3 CFR, 1982 Comp., p.166; 8 CFR part 2; Pub. L. 112–54.

■ 2. Section 103.6 is amended by:

a. Revising paragraphs (a)(1), (a)(2)(i), and (c)(1);

■ b. Adding paragraph (d)(3); and

■ c. Revising paragraph (e) The revisions and additions read as follows:

§ 103.6 Surety bonds.

(a) * * *

(1) *Extension agreements; consent of surety; collateral security.* All surety bonds posted in immigration cases must be executed on the forms designated by DHS, a copy of which, and any rider attached thereto, must be furnished to the obligor. DHS is authorized to approve a bond, a formal agreement for the extension of liability of surety, a request for delivery of collateral security to a duly appointed and undischarged administrator or executor of the estate of a deceased depositor, and a power of attorney executed on the form designated by DHS, if any. All other matters relating to bonds, including a power of attorney not executed on the form designated by DHS and a request for delivery of collateral security to other than the depositor or his or her approved attorney in fact, will be forwarded to the appropriate office for approval.

(2) *Bond riders*—(i) *General.* A bond rider must be prepared on the form(s) designated by DHS, and attached to the bond. If a condition to be included in a bond is not on the original bond, a rider containing the condition must be executed.

* * * * *

(c) * * *

(1) Public charge bonds. Special rules for the cancellation of public charge bonds are described in 8 CFR 213.1.

* * * * *

(d) * * *

(3) *Public charge bonds.* The threshold bond amount for public charge bonds is set forth in 8 CFR 213.1.

(e) *Breach of bond.* Breach of public charge bonds is governed by 8 CFR 213.1. For other immigration bonds, a bond is breached when there has been a substantial violation of the stipulated conditions. A final determination that a bond has been breached creates a claim in favor of the United States which may not be released by the officer. DHS will determine whether a bond has been breached. If DHS determines that a bond has been breached, it will notify the obligor of the decision, the reasons therefor, and inform the obligor of the right to appeal the decision in accordance with the provisions of this part.

■ 3. Section 103.7 is amended by adding paragraphs (b)(1)(i)(LLL) and (MMM) to read as follows:

§ 103.7 Fees.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(LLL) Public Charge Bond, Form I–945. $25.

(MMM) Request for Cancellation of Public Charge Bond, Form I–356. $25.

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

■ 4. The authority citation for part 212 continues to read as follows:

Authority: 6 U.S.C. 111, 202(4) and 271; 8 U.S.C. 1101 and note, 1102, 1103, 1182 and note, 1184, 1185 note (section 7209 of Pub. L. 108–458), 1187, 1223, 1225, 1226, 1227, 1255, 1359; 8 CFR part 2.

■ 5. Amend § 212.18 by revising paragraph (b)(2) and (3) to read as follows:

§ 212.18 Application for Waivers of inadmissibility in connection with an application for adjustment of status by T nonimmigrant status holders

* * * * *

(b) * * *

(2) If an applicant is inadmissible under section 212(a)(1) of the Act, USCIS may waive such inadmissibility if it determines that granting a waiver is in the national interest.

(3) If any other applicable provision of section 212(a) renders the applicant inadmissible, USCIS may grant a waiver of inadmissibility if the activities rendering the alien inadmissible were caused by or were incident to the victimization and USCIS determines that it is in the national interest to waive the applicable ground or grounds of inadmissibility.

■ 6. Add §§ 212.20 through 212.23 to read as follows:

Sec.

* * * * *

212.20 Applicability of public charge inadmissibility.
212.21 Definitions.
212.22 Public charge inadmissibility determination.
212.23 Exemptions and waivers for public charge ground of inadmissibility.

§ 212.20 Applicability of public charge inadmissibility.

8 CFR 212.20 through 212.23 address the public charge ground of inadmissibility under section 212(a)(4) of the Act. Unless the alien requesting the immigration benefit or classification has been exempted from section 212(a)(4) of the Act as listed in 8 CFR 212.23(a), the provisions of §§ 212.20 through 212.23 of this part apply to an applicant for admission or adjustment of status to lawful permanent resident, if the application is postmarked (or, if applicable, submitted electronically) on or after October 15, 2019.

§ 212.21 Definitions.

For the purposes of 8 CFR 212.20 through 212.23, the following definitions apply:

(a) *Public Charge.* Public charge means an alien who receives one or more public benefits, as defined in paragraph (b) of this section, for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months).

(b) *Public benefit.* Public benefit means:

(1) Any Federal, State, local, or tribal cash assistance for income maintenance (other than tax credits), including:

(i) Supplemental Security Income (SSI), 42 U.S.C. 1381 *et seq.;*

(ii) Temporary Assistance for Needy Families (TANF), 42 U.S.C. 601 *et seq.;* or

(iii) Federal, State or local cash benefit programs for income maintenance (often called ''General Assistance'' in the State context, but which also exist under other names); and

(2) Supplemental Nutrition Assistance Program (SNAP), 7 U.S.C. 2011 to 2036c;

(3) Section 8 Housing Assistance under the Housing Choice Voucher Program, as administered by HUD under 42 U.S.C. 1437f;

(4) Section 8 Project-Based Rental Assistance (including Moderate Rehabilitation) under Section 8 of the U.S. Housing Act of 1937 (42 U.S.C. 1437f); and

(5) Medicaid under 42 U.S.C. 1396 *et seq.,* except for:

(i) Benefits received for an emergency medical condition as described in 42 U.S.C. 1396b(v)(2)–(3), 42 CFR 440.255(c);

(ii) Services or benefits funded by Medicaid but provided under the Individuals with Disabilities Education Act (IDEA) 20 U.S.C. 1400 *et seq.;*

(iii) School-based services or benefits provided to individuals who are at or below the oldest age eligible for secondary education as determined under State or local law;

(iv) Benefits received by an alien under 21 years of age, or a woman during pregnancy (and during the 60-day period beginning on the last day of the pregnancy).

(6) Public Housing under section 9 of the U.S. Housing Act of 1937.

(7) Public benefits, as defined in paragraphs (b)(1) through (b)(6) of this section, do not include any public benefits received by an alien who at the time of receipt of the public benefit, or at the time of filing or adjudication of the application for admission or adjustment of status, or application or request for extension of stay or change of status is—

(i) Enlisted in the U.S. Armed Forces under the authority of 10 U.S.C. 504(b)(1)(B) or 10 U.S.C. 504(b)(2), or

(ii) Serving in active duty or in the Ready Reserve component of the U.S. Armed Forces, or

(iii) Is the spouse or child, as defined in section 101(b) of the Act, of an alien described in paragraphs (b)(7)(i) or (ii) of this section.

(8) In a subsequent adjudication for a benefit for which the public charge ground of inadmissibility applies, public benefits, as defined in this section, do not include any public benefits received by an alien during periods in which the alien was present in the United States in an immigration category that is exempt from the public charge ground of inadmissibility, as set forth in 8 CFR 212.23(a), or for which the alien received a waiver of public charge inadmissibility, as set forth in 8 CFR 212.23(b).

(9) Public benefits, as defined in this section, do not include any public benefits that were or will be received by—

(i) Children of U.S. citizens whose lawful admission for permanent residence and subsequent residence in the legal and physical custody of their U.S. citizen parent will result automatically in the child's acquisition of citizenship, upon meeting the eligibility criteria of section 320(a)–(b) of the Act, in accordance with 8 CFR part 320; or

(ii) Children of U.S. citizens whose lawful admission for permanent residence will result automatically in the child's acquisition of citizenship upon finalization of adoption (if the child satisfies the requirements applicable to adopted children under INA 101(b)(1)), in the United States by the U.S. citizen parent(s), upon meeting the eligibility criteria of section 320(a)–(b) of the Act, in accordance with 8 CFR part 320; or

(iii) Children of U.S. citizens who are entering the United States for the purpose of attending an interview under section 322 of the Act in accordance with 8 CFR part 322.

(c) *Likely at any time to become a public charge.* Likely at any time to become a public charge means more likely than not at any time in the future to become a public charge, as defined in 212.21(a), based on the totality of the alien's circumstances.

(d) *Alien's household.* For purposes of public charge inadmissibility determinations under section 212(a)(4) of the Act:

(1) If the alien is 21 years of age or older, or under the age of 21 and married, the alien's household includes:

(i) The alien;

(ii) The alien's spouse, if physically residing with the alien;

(iii) The alien's children, as defined in 101(b)(1) of the Act, physically residing with the alien;

(iv) The alien's other children, as defined in section 101(b)(1) of the Act, not physically residing with the alien for whom the alien provides or is required to provide at least 50 percent of the children's financial support, as evidenced by a child support order or agreement a custody order or agreement, or any other order or agreement specifying the amount of financial support to be provided by the alien;

(v) Any other individuals (including a spouse not physically residing with the alien) to whom the alien provides, or is required to provide, at least 50 percent of the individual's financial support or who are listed as dependents on the alien's federal income tax return; and

(vi) Any individual who provides to the alien at least 50 percent of the alien's financial support, or who lists the alien as a dependent on his or her federal income tax return.

(2) If the alien is a child as defined in section 101(b)(1) of the Act, the alien's household includes the following individuals:

(i) The alien;

(ii) The alien's children as defined in section 101(b)(1) of the Act physically residing with the alien;

(iii) The alien's other children as defined in section 101(b)(1) of the Act not physically residing with the alien for whom the alien provides or is required to provide at least 50 percent of the children's financial support, as evidenced by a child support order or agreement, a custody order or agreement, or any other order or agreement specifying the amount of financial support to be provided by the alien;

(iv) The alien's parents, legal guardians, or any other individual providing or required to provide at least 50 percent of the alien's financial support to the alien as evidenced by a child support order or agreement, a custody order or agreement, or any other order or agreement specifying the amount of financial support to be provided to the alien;

(v) The parents' or legal guardians' other children as defined in section 101(b)(1) of the Act physically residing with the alien;

(vi) The alien's parents' or legal guardians' other children as defined in section 101(b)(1) of the Act, not physically residing with the alien for whom the parent or legal guardian provides or is required to provide at least 50 percent of the other children's financial support, as evidenced by a child support order or agreement, a custody order or agreement, or any other order or agreement specifying the amount of financial support to be provided by the parents or legal guardians; and

(vii) Any other individual(s) to whom the alien's parents or legal guardians provide, or are required to provide at least 50 percent of such individual's financial support or who is listed as a dependent on the parent's or legal guardian's federal income tax return.

(e) *Receipt of public benefits.* Receipt of public benefits occurs when a public benefit-granting agency provides a public benefit, as defined in paragraph (b) of this section, to an alien as a beneficiary, whether in the form of cash, voucher, services, or insurance coverage. Applying for a public benefit does not constitute receipt of public benefits although it may suggest a likelihood of future receipt. Certification for future receipt of a public benefit does not constitute receipt of public benefits, although it may suggest a likelihood of future receipt. An alien's receipt of, application for, or certification for public benefits solely on behalf of another individual does not constitute receipt of, application for, or certification for such alien.

(f) Primary caregiver means an alien who is 18 years of age or older and has significant responsibility for actively caring for and managing the well-being of a child or an elderly, ill, or disabled person in the alien's household.

§ 212.22 Public charge inadmissibility determination.

This section relates to the public charge ground of inadmissibility under section 212(a)(4) of the Act.

(a) *Prospective determination based on the totality of circumstances.* The determination of an alien's likelihood of becoming a public charge at any time in the future must be based on the totality of the alien's circumstances by weighing all factors that are relevant to whether the alien is more likely than not at any time in the future to receive one or more public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within any 36-month period. Except as necessary to fully evaluate evidence provided in paragraph (b)(4)(ii)(E)(*3*) of this section, DHS will not specifically assess whether an alien qualifies or would qualify for any public benefit, as defined in 8 CFR 212.21(b).

(b) *Minimum factors to consider.* A public charge inadmissibility determination must at least entail consideration of the alien's age; health; family status; education and skills; and assets, resources, and financial status, as follows:

(1) *The alien's age*—(i) *Standard.* When considering an alien's age, DHS will consider whether the alien's age makes the alien more likely than not to become a public charge at any time in the future, such as by impacting the alien's ability to work, including whether the alien is between the age of 18 and the minimum ''early retirement age'' for Social Security set forth in 42 U.S.C. 416(*l*)(2).

(ii) [Reserved]

(2) *The alien's health*—(i) *Standard.* DHS will consider whether the alien's health makes the alien more likely than not to become a public charge at any time in the future, including whether the alien has been diagnosed with a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide and care for himself or herself, to attend school, or to work upon admission or adjustment of status.

(ii) *Evidence.* USCIS' consideration includes but is not limited to the following:

(A) A report of an immigration medical examination performed by a civil surgeon or panel physician where such examination is required (to which USCIS will generally defer absent evidence that such report is incomplete); or

(B) Evidence of a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide and care for himself or herself, to attend school, or to work upon admission or adjustment of status.

(3) *The alien's family status*—(i) *Standard.* When considering an alien's family status, DHS will consider the alien's household size, as defined in 8 CFR 212.21(d), and whether the alien's household size makes the alien more likely than not to become a public charge at any time in the future.

(ii) [Reserved]

(4) *The alien's assets, resources, and financial status*—(i) *Standard.* When considering an alien's assets, resources, and financial status, DHS will consider whether such assets, resources, and financial status excluding any income from illegal activities or sources (*e.g.,* proceeds from illegal gambling or drug sales, and income from public benefits listed in 8 CFR 212.21(b)), make the alien more likely than not to become a public charge at any time in the future, including whether:

(A) The alien's household's annual gross income is at least 125 percent of the most recent Federal Poverty Guideline (100 percent for an alien on active duty, other than training, in the U.S. Armed Forces) based on the alien's household size as defined by section 212.21(d);

(B) If the alien's household's annual gross income is less than 125 percent of the most recent Federal Poverty Guideline (100 percent for an alien on active duty, other than training, in the U.S. Armed Forces), the alien may submit evidence of ownership of significant assets. For purposes of this paragraph, an alien may establish ownership of significant assets, such as savings accounts, stocks, bonds, certificates of deposit, real estate or other assets, in which the combined cash value of all the assets (the total value of the assets less any offsetting liabilities) exceeds:

(*1*) If the intending immigrant is the spouse or child of a United States citizen (and the child has reached his or her 18th birthday), three times the difference between the alien's household income and 125 percent of the FPG (100 percent for those on active duty, other than training, in the U.S. Armed Forces) for the alien's household size;

(*2*) If the intending immigrant is an orphan who will be adopted in the United States after the alien orphan acquires permanent residence (or in whose case the parents will need to seek a formal recognition of a foreign adoption under the law of the State of the intending immigrant's proposed residence because at least one of the parents did not see the child before or during the adoption), and who will, as a result of the adoption or formal recognition of the foreign adoption, acquire citizenship under section 320 of the Act, the difference between the alien's household income and 125 percent of the FPG (100 percent for those on active duty, other than training, in the U.S. Armed Forces) for the alien's household size; or

(*3*) In all other cases, five times the difference between the alien's household income and 125 percent of the FPG (100 percent for those on active duty, other than training, in the U.S. Armed Forces) for the alien's household size.

(C) The alien has sufficient household assets and resources to cover any reasonably foreseeable medical costs, including as related to a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide care for himself or herself, to attend school, or to work;

(D) The alien has any financial liabilities; and whether

(E) The alien has applied for, been certified to receive, or received public benefits, as defined in 8 CFR 212.21(b), on or after October 15, 2019.

(ii) *Evidence.* USCIS' consideration includes, but is not limited to the following:

(A) The alien's annual gross household income including, but not limited to:

(*1*) For each member of the household whose income will be considered, the most recent tax-year transcript from the U.S. Internal Revenue Service (IRS) of such household member's IRS Form 1040, U.S. Individual Income Tax Return; or

(*2*) If the evidence in paragraph (b)(4)(ii)(A)(*1*) of this section is unavailable for a household member, other credible and probative evidence of such household member's income, including an explanation of why such transcript is not available, such as if the household member is not subject to taxation in the United States.

(B) Any additional income from individuals not included in the alien's household provided to the alien's household on a continuing monthly or yearly basis for the most recent calendar year and on which the alien relies or will rely to meet the standard at 8 CFR 212.22(b)(4)(i);

(C) The household's cash assets and resources. Evidence of such cash assets and resources may include checking and savings account statements covering 12 months prior to filing the application;

(D) The household's non-cash assets and resources, that can be converted into cash within 12 months, such as net cash value of real estate holdings minus the sum of all loans secured by a mortgage, trust deed, or other lien on the home; annuities; securities; retirement and educational accounts; and any other assets that can easily be converted into cash;

(E) Evidence that the alien has:

(*1*) Applied for or received any public benefit, as defined in 8 CFR 212.21(b), on or after October 15, 2019 or disenrolled or requested to be disenrolled from such benefit(s); or

(*2*) Been certified or approved to receive any public benefit, as defined in 8 CFR 212.21(b), on or after October 15, 2019 or withdrew his or her application or disenrolled or requested to be to disenrolled from such benefit(s);

(*3*) Submitted evidence from a Federal, State, local, or tribal agency administering a public benefit, as defined in 212.21(b), that the alien has specifically identified as showing that the alien does not qualify or would not qualify for such public benefit by virtue of, for instance, the alien's annual gross household income or prospective immigration status or length of stay;

(F) Whether the alien has applied for or has received a USCIS fee waiver for an immigration benefit request on or after October 15, 2019, unless the fee waiver was applied for or granted as part of an application for which a public charge inadmissibility determination under section 212(a)(4) of the Act was not required.

(G) The alien's credit history and credit score in the United States, and other evidence of the alien's liabilities not reflected in the credit history and credit score (*e.g.,* any mortgages, car loans, unpaid child or spousal support, unpaid taxes, and credit card debt); and

(H) Whether the alien has sufficient household assets and resources (including, for instance, health insurance not designated as a public benefit under 8 CFR 212.21(b)) to pay for reasonably foreseeable medical costs, such as costs related to a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide care for himself or herself, to attend school, or to work;

(5) *The alien's education and skills.* (i) *Standard.* When considering an alien's education and skills, DHS will consider whether the alien has adequate education and skills to either obtain or maintain lawful employment with an income sufficient to avoid being more likely than not to become a public charge.

(ii) *Evidence.* USCIS' consideration includes but is not limited to the following: (A) The alien's history of employment, excluding employment involving illegal activities, *e.g.,* illegal gambling or drug sales. The alien must provide the following:

(*1*) The last 3 years of the alien's tax transcripts from the U.S. Internal Revenue Service (IRS) of the alien's IRS Form 1040, U.S. Individual Income Tax Return; or

(*2*) If the evidence in paragraph (b)(5)(ii)(A)(*1*) of this section is unavailable, other credible and probative evidence of the alien's history of employment for the last 3 years, including an explanation of why such transcripts are not available, such as if the alien is not subject to taxation in the United States;

(B) Whether the alien has a high school diploma (or its equivalent) or has a higher education degree;

(C) Whether the alien has any occupational skills, certifications, or licenses; and

(D) Whether the alien is proficient in English or proficient in other languages in addition to English.

(E) Whether the alien is a primary caregiver as defined in 8 CFR 212.21(f), such that the alien lacks an employment history, is not currently employed, or is not employed full time. Only one alien within a household can be considered a primary caregiver of the same individual within the household. USCIS' consideration with respect this paragraph includes but is not limited to evidence that an individual the alien is caring for resides in the alien's household, evidence of the individual's age, and evidence of the individual's medical condition, including disability, if any.

(6) *The alien's prospective immigration status and expected period of admission.*

(i) *Standard.* DHS will consider the immigration status that the alien seeks and the expected period of admission as it relates to the alien's ability to financially support for himself or herself during the duration of the alien's stay, including:

(A) Whether the alien is applying for adjustment of status or admission in a nonimmigrant or immigrant classification; and

(B) If the alien is seeking admission as a nonimmigrant, the nonimmigrant classification and the anticipated period of temporary stay.

(ii) [Reserved]

(7) *An affidavit of support under section 213A of the Act, when required under section 212(a)(4) of the Act, that meets the requirements of section 213A of the Act and 8 CFR 213a*—(i) *Standard.* If the alien is required under sections 212(a)(4)(C) or (D) to submit an affidavit of support under section 213A of the Act and 8 CFR part 213a, and submits such a sufficient affidavit of support, DHS will consider the likelihood that the sponsor would actually provide the statutorily-required amount of financial support to the alien, and any other related considerations.

(A) *Evidence.* USCIS consideration includes but is not limited to the following:

(*1*) The sponsor's annual income, assets, and resources;

(*2*) The sponsor's relationship to the applicant, including but not limited to whether the sponsor lives with the alien; and

(*3*) Whether the sponsor has submitted an affidavit of support with respect to other individuals.

(c) *Heavily weighted factors.* The factors below will weigh heavily in a public charge inadmissibility determination. The mere presence of any one heavily weighted factor does not, alone, make the alien more or less likely than not to become a public charge.

(1) *Heavily weighted negative factors.* The following factors will weigh heavily in favor of a finding that an alien is likely at any time in the future to become a public charge:

(i) The alien is not a full-time student and is authorized to work, but is unable to demonstrate current employment, recent employment history, or a reasonable prospect of future employment;

(ii) The alien has received or has been certified or approved to receive one or more public benefits, as defined in § 212.21(b), for more than 12 months in the aggregate within any 36-month period, beginning no earlier than 36 months prior to the alien's application for admission or adjustment of status on or after October 15, 2019;

(iii)(A) The alien has been diagnosed with a medical condition that is likely to require extensive medical treatment or institutionalization or that will interfere with the alien's ability to provide for himself or herself, attend school, or work; and

(B) The alien is uninsured and has neither the prospect of obtaining private health insurance, nor the financial resources to pay for reasonably foreseeable medical costs related to such medical condition; or

(iv) The alien was previously found inadmissible or deportable on public charge grounds by an Immigration Judge or the Board of Immigration Appeals.

(2) *Heavily weighted positive factors.* The following factors will weigh heavily in favor of a finding that an alien is not likely to become a public charge:

(i) The alien's household has income, assets, or resources, and support (excluding any income from illegal activities, *e.g.,* proceeds from illegal gambling or drug sales, and any income from public benefits as defined in § 212.21(b)) of at least 250 percent of the Federal Poverty Guidelines for the alien's household size;

(ii) The alien is authorized to work and is currently employed in a legal industry with an annual income, excluding any income from illegal activities such as proceeds from illegal gambling or drug sales, of at least 250 percent of the Federal Poverty Guidelines for the alien's household size; or

(iii) The alien has private health insurance, except that for purposes of this paragraph (c)(2)(iii), private health insurance must be appropriate for the expected period of admission, and does not include health insurance for which the alien receives subsidies in the form of premium tax credits under the Patient Protection and Affordable Care Act, as amended.

(d) *Treatment of benefits received before* October 15, 2019. For purposes of this regulation, DHS will consider, as a negative factor, but not as a heavily weighted negative factor as described in paragraph (c)(1) of this section, any amount of cash assistance for income maintenance, including Supplemental Security Income (SSI), Temporary Assistance for Needy Families (TANF), State and local cash assistance programs that provide benefits for income maintenance (often called ''General Assistance'' programs), and programs (including Medicaid) supporting aliens who are institutionalized for long-term care, received, or certified for receipt, before October 15, 2019, as provided under the 1999 Interim Field Guidance, also known as the 1999 Field Guidance on Deportability and Inadmissibility on Public Charge Grounds. DHS will not consider as a negative factor any other public benefits received, or certified for receipt, before October 15, 2019.

§ 212.23 Exemptions and waivers for public charge ground of inadmissibility.

(a) *Exemptions.* The public charge ground of inadmissibility under section 212(a)(4) of the Act does not apply, based on statutory or regulatory authority, to the following categories of aliens:

(1) Refugees at the time of admission under section 207 of the Act and at the time of adjustment of status to lawful permanent resident under section 209 of the Act;

(2) Asylees at the time of grant under section 208 of the Act and at the time of adjustment of status to lawful permanent resident under section 209 of the Act;

(3) Amerasian immigrants at the time of application for admission as described in sections 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1988, Public Law 100–202, 101 Stat. 1329–183, section 101(e) (Dec. 22, 1987), as amended, 8 U.S.C. 1101 note;

(4) Afghan and Iraqi Interpreter, or Afghan or Iraqi national employed by or on behalf of the U.S. Government as described in section 1059(a)(2) of the National Defense Authorization Act for Fiscal Year 2006 Public Law 109–163 (Jan. 6, 2006), as amended, and section 602(b) of the Afghan Allies Protection Act of 2009, Public Law 111–8, title VI

(Mar. 11, 2009), as amended, 8 U.S.C. 1101 note, and section 1244(g) of the National Defense Authorization Act for Fiscal Year 2008, as amended Public Law 110–181 (Jan. 28, 2008);

(5) Cuban and Haitian entrants applying for adjustment of status under section 202 of the Immigration Reform and Control Act of 1986 (IRCA), Public Law 99–603, 100 Stat. 3359 (Nov. 6, 1986), as amended, 8 U.S.C. 1255a note;

(6) Aliens applying for adjustment of status under the Cuban Adjustment Act, Public Law 89–732 (Nov. 2, 1966), as amended, 8 U.S.C. 1255 note;

(7) Nicaraguans and other Central Americans applying for adjustment of status under sections 202(a) and section 203 of the Nicaraguan Adjustment and Central American Relief Act (NACARA), Public Law 105–100, 111 Stat. 2193 (Nov. 19, 1997), as amended, 8 U.S.C. 1255 note;

(8) Haitians applying for adjustment of status under section 902 of the Haitian Refugee Immigration Fairness Act of 1998, Public Law 105–277, 112 Stat. 2681 (Oct. 21, 1998), as amended, 8 U.S.C. 1255 note;

(9) Lautenberg parolees as described in section 599E of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1990, Public Law 101–167, 103 Stat. 1195, title V (Nov. 21, 1989), as amended, 8 U.S.C. 1255 note;

(10) Special immigrant juveniles as described in section 245(h) of the Act;

(11) Aliens who entered the United States prior to January 1, 1972, and who meet the other conditions for being granted lawful permanent residence under section 249 of the Act and 8 CFR part 249 (Registry);

(12) Aliens applying for or re-registering for Temporary Protected Status as described in section 244 of the Act in accordance with section 244(c)(2)(A)(ii) of the Act and 8 CFR 244.3(a);

(13) A nonimmigrant described in section 101(a)(15)(A)(i) and (A)(ii) of the Act (Ambassador, Public Minister, Career Diplomat or Consular Officer, or Immediate Family or Other Foreign Government Official or Employee, or Immediate Family), in accordance with section 102 of the Act and 22 CFR 41.21(d);

(14) A nonimmigrant classifiable as C–2 (alien in transit to U.N. Headquarters) or C–3 (foreign government official), 22 CFR 41.21(d);

(15) A nonimmigrant described in section 101(a)(15)(G)(i), (G)(ii), (G)(iii), and (G)(iv), of the Act (Principal Resident Representative of Recognized Foreign Government to International Organization, and related categories), in accordance with section 102 of the Act and 22 CFR 41.21(d);

(16) A nonimmigrant classifiable as NATO–1, NATO–2, NATO–3, NATO–4 (NATO representatives), and NATO–6 in accordance with 22 CFR 41.21(d);

(17) An applicant for nonimmigrant status under section 101(a)(15)(T) of the Act, in accordance with 8 CFR 212.16(b);

(18) Except as provided in section 212.23(b), an individual who is seeking an immigration benefit for which admissibility is required, including but not limited to adjustment of status under section 245(a) of the Act and section 245(l) of the Act and who:

(i) Has a pending application that sets forth a prima facie case for eligibility for nonimmigrant status under section 101(a)(15)(T) of the Act, or

(ii) Has been granted nonimmigrant status under section 101(a)(15)(T) of the Act, provided that the individual is in valid T nonimmigrant status at the time the benefit request is properly filed with USCIS and at the time the benefit request is adjudicated;

(19) Except as provided in § 212.23(b),

(i) A petitioner for nonimmigrant status under section 101(a)(15)(U) of the Act, in accordance with section 212(a)(4)(E)(ii) of the Act; or

(ii) An individual who is granted nonimmigrant status under section 101(a)(15)(U) of the Act in accordance with section 212(a)(4)(E)(ii) of the Act, who is seeking an immigration benefit for which admissibility is required, including, but not limited to, adjustment of status under section 245(a) of the Act, provided that the individual is in valid U nonimmigrant status at the time the benefit request is properly filed with USCIS and at the time the benefit request is adjudicated.

(20) Except as provided in section 212.23(b), any alien who is a VAWA self-petitioner under section 212(a)(4)(E)(i) of the Act;

(21) Except as provided in section 212.23(b), a qualified alien described in section 431(c) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, 8 U.S.C. 1641(c), under section 212(a)(4)(E)(iii) of the Act;

(22) Applicants adjusting status who qualify for a benefit under section 1703 of the National Defense Authorization Act, Public Law 108–136, 117 Stat. 1392 (Nov. 24, 2003), 8 U.S.C. 1151 note (posthumous benefits to surviving spouses, children, and parents);

(23) American Indians born in Canada determined to fall under section 289 of the Act;

(24) Texas Band of Kickapoo Indians of the Kickapoo Tribe of Oklahoma, Public Law 97–429 (Jan. 8, 1983);

(25) Nationals of Vietnam, Cambodia, and Laos applying for adjustment of status under section 586 of Public Law 106–429 under 8 CFR 245.21;

(26) Polish and Hungarian Parolees who were paroled into the United States from November 1, 1989 to December 31, 1991 under section 646(b) of the IIRIRA, Public Law 104–208, Div. C, Title VI, Subtitle D (Sept. 30, 1996), 8 U.S.C. 1255 note; and

(27) Any other categories of aliens exempt under any other law from the public charge ground of inadmissibility provisions under section 212(a)(4) of the Act.

(b) *Limited Exemption.* Aliens described in §§ 212.23(a)(18) through (21) must submit an affidavit of support as described in section 213A of the Act if they are applying for adjustment of status based on an employment-based petition that requires such an affidavit of support as described in section 212(a)(4)(D) of the Act.

(c) *Waivers.* A waiver for the public charge ground of inadmissibility may be authorized based on statutory or regulatory authority, for the following categories of aliens:

(1) Applicants for admission as nonimmigrants under 101(a)(15)(S) of the Act;

(2) Nonimmigrants admitted under section 101(a)(15)(S) of the Act applying for adjustment of status under section 245(j) of the Act (witnesses or informants); and

(3) Any other waiver of the public charge ground of inadmissibility that is authorized by law or regulation.

PART 213—PUBLIC CHARGE BONDS

■ 7. The authority citation for part 213 is revised to read as follows:

Authority: 8 U.S.C. 1103; 1183; 8 CFR part 2.

■ 8. Revise the part heading to read as set forth above.

■ 9. Revise § 213.1 to read as follows:

§ 213.1 Adjustment of status of aliens on submission of a public charge bond.

(a) *Inadmissible aliens.* In accordance with section 213 of the Act, after an alien seeking adjustment of status has been found inadmissible as likely at any time in the future to become a public charge under section 212(a)(4) of the Act, DHS may allow the alien to submit a public charge bond, if the alien is otherwise admissible, in accordance with the requirements of 8 CFR 103.6 and this section. The public charge

bond must meet the conditions set forth in 8 CFR 103.6 and this section.

(b) *Discretion.* The decision to allow an alien inadmissible under section 212(a)(4) of the Act to submit a public charge bond is in DHS's discretion. If an alien has one or more heavily weighted negative factors as defined in 8 CFR 212.22 in his or her case, DHS generally will not favorably exercise discretion to allow submission of a public charge bond.

(c) *Public Charge Bonds.* (1) *Types.* DHS may require an alien to submit a surety bond, as listed in 8 CFR 103.6, or cash or any cash equivalents specified by DHS. DHS will notify the alien of the type of bond that may be submitted. All surety, cash, or cash equivalent bonds must be executed on a form designated by DHS and in accordance with form instructions. When a surety bond is accepted, the bond must comply with requirements applicable to surety bonds in 8 CFR 103.6 and this section. If cash or a cash equivalent, is being provided to secure a bond, DHS must issue a receipt on a form designated by DHS.

(2) *Amount.* Any public charge bond must be in an amount decided by DHS, not less than $8,100, annually adjusted for inflation based on the Consumer Price Index for All Urban Consumers (CPI–U), and rounded up to the nearest dollar. The bond amount decided by DHS may not be appealed by the alien or the bond obligor.

(d) *Conditions of the bond.* A public charge bond must remain in effect until USCIS grants a request to cancel the bond in accordance with paragraph (g) of this section, whereby the alien naturalizes or otherwise obtains U.S. citizenship, permanently departs the United States, dies, the alien has reached his or her 5-year anniversary since becoming a lawful permanent resident, or the alien changes immigration status to one not subject to public charge ground of inadmissibility. An alien on whose behalf a public charge bond has been submitted may not receive any public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within any 364month period (such that, for instance, receipt of two benefits in one month counts as two months, after the alien's adjustment of status to that of a lawful permanent resident, until the bond is cancelled in accordance with paragraph (g) of this section. An alien must also comply with any other conditions imposed as part of the bond.

(e) *Submission.* A public charge bond may be submitted on the alien's behalf only after DHS notifies the alien and the alien's representative, if any, that a bond may be submitted. The bond must be submitted to DHS in accordance with the instructions of the form designated by DHS for this purpose, with the fee prescribed in 8 CFR 103.7(b), and any procedures contained in the DHS notification to the alien. DHS will specify the bond amount and any other conditions, as appropriate for the alien and the immigration benefit being sought. USCIS will notify the alien and the alien's representative, if any, that the bond has been accepted, and will provide a copy to the alien and the alien's representative, if any, of any communication between the obligor and the U.S. government. An obligor must notify DHS within 30 days of any change in the obligor's or the alien's physical and mailing address.

(f) *Substitution.* (1) *Substitution Process.* Either the obligor of the bond previously submitted to DHS or a new obligor may submit a substitute bond on the alien's behalf. The substitute bond must specify an effective date. The substitute bond must meet all of the requirements applicable to the initial bond as required by this section and 8 CFR 103.6, and if the obligor is different from the original obligor, the new obligor must assume all liabilities of the initial obligor. The substitute bond must also cover any breach of the bond conditions which occurred before DHS accepted the substitute bond, in the event DHS did not learn of the breach until after DHS accepted the substitute bond.

(2) *Acceptance.* Upon submission of the substitute bond, DHS will review the substitute bond for sufficiency as set forth in this section. If the substitute bond is sufficient DHS will cancel the bond previously submitted to DHS, and replace it with the substitute bond. If the substitute bond is insufficient, DHS will notify the obligor of the substitute bond to correct the deficiency within the timeframe specified in the notice. If the deficiency is not corrected within the timeframe specified, the previously submitted bond will remain in effect.

(g) *Cancellation of the Public Charge Bond.* (1) An alien or obligor may request that DHS cancel a public charge bond if the alien:

(i) Naturalized or otherwise obtained United States citizenship;

(ii) Permanently departed the United States;

(iii) Died;

(iv) Reached his or her 5-year anniversary since becoming a lawful permanent resident; or

(v) Obtained a different immigration status not subject to public charge inadmissibility, as listed in 8 CFR 212.23, following the grant of lawful permanent resident status associated with the public charge bond.

(2) *Permanent Departure Defined.* For purposes of this section, permanent departure means that the alien lost or abandoned his or her lawful permanent resident status, whether by operation of law or voluntarily, and physically departed the United States. An alien is only deemed to have voluntarily lost lawful permanent resident status when the alien has submitted a record of abandonment of lawful permanent resident status, on the form prescribed by DHS, from outside the United States, and in accordance with the form's instructions.

(3) *Cancellation Request.* A request to cancel a public charge bond must be made by submitting a form designated by DHS, in accordance with that form's instructions and the fee prescribed in 8 CFR 103.7(b). If a request for cancellation of a public charge bond is not filed, the bond shall remain in effect until the form is filed, reviewed, and a decision is rendered. DHS may in its discretion cancel a public charge bond if it determines that an alien otherwise meets the eligibility requirements of paragraphs (g)(1) of this section.

(4) *Adjudication and Burden of Proof.* The alien and the obligor have the burden to establish, by a preponderance of the evidence, that one of the conditions for cancellation of the public charge bond listed in paragraph (g)(1) of this section has been met. If DHS determines that the information included in the cancellation request is insufficient to determine whether cancellation is appropriate, DHS may request additional information as outlined in 8 CFR 103.2(b)(8). DHS must cancel a public charge bond if DHS determines that the conditions of the bond have been met, and that the bond was not breached, in accordance with paragraph (h) of this section. For cancellations under paragraph (g)(1)(iv) of this section, the alien or the obligor must establish that the public charge bond has not been breached during the 5-year period preceding the alien's fifth anniversary of becoming a lawful permanent resident.

(5) *Decision.* DHS will notify the obligor, the alien, and the alien's representative, if any, of its decision regarding the request to cancel the public charge bond. When the public charge bond is cancelled, the obligor is released from liability. If the public charge bond has been secured by a cash deposit or a cash equivalent, DHS will refund the cash deposit and any interest earned to the obligor consistent with 8 U.S.C. 1363 and 8 CFR 293.1. If DHS denies the request to cancel the bond,

DHS will notify the obligor and the alien, and the alien's representative, if any, of the reasons why, and of the right of the obligor to appeal in accordance with the requirements of 8 CFR part 103, subpart A. An obligor may file a motion pursuant to 8 CFR 103.5 after an unfavorable decision on appeal.

(h) *Breach.* (1) *Breach and Claim in Favor of the United States.* An administratively final determination that a bond has been breached creates a claim in favor of the United States. Such claim may not be released or discharged by an immigration officer. A breach determination is administratively final when the time to file an appeal with the Administrative Appeals Office (AAO) pursuant to 8 CFR part 103, subpart A, has expired or when the appeal is dismissed or rejected.

(2) *Breach of Bond Conditions.* (i) The conditions of the bond are breached if the alien has received public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months), after the alien's adjustment of status to that of a lawful permanent resident and before the bond is cancelled under paragraph (g) of this section. DHS will not consider any public benefits, as defined in 8 CFR 212.21(b), received by the alien during periods while an alien was present in the United States in a category that is exempt from the public charge ground of inadmissibility or for which the alien received a waiver of public charge inadmissibility, as set forth in 8 CFR 212.21(b) and 8 CFR 212.23, and public benefits received after the alien obtained U.S. citizenship, when determining whether the conditions of the bond have been breached. DHS will not consider any public benefits, as defined in 8 CFR 212.21 (b)(1) through (b)(3), received by an alien who, at the time of receipt filing, adjudication or bond breach or cancellation determination, is enlisted in the U.S. Armed Forces under the authority of 10 U.S.C. 504(b)(1)(B) or 10 U.S.C. 504(b)(2), serving in active duty or in the Ready Reserve component of the U.S. Armed Forces, or if received by such an individual's spouse or child as defined in section 101(b) of the Act; or

(ii) The conditions of the bond otherwise imposed by DHS as part of the public charge bond are breached.

(3) *Adjudication.* DHS will determine whether the conditions of the bond have been breached. If DHS determines that it has insufficient information from the benefit-granting agency to determine whether a breach occurred, DHS may request additional information from the benefit-granting agency. If DHS determines that it has insufficient information from the alien or the obligor, it may request additional information as outlined in 8 CFR part 103 before making a breach determination. If DHS intends to declare a bond breached based on information that is not otherwise protected from disclosure to the obligor, DHS will disclose such information to the obligor to the extent permitted by law, and provide the obligor with an opportunity to respond and submit rebuttal evidence, including specifying a deadline for a response. DHS will send a copy of this notification to the alien and the alien's representative, if any. After the obligor's response, or after the specified deadline has passed, DHS will make a breach determination.

(4) *Decision.* DHS will notify the obligor and the alien, and the alien's representative, if any, of the breach determination. If DHS determines that a bond has been breached, DHS will inform the obligor of the right to appeal in accordance with the requirements of 8 CFR part 103, subpart A. With respect to a breach determination for a surety bond, the alien or the alien's representative, if any, may not appeal the breach determination or file a motion.

(5) *Demand for Payment.* Demands for amounts due under the terms of the bond will be sent to the obligor and any agent/co-obligor after a declaration of breach becomes administratively final.

(6) *Amount of Bond Breach and Effect on Bond.* The bond must be considered breached in the full amount of the bond.

(i) *Exhaustion of administrative remedies.* Unless an administrative appeal is precluded by regulation, a party has not exhausted the administrative remedies available with respect to a public charge bond under this section until the party has obtained a final decision in an administrative appeal under 8 CFR part 103, subpart A.

(ii) [Reserved]

PART 214—NONIMMIGRANT CLASSES

■ 10. The authority citation for part 214 continues to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305 and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Public Law 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note, and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2.

■ 11. Section 214.1 is amended by:

■ a. Adding paragraph (a)(3)(iv),

■ b. Removing the term, ''and'' in paragraph (c)(4)(iii);

The additions read as follows:

§ 214.1 Requirements for admission, extension, and maintenance of status.

(a) * * *

(3) * * *

(iv) Except where the nonimmigrant classification for which the alien seeks to extend is exempt from section 212(a)(4) of the Act or that section has been waived, as a condition for approval of extension of status, the alien must demonstrate that he or she has not received since obtaining the nonimmigrant status he or she seeks to extend one or more public benefits as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months). For the purposes of this determination, DHS will only consider public benefits received on or after October 15, 2019 for petitions or applications postmarked (or, if applicable, submitted electronically) on or after that date.

* * * * *

PART 245—ADJUSTMENT OF STATUS TO THAT OF A PERSON ADMITTED FOR PERMANENT RESIDENCE

■ 12. The authority citation for part 245 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1182, 1255; Pub. L. 105–100, section 202, 111 Stat. 2160, 2193; Pub. L. 105–277, section 902, 112 Stat. 2681; Pub. L. 110–229, tit. VII, 122 Stat. 754; 8 CFR part 2.

■ 13. Amend § 245.4 by redesignating the undesignated text as paragraph (a) and adding paragraph (b) to read as follows:

§ 245.4 Documentary requirements.

* * * * *

(b) For purposes of public charge determinations under section 212(a)(4) of the Act and 8 CFR 212.22, an alien who is seeking adjustment of status under this part must submit a declaration of self-sufficiency on a form designated by DHS, in accordance with form instructions.

■ 14. In § 245.23, revise paragraph (c)(3) to read as follows:

§ 245.23 Adjustment of aliens in T nonimmigrant classification.

* * * * *

(c) * * *

(3) The alien is inadmissible under any applicable provisions of section 212(a) of the Act and has not obtained a waiver of inadmissibility in accordance with 8 CFR 212.18 or

214.11(j). Where the alien establishes that the victimization was a central reason for the applicant's unlawful presence in the United States, section 212(a)(9)(B)(iii) of the Act is not applicable, and the applicant need not obtain a waiver of that ground of inadmissibility. The alien, however, must submit with the Form I–485 evidence sufficient to demonstrate that the victimization suffered was a central reason for the unlawful presence in the United States. To qualify for this exception, the victimization need not be the sole reason for the unlawful presence but the nexus between the victimization and the unlawful presence must be more than tangential, incidental, or superficial.

PART 248—CHANGE OF NONIMMIGRANT CLASSIFICATION

■ 15. The authority citation for part 248 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1184, 1258; 8 CFR part 2.

■ 16. Section 248.1 is amended by:

■ a. Revising paragraph (a);

■ b. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f), respectively; and

■ c. Adding a new paragraph (b); and

■ d. Revising newly redesignated paragraph (c)(4).

The revisions and additions read as follows:

§ 248.1 Eligibility.

(a) *General.* Except for those classes enumerated in § 248.2 of this part, any alien lawfully admitted to the United States as a nonimmigrant, including an alien who acquired such status in accordance with section 247 of the Act who is continuing to maintain his or her nonimmigrant status, may apply to have his or her nonimmigrant classification changed to any nonimmigrant classification other than that of a spouse or fiance(e), or the child of such alien, under section 101(a)(15)(K) of the Act or as an alien in transit under section 101(a)(15)(C) of the Act. Except where the nonimmigrant classification to which the alien seeks to change is exempted by law or regulation from section 212(a)(4) of the Act, as a condition for approval of a change of nonimmigrant status, the alien must demonstrate that he or she has not received since obtaining the nonimmigrant status from which he or she seeks to change, public benefits, as described in 8 CFR 212.21(b), for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months). DHS will only consider public benefits received on or after October 15, 2019 for petitions or applications postmarked (or, if applicable, submitted electronically) on or after that date . An alien defined by section 101(a)(15)(V) or 101(a)(15)(U) of the Act may be accorded nonimmigrant status in the United States by following the procedures set forth in 8 CFR 214.15(f) and 214.14, respectively.

(b) *Decision in change of status proceedings.* Where an applicant or petitioner demonstrates eligibility for a requested change of status, it may be granted at the discretion of DHS. There is no appeal from the denial of an application for change of status.

(c) * * *

(4) As a condition for approval, an alien seeking to change nonimmigrant classification must demonstrate that he or she has not received, since obtaining the nonimmigrant status from which he or she seeks to change, one or more public benefits, as defined in 8 CFR 212.21(b), for more than 12 months in the aggregate within any 36-month period (such that, for instance, receipt of two benefits in one month counts as two months). For purposes of this determination, DHS will only consider public benefits received on or after October 15, 2019 for petitions or applications postmarked (or, if applicable, submitted electronically) on or after that date. This provision does not apply to classes of nonimmigrants who are explicitly exempt by law or regulation from section 212(a)(4) of the Act.

* * * * *

Kevin K. McAleenan,

Acting Secretary of Homeland Security.

[FR Doc. 2019–17142 Filed 8–12–19; 8:45 am]

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Part IV

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone: Adjustments to the Allowance System for Controlling HCFC Production and Import, 2020–2029; and Other Updates; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2016–0271; FRL–9997–57–OAR]

RIN 2060–AU26

Protection of Stratospheric Ozone: Adjustments to the Allowance System for Controlling HCFC Production and Import, 2020–2029; and Other Updates

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to allocate production and consumption allowances for specific hydrochlorofluorocarbons, a type of ozone-depleting substance, for the years 2020 through 2029. These hydrochlorofluorocarbons may be used to service certain equipment manufactured before 2020. The EPA is also proposing to update other requirements under the program for controlling production and consumption of ozone-depleting substances, as well as proposing edits to the regulatory text for improved readability and clarity. These updates include revising the labeling requirements for containers of specific hydrochlorofluorocarbons; prohibiting the conversion of hydrochlorofluorocarbon allowances allocated through this rulemaking into allowances for hydrochlorofluorocarbons that have already been phased out; requiring the use of an electronic reporting system for producers, importers, exporters, transformers, and destroyers of class I and class II ozone-depleting substances; revising and removing recordkeeping and reporting requirements; improving the process for petitioning to import used substances for reuse; creating a certification process for importing used and virgin substances for destruction; and restricting the sale of known illegally imported substances. This notice further includes proposed clarifications to the certification requirements for methyl bromide quarantine and preshipment uses. The EPA is also proposing to add polyurethane foam systems containing ozone-depleting chlorofluorocarbons to the list of nonessential products. Lastly, the agency is proposing to update the definition of ''destruction'' as used in the context of the production and consumption phaseout and remove obsolete provisions.

DATES: Comments on this notice of proposed rulemaking must be received on or before September 30, 2019. Any party requesting a public hearing must notify the contact listed below under **FOR FURTHER INFORMATION CONTACT** by 5 p.m. Eastern Daylight Time on August 19, 2019. If a public hearing is requested, the hearing will be held on August 29, 2019. The hearing will be held in Washington, DC. More details concerning the hearing, including whether a hearing has been requested, will be available at *https://www.epa.gov/ods-phaseout/phaseout-class-ii-ozone-depleting-substances.*

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2016–0271, to the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*e.g.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Stratospheric Protection Division, Office of Atmospheric Programs, Mail Code 6205T, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number (202) 564–7716; email address *sleasman.katherine@epa.gov.* You may also visit the Ozone Protection website of the EPA's Stratospheric Protection Division at *https://www.epa.gov/ods-phaseout* for further information about reporting and recordkeeping, other Stratospheric Ozone Protection regulations, the science of ozone layer depletion, and related topics.

SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations. The following acronyms and abbreviations are used in this document.

ACE/ITDS—Automated Commercial Environment/International Trade Data System
ARFF—Aircraft Rescue and Fire Fighting
CAA—Clean Air Act
CBP—Customs and Border Protection
CDC—Centers for Disease Control and Prevention
CDX—Central Data Exchange
CFC—Chlorofluorocarbon
CFR—Code of Federal Regulations
CROMERR—Cross-Media Electronic Reporting Regulation
DOT—Department of Transportation
EPA—Environmental Protection Agency
FAA—Federal Aviation Administration
FR—Federal Register
GPEA—Government Paperwork Elimination Act
HCFC—Hydrochlorofluorocarbon
HTSA—Harmonized Tariff Schedule of the United States Annotated
MMWR—Morbidity and Mortality Weekly Report
Montreal Protocol—Montreal Protocol on Substances that Deplete the Ozone Layer
MOP—Meeting of the Parties
MT—Metric Ton
NFPA—National Fire Protection Association
ODP—Ozone Depletion Potential
ODS—Ozone-Depleting Substance
Parties to the Montreal Protocol or Party—Nations and regional economic integration organizations that have consented to be bound by the Montreal Protocol on Substances that Deplete the Ozone Layer
RACA—Request for Additional Consumption Allowances
SNAP—Significant New Alternatives Policy
TEAP—Technology and Economic Assessment Panel
UNEP—United Nations Environment Programme

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D. Changes to Provisions for the Import of ODS in § 82.3, 82.4, 82.13, 82.15, and 82.24

E. Prohibiting the Sale of Illegally Imported Controlled Substances
V. Addition of Polyurethane Foam Systems Containing CFCs to the Nonessential Product Ban
VI. Updates to §§ 82.3, 82.104, and 82.270 Related to Destruction
VII. Removing Obsolete Provisions in §§ 82.3, 82.4, 82.9, 82.10, 82.12, 82.13, 82.15, 82.16, and 82.24
VIII. Economic Analysis
IX. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Paperwork Reduction Act (PRA)
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F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this Proposed Action apply to me?

You may be potentially affected by any final action on this proposal if you manufacture, process, import, or distribute into commerce certain ozone-depleting substances (ODS) and mixtures. Potentially affected entities may include but are not limited to:

- Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing entities (NAICS 333415)
- Air-Conditioning Equipment and Supplies Merchant Wholesalers (NAICS 423620)
- Basic Chemical Manufacturing (NAICS 3251)
- Chlorofluorocarbon Gas Manufacturing and Import (NAICS 325120)
- Farm Product Warehousing and Storage (NAICS 493130)
- Farm Supplies and Merchant Wholesalers (NAICS 424910)
- Flour Milling (NAICS 311211)
- Fire Extinguisher Chemical Preparations Manufacturing (NAICS 325998)
- Fruit and Nut Tree Farming (NAICS 1113)
- General Warehousing and Storage (NAICS 493130)
- Greenhouse, Nursery, and Floriculture Production (NAICS 1114)
- Hazardous Waste Treatment and Disposal, Cement Manufacturing, Clinker (NAICS 327310)
- Hazardous Waste Treatment and Disposal, Incinerator, Hazardous Waste (NAICS 562211)
- Industrial Gas Manufacturing (NAICS 325120)
- Materials Recovery Facilities (NAICS 562920)
- Other Aircraft Parts and Auxiliary Equipment Manufacturing (NAICS 336413)
- Other Chemical and Allied Production Merchant Wholesalers (NAICS 424690)
- Other Crop Farming (NAICS 1119)
- Pesticide and Other Agricultural Chemical Manufacturing (NAICS 325320)
- Plumbing, Heating, and Air-Conditioning Contractors (NAICS 238220)
- Portable Fire Extinguishers Manufacturing (NAICS 339999)
- Postharvest Crop Activities (except Cotton Ginning) (NAICS 115114)
- Research and Development in Physical, Engineering, and Life Sciences (NAICS 541710)
- Rice Milling (NAICS 311212)
- Soil Preparation, Planting, and Cultivating (NAICS 115112)
- Vegetable and Melon Farming (NAICS 1112)

This list is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this section could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. What action is the Agency proposing?

The EPA is proposing a number of revisions to the production and consumption control program for ODS [1] in 40 CFR part 82, subpart A, which are divided into ''class I'' and ''class II'' substances. Section 602 of the Clean Air Act (CAA) contains initial lists of class I and class II substances and addresses additions to those lists. The current lists appear in appendices A and B in subpart A. The list of class I substances includes chlorofluorocarbons (CFCs), halons, carbon tetrachloride, methyl chloroform, and methyl bromide. The list of class II substances consists entirely of hydrochlorofluorocarbons (HCFCs). This action proposes specific revisions to the production and consumption control program including:

- The allocation of production and consumption allowances for HCFC–123 and HCFC–124 to service certain equipment manufactured before January 1, 2020;
- Requiring the use of an electronic reporting system for producers, importers, exporters, transformers, and destroyers of ODS;
- Revisions and removal of certain recordkeeping and reporting requirements;
- Clarifications to the certification requirements for methyl bromide quarantine and preshipment uses;
- Improvements to the process for petitioning to import used substances for reuse;
- Creation of a certification process for importing used and virgin substances for destruction; and
- Restrictions on the sale of known illegally imported ODS.

In addition, this action proposes changes to other subparts supporting the ODS phaseout, specifically:

- Changes to the subpart E requirements for labeling of products containing HCFC–123 to clarify permitted uses;
- Adding to the subpart C ban on sale and distribution or offer for sale and distribution in interstate commerce of certain products that contain class I ODS; and
- Changes to subpart H for reducing halon emissions.

As summarized below, the proposed changes outlined are grouped by relevance and thus may not be grouped by subparts as described above. The EPA is proposing to allocate annual production and consumption allowances for HCFC–123 and HCFC–124 for the years 2020 through 2029 to be used for servicing certain equipment manufactured before January 1, 2020. Section 605 of the CAA addresses the production, consumption, use, and introduction into interstate commerce of class II substances (listed HCFCs) within the United States. Sections 605 and 606 taken together constitute the primary source of authority for the domestic implementation of United States' obligations to phase out HCFCs under the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol). The EPA regulations issued under sections 605 and 606 appear at 40 CFR part 82, subpart A. Those regulations reflect the agreed Montreal Protocol HCFC phaseout schedule. An element of that schedule is to phase out HCFC production and consumption by January 1, 2020, other than production and consumption for certain narrowly

[1] Generally speaking, when the EPA refers to ODS in this preamble, it is referring to class I and/or class II controlled substances. The terms ''controlled substance'' and ''ODS'' are used interchangeably, as are the terms ''HCFC'' and ''class II substance.''

defined uses in an amount up to 0.5% of baseline annually. Under a previous adjustment to the Montreal Protocol in 1995, production and consumption during the years 2020 through 2029 was restricted to the servicing of refrigeration and air-conditioning equipment existing on January 1, 2020.[2] In November 2018, the Parties to the Montreal Protocol adopted another adjustment that, among other things, added ''the servicing of fire suppression and fire protection equipment'' existing on January 1, 2020 as a permissible use.[3] Consistent with this adjustment and a continuing servicing demand in fire suppression equipment using HCFCs in the United States, the EPA is proposing to revise subpart A to add servicing of existing ''fire suppression equipment'' to the authorized uses of newly produced or imported quantities of HCFC–123 and HCFC–124 during the years 2020 through 2029. To facilitate compliance, the EPA is proposing to revise labeling requirements for containers of fire suppression agent containing HCFC–123 that is imported during the years 2020 through 2029 in subpart E. To align with existing regulations that prohibit the production and import of phased out HCFCs, in particular HCFC–22, the agency is proposing to modify the inter-pollutant allowance transfer provisions authorized by CAA section 607 to prohibit transfers into ODS that are already phased out.

In addition, the EPA is proposing to update the requirements under other provisions of 40 CFR part 82, subpart A. To increase the accuracy of reported data and to reduce burden associated with reporting ODS data, the EPA is proposing to require that certain reports, import petitions, and certifications of intent to import for destruction be submitted electronically through the agency's Central Data Exchange (CDX). Each entity must establish an account in CDX in order to prepare, transmit, certify, and submit reports and submissions. The EPA is also proposing to amend the recordkeeping and reporting requirements by harmonizing requirements for class I and class II substances and removing reporting elements that would be made unnecessary by moving to electronic reporting. Required electronic reporting and reducing the number of reporting elements reduce the reporting burden.

The EPA is proposing two changes to provisions related to the sale of quarantine and preshipment (QPS) methyl bromide, a fumigant used to control pests in agriculture and shipping, in response to the misapplication of this ODS in Puerto Rico and the U.S. Virgin Islands. First, the EPA is proposing to extend to all distributors of QPS methyl bromide a certification requirement that currently applies only to certain distributors and end users. This proposed change would help ensure that all distributors and applicators are aware of the restrictions on the use and sale of QPS methyl bromide. Second, the EPA is proposing to explicitly prohibit the use of methyl bromide produced under the QPS exemption for any use other than a quarantine use or a preshipment use. Additionally, the EPA is proposing revisions in §§ 82.4, 82.8, and 82.13 for readability, including changes to the naming convention for methyl bromide.

The EPA is also proposing to revise provisions related to the import of ODS. The agency is proposing to modify the import petition process by clarifying that failure to provide additional information requested by the EPA during the process is grounds for objection, and by allowing for information from the government of the exporting country to be submitted in lieu of certain currently required information for petitions to import recovered class I ODS held in ODS banks. The agency would modify the petition process to import used class I substances for reuse and provide a new certification process for the import of ODS (used and virgin) for destruction in the United States. Additionally, the EPA is proposing to exempt halon 1211, a potent ODS used as a fire suppression streaming agent, in extinguishers used onboard aircraft from the import petition process to make it easier for companies to service fire suppression equipment, promoting proper maintenance of these bottles and preventing the emission of halon 1211.

The EPA is also proposing two changes to reduce the likelihood that phased out ODS will be sold and distributed in the United States, and thus reduce the potential for emissions of those substances in this country. First, the agency is proposing to prohibit the sale or offer for sale or distribution of any ODS that the seller knows, or has reason to know, has been imported into the United States without consumption allowances or is otherwise not subject to an exemption. Second, the EPA is proposing to add polyurethane foam systems containing CFCs to the list of class I nonessential products under 40 CFR part 82, subpart C to prohibit them from being sold or distributed in the United States.

The agency is proposing to revise the definition of ''destruction'' to include additional technologies such as chemical conversion processes, all of which have been approved in decisions of the Parties to the Montreal Protocol which is found or otherwise discussed in subparts A, E, and H. Lastly, the EPA proposes to remove outdated provisions related to the allocation and transfer of class I ODS credits and allowances that are no longer in use in subpart A.

C. What is the Agency's authority for this Proposed Action?

Several sections of the CAA[4] provide authority for the actions proposed by the EPA in this notice of proposed rulemaking. Section 603 provides authority to establish monitoring and reporting requirements for ODS. Sections 604 and 605 provide authority to phase out production and consumption of class I and class II substances, respectively, and to restrict the use of class II ODS. Section 606 provides the EPA authority to establish a more stringent phaseout schedule[5] than that set out in sections 604 and 605 based on: (1) Current scientific information that a more stringent schedule may be necessary to protect human health and the environment, (2) the availability of substitutes, or (3) to conform to any acceleration under the Montreal Protocol. Section 607 provides the EPA with authority to issue production and consumption allowances and to authorize allowance transfers, including inter-pollutant and inter-company transfers. Section 610, in relevant part, directs the EPA to issue regulations that identify nonessential products that release class I substances into the environment (including any release during manufacture, use, storage, or disposal) and prohibit any person from selling or distributing any such product, or offering any such products for sale or distribution, in interstate commerce. Section 611 requires the EPA to establish and implement labeling requirements for containers of, and products containing or manufactured with, class I or class II ODS.

[2] Section 605(a)(3) of the CAA refers to equipment ''manufactured'' prior to January 1, 2020. The EPA interprets this to mean that an appliance ''existing on'' January 1, 2020 is one that is ''manufactured'' by that date. The definition of ''manufactured'' can be found at 40 CFR 82.3. See also 74 FR 66439.

[3] Decision XXX/2 and Annex I of the ''Compilation of decisions adopted by the parties,'' adjust Article 2F of the Montreal Protocol.

[4] The Clean Air Act provisions addressing stratospheric ozone protection are codified at 42 U.S.C. 7671–7671q.

[5] The following documents are available in the docket: ''EPA. 1999. The Benefits and Costs of the Clean Air Act: 1990 to 2010,'' and ''EPA. 2018. Overview of CFC and HCFC Phaseout.''

The EPA's authority for this rulemaking is supplemented by section 114, which authorizes the EPA Administrator to require recordkeeping and reporting in carrying out any provision of the CAA (with certain exceptions that do not apply here). Section 301 further provides authority for the EPA to ''prescribe such regulations as are necessary to carry out [the EPA Administrator's] functions'' under the CAA. Additional authority for electronic reporting comes from the Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504), which provides ''(1) for the option of the electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.''

Additional information on the EPA's authority to establish and manage an allocation system for the phaseout of class I and class II substances can be found at 58 FR 65018 (December 10, 1993) and 68 FR 2820 (January 21, 2003) respectively.

D. What are the incremental costs and benefits of this Proposed Action?

The EPA considered the incremental costs and benefits associated with this rulemaking which stem from proposed changes to reporting and recordkeeping requirements. The revisions proposed here would require electronic submissions through CDX, create a streamlined Certification of Intent to Import ODS for Destruction, exempt halon 1211 in aircraft bottles from the import petitions process, and add recordkeeping certification requirement for methyl bromide QPS. The agency has analyzed the impact on the regulated community associated with the proposed regulatory changes, and the EPA estimates changes to reporting and recordkeeping would result in a cost of approximately $5,000 per year. However, the EPA estimates the annual costs savings to reporters as a result of reductions in reporting elements, streamlining forms, and added efficiencies to be approximately $13,000 per year. The one-time redesign labeling costs for containers of fire suppression agents are estimated to cost between $1,000 to $3,000. In addition, the EPA analyzed the impact on small businesses and found there would be no additional costs imposed on small business, see the docket for the screening analysis on small businesses. A description of the results of the analysis and the methods used can be found in Section VIII of this notice.

II. Background

The United States was one of the original signatories to the 1987 Montreal Protocol and ratified it on April 12, 1988. After ratification, Congress enacted, and President George H.W. Bush signed into law, the CAA Amendments of 1990, which included Title VI on Stratospheric Ozone Protection, codified as 42 U.S.C. Chapter 85, Subchapter VI, to ensure that the United States could satisfy its obligations under the Montreal Protocol, in addition to establishing complementary measures such as the national recycling and emission reduction programs under section 608 and the labeling requirements under section 611.

The 1992 Copenhagen Amendment [6] to the Montreal Protocol created the stepwise reduction schedule, subsequently revised, and the eventual phaseout of HCFC consumption.[7] The next milestone is a commitment to reduce HCFC consumption by 99.5% below the baseline by January 1, 2020, with consumption for the years 2020 through 2029 restricted to the servicing of refrigeration, air-conditioning, and fire suppression equipment existing on January 1, 2020.[8] This is referred to as the ''servicing tail.'' In November 2018, the Parties to the Montreal Protocol agreed to add fire suppression equipment existing on January 1, 2020 to the list of permissible servicing tail uses.

The United States has chosen to implement the Montreal Protocol phaseout schedule of HCFCs on a chemical-by-chemical basis that employs a ''worst-first'' approach focusing on the phaseout of certain chemicals with higher ozone depletion potential (ODP) earlier than others. In 1993, the EPA established a phaseout schedule to eliminate HCFC–141b first, to greatly restrict HCFC–142b and HCFC–22 next, and to subsequently place restrictions on all other HCFCs ultimately leading to a complete phaseout of all HCFCs by 2030 (58 FR 15014, March 18, 1993; 58 FR 65018, December 10, 1993).

The EPA designed the allowance program to implement the production and consumption controls of the CAA and to facilitate an orderly phaseout. To control production, the EPA allocated baseline production allowances to producers of specific ODS. To control consumption,[9] the EPA allocated baseline consumption allowances to producers and importers of specific ODS. In the allowance program, the EPA allocates ''calendar-year'' or ''annual'' allowances to companies who expend them when they produce or import ODS. The allowances can be traded among companies both domestically and internationally (between countries that are Parties to the Protocol), with certain restrictions. Allocation of production and consumption allowances for most class I substances (CFCs, methyl chloroform, carbon tetrachloride, and halons) ended in 1996, and in 2005 for methyl bromide. Production and consumption allowances for class II substances (HCFCs) will be reduced to zero in 2030.[10]

Since the EPA is implementing the HCFC phaseout on a chemical-by-chemical basis, it allocates and tracks production and consumption allowances on an absolute kilogram basis for each chemical. An allowance is the unit of measure that controls production and consumption of ODS. The EPA allocates allowances for specific years; they are valid between January 1 and December 31 of a given control period (*i.e.,* calendar year). In previous rulemakings, the EPA has allocated calendar-year allowances equal to a percentage of the baseline for specified control periods. A calendar-year allowance represents the privilege granted to a company to produce or import one kilogram (not ODP-weighted) of the specific substance. The EPA allocates two types of calendar-year allowances—production allowances and consumption allowances. To produce an HCFC, an allowance holder must expend both production and consumption allowances. To import an HCFC, an allowance holder must expend only consumption allowances. An allowance holder exporting HCFCs for which it has expended consumption allowances may obtain a refund of those consumption allowances upon submittal of proper documentation to the EPA. Production and import of

[6] Further information on the Copenhagen Amendment is available at *https://ozone.unep.org/en/handbook-montreal-protocol-substances-deplete-ozone-layer/2199.*

[7] Consumption is defined in § 82.3 as production plus imports minus exports of a controlled substance (other than transshipments or used controlled substances). Production is defined in § 82.3 as the manufacture of a controlled substance from any raw material or feedstock chemical, but does not include: (1) The manufacture of a controlled substance that is subsequently transformed; (2) the reuse or recycling of a controlled substance; (3) amounts that are destroyed by the approved technologies; or (4) amounts that are spilled or vented unintentionally.

[8] *See* Montreal Protocol Article 2F, paragraph 6.

[9] *See* CAA section 601(6), 42 U.S.C. 7671(6); 40 CFR 82.3.

[10] *See* CAA section 605 (b)(2), 42 U.S.C. 7671(d) and Montreal Protocol Article 2F, paragraph 6.

virgin HCFCs without allowances are prohibited except for transformation, destruction, transshipments, or heels (§ 82.15(a) and (b)).

Under the chemical-by-chemical phaseout schedule for HCFCs, the EPA stopped allocating production and consumption allowances for HCFC–141b as of 2003; there will be no more production and consumption allowances for HCFC–22 and HCFC–142b as of 2020; and beginning in 2020 the use of newly produced or imported quantities of the remaining HCFCs will be limited to servicing refrigeration, air-conditioning, and fire suppression equipment existing at that date.

The EPA notes that absent specific use restrictions, HCFCs can continue to be used after their production and import has ceased, for example, to service existing equipment such as refrigeration and air-conditioning systems. The EPA's intent has always been to facilitate a smooth transition to alternatives, which means avoiding stranding equipment that has not yet reached the end of its useful life. For example, used HCFC–22 that is recovered and reclaimed, or virgin material produced before the 2020 phaseout may continue to be used for as long as it is available to service existing HCFC–22 systems.

The allowance system for production and import that reduces the number of allowances over time is a central component of the ODS phaseout in the United States. The EPA limits how much ODS enters the market to meet the CAA and Montreal Protocol phaseout milestones. To smooth the phaseout steps, the EPA also takes complementary actions that reduce the demand for ODS, encourage recovery and recycling or reclamation of used ODS, allow for continued servicing to avoid stranding existing equipment, and encourage transition to alternatives that ''reduce overall risks to human health and the environment.'' [11]

The EPA's most recent action related to the phaseout of HCFCs was a 2014 rule that allocated production and consumption allowances for HCFC–22, HCFC–142b, HCFC–123, and HCFC–124 for 2015–2019 (79 FR 64254, October 28, 2014). In that action, the EPA also implemented the provisions in CAA section 605(a) that limit production and consumption to servicing refrigeration and air-conditioning appliances and for use in fire suppression applications. That notice provides additional discussion of the history of the phaseout of HCFCs.

[11] CAA section 612, 42 U.S.C. 7671(k).

III. Allocation of HCFC Allowances for the Years 2020 Through 2029

This section presents the EPA's proposed approach for issuing HCFC allowances for the next regulatory period that extends from 2020 through 2029, as well as complementary changes to implement a recent adjustment to the Montreal Protocol. The EPA is proposing to issue consumption allowances for HCFC–123 and consumption and production allowances for HCFC–124 consistent with the CAA, EPA regulations, and obligations of the United States under the Montreal Protocol. These are the two HCFCs not already slated for phaseout in the United States by 2020 under existing regulations. These HCFCs are currently used in the refrigeration, air-conditioning, and fire suppression sectors. The EPA is also proposing to add servicing of fire suppression equipment to the authorized uses of newly produced or imported quantities of these HCFCs during the years 2020 through 2029. In addition, the EPA is proposing changes to the current labeling requirements for containers of fire suppression agent using HCFC–123.

In this proposed action, the EPA is relying on its authority under CAA section 605(c) to promulgate regulations phasing out the production and restricting the use of class II substances in accordance with section 605, subject to previous accelerations under section 606 (See 58 FR 65018, December 19, 1993 and 74 FR 66411, December 15, 2009). The EPA is proposing limited changes to the existing regulations on production, consumption, and use of class II ODS to provide flexibility for the years 2020 through 2029 consistent with the requirements of section 605 and obligations of the United States under the Montreal Protocol.

In developing the proposed allocations for HCFC–123 and HCFC–124 for the years 2020 through 2029, the EPA considered a number of factors, including existing company-specific consumption baselines listed in § 82.19; the uses of HCFCs that are permissible for the years 2020 through 2029 under CAA section 605(a) and the availability of alternatives for those uses; the types of HCFCs that may be produced and consumed consistent with existing obligations and regulations; the quantity needed to meet the estimated demand for each permissible use; the estimated quantity of HCFCs that will be available from recycling and reclamation, as well as from the potential stockpiling of virgin HCFCs in advance of the 2020 phaseout step; [12] and the transition that must occur by 2030 when HCFC production and consumption will be phased out completely. For each HCFC that will be allocated, the EPA identifies a total number of allowances to be allocated and then sets calendar-year allowances equal to a percentage of each company's baseline.[13] The following discussion describes how the EPA considered each of these factors broadly in developing the proposed allocations.

The first factor the EPA considered when developing this proposal was the existing limitation on permissible uses of HCFCs and the availability of alternatives for those uses. Section 605(a) of the CAA limited the use of newly-produced (*i.e.,* virgin) HCFCs beginning January 1, 2015. The statute provides that starting on that date, it shall be unlawful for any person to introduce into interstate commerce or use any class II substance unless such substance: (1) Has been used, recovered, and recycled; (2) is used and entirely consumed (except for trace quantities) in the production of other chemicals; (3) is used as a refrigerant in appliances manufactured before January 1, 2020; or (4) is listed as acceptable under the Significant New Alternatives Policy (SNAP) program for use as a fire suppression agent for nonresidential applications. As detailed in the draft report in the docket titled *The U.S. Phaseout of HCFCs: Projected Servicing Demands in the U.S. Air Conditioning, Refrigeration, and Fire Suppression Sector (2020–2030),* hereafter referred to as the *Draft Servicing Tail Report,* the EPA considered the availability of alternatives for the latter two uses, with the understanding that it is typically best to service equipment with the same refrigerant or fire suppression agent it was designed to use. The SNAP program continues to review and list alternatives for applications that use HCFCs, including refrigeration and air conditioning and fire suppression applications that use HCFC–123. Substitutes are listed under that regulatory program as acceptable, unacceptable, or acceptable subject to use restrictions for specific uses. Any future use of substitutes listed as acceptable subject to use restrictions

[12] EPA. 2019. The U.S. Phaseout of HCFCs: Projected Servicing Demands in the U.S. Air Conditioning, Refrigeration, and Fire Suppression Sector (2020–2030).

[13] The percentage of baseline allowances to be allocated for each HCFC is determined as follows: First, all the company-specific consumption baselines (listed in the table at § 82.19) are added to determine the aggregate amount of consumption baseline. The total number of allowances to be allocated in a given year are then divided by the aggregate amount of baseline allowances.

must comport with any conditions of the SNAP program, if applicable. Currently, the SNAP program lists a number of acceptable substitutes for HCFCs for use as a fire suppression agent for nonresidential applications, making a variety of allocation options practicable for the years 2020 through 2029.

In addition to the statutory provisions in CAA section 605, the EPA established a ''worst-first approach'' in 1993 which addressed which HCFCs may be produced and consumed and prioritized the phaseout of HCFCs based on their ODPs (58 FR 15014 and 58 FR 65018). These regulations can be found in § 82.16. HCFC–141b was phased out in 2003, except for certain exempted uses. HCFC–22 and HCFC–142b will be fully phased out of production and consumption starting in 2020, with exceptions for destruction and transformation. Consistent with that approach, the EPA is proposing to issue allowances for production and consumption of only HCFC–123 and HCFC–124, as these are the remaining HCFCs that have not been phased out domestically.

Under the Montreal Protocol, the United States has committed to phase out HCFC production and consumption by January 1, 2020, other than production and consumption for certain narrowly defined uses in an amount up to 0.5% of baseline annually. Under a previous Montreal Protocol adjustment in 1995, production and consumption during the years 2020 through 2029 were restricted to the servicing of refrigeration and air-conditioning equipment existing on January 1, 2020. In the spring of 2018, the United States proposed adjusting the Montreal Protocol to allow for new production and import of HCFCs within the 0.5% cap for servicing fire suppression equipment existing on January 1, 2020. This proposal was based on extensive stakeholder consultation on HCFC needs during the years 2020 through 2029 and the EPA's analysis of available information, including the *2018 Draft Servicing Tail Report.* In November 2018, the Parties to the Montreal Protocol decided to adopt an adjustment that, among other things,[14] added to Article 2F ''the servicing of fire suppression and fire protection equipment'' existing on January 1, 2020 as a permissible use for newly produced or imported HCFCs.[15] While the term ''fire protection'' can be understood in some contexts to refer broadly to all measures taken to protect persons or property from harm, the terms ''fire protection'' and ''fire suppression'' have been used interchangeably in the Montreal Protocol context to refer to suppressing or putting out fires through the use of chemical substances. Section 605(a) of the Clean Air Act uses the term ''fire suppression.'' In addition, the EPA views this term as the more precise term in the context of regulating ozone-depleting substances. Therefore, the EPA is proposing to add servicing of ''fire suppression equipment'' to the authorized uses of newly produced or imported quantities of these HCFCs during the years 2020 through 2029. The adjustment adopted in November 2018 will enter into force on June 21, 2019. The final meeting report from the 30th Meeting of the Parties and Decision XXX/2 adopting the adjustment are included in the docket for this rulemaking.

In developing the proposed allocations, the EPA considered the quantities needed to satisfy estimated demand for HCFC–123 and HCFC–124 to service certain equipment manufactured before 2020. These estimates are discussed in more detail in an updated *2019 Draft Servicing Tail Report,* which is available in the docket. This report and the proposed allocation are based on demand projections contained in the EPA's Vintaging Model,[16] recent market research, discussions with industry on current HCFC uses and trends, and the expected availability of recovered, recycled/reclaimed, and reused material. The agency made the April 2018 draft report available on its website and in the docket along with a Notice of Data Availability published in the **Federal Register** on May 4, 2018 (83 FR 19757) and requested comment on the data and assumptions in the report. The EPA did not receive any substantive comments on the report but continues to welcome further input on all aspects of the revised report, including but not limited to the underlying assumptions and sensitivity analyses. As a result of the adjustment to Article 2F of the Montreal Protocol, the EPA has since revised the *2018 Draft Servicing Tail Report* to reflect the demand for servicing fire suppression equipment manufactured before January 1, 2020. The EPA seeks comment on the *2019 Draft Servicing Tail Report* specifically related to the fire suppression sector. Since the EPA will use the report to support the final rule, the agency requests any relevant data and market information that would improve the accuracy of the agency's projections. These data may be used in determining the final allocation.

The last overarching factor the EPA considered is the 2030 phaseout date for HCFC production and import, with limited exceptions, under CAA section 605(b)(2) and (c). As for prior HCFC phaseout steps, the agency's intent is to accomplish the 2030 phaseout step in a manner that achieves a smooth transition to alternatives without stranding equipment. The goal is to allow equipment owners to continue servicing their HCFC–123 and HCFC–124 equipment that is still within its expected lifetime. Experience with prior HCFC–22 phaseout steps indicates that gradually decreasing allocation levels is better than an abrupt increase or decrease to foster recovery, recycling, and reclamation of HCFCs and an orderly transition to approved alternatives.

A. Allocation of HCFC–123 Production and Consumption Allowances

This section presents the EPA's proposed approach for determining the amount of HCFC–123 production and consumption allowances to be issued and takes comment on two alternatives.

The agency is proposing to not provide any HCFC–123 production allowances for the years 2020 through 2029. In 2009, the EPA issued zero production baseline allowances for HCFC–123 because no companies produced HCFC–123 production in the baseline years of 2005 through 2007. As such, the EPA has not issued production allowances for HCFC–123 in subsequent years (74 FR 66431). Under section 605(b)(1) of the CAA, it is unlawful for any person to produce any class II substance in an annual quantity greater than the quantity of such substance produced by such person during the baseline year. The EPA does not propose to issue any production allowances for HCFC–123 for the years 2020 through 2029.

[14] The adjustment adopted at the Meeting of the Parties in November 2018 included an essential use provision as well as the addition of two niche applications under the 0.5% cap. In this proposed rule, the EPA is only proposing to address the addition of fire suppression. We are not proposing to take any action with regard to other elements of the adjustment at this time.

[15] Decision XXX/2 and Annex I of the ''Compilation of decisions adopted by the parties,'' adjust Article 2F of the Montreal Protocol.

[16] The EPA's Vintaging Model estimates the annual chemical emissions from industry sectors that historically used ODS, including Ref/AC and fire suppression. The model uses information on the market size and growth for each end-use, as well as a history and projections of the market transition from ODS to alternatives. The model tracks emissions of annual ''vintages'' of new equipment that enter into operation by incorporating information on estimates of the quantity of equipment or products sold, serviced, and retired or converted each year, and the quantity of the compound required to manufacture, charge, and/or maintain the equipment.

In 2020, the consumption baseline of the United States for all HCFCs will be 0.5% which equates to 76.2 ODP-weighted metric tons that could be available for servicing.[17] Under section 605(c) of the CAA, the consumption of HCFCs by any person is also to be limited to the quantity consumed by that person during the baseline year. The EPA has implemented this requirement by limiting the number of annual allowances allocated for each chemical in § 82.16. Consumption of HCFC–123 during the baseline year equates to 2,014 MT (40 ODP-weighted MT).

Table 1 shows the number of HCFC–123 consumption allowances that would be allocated each year from 2020 to 2030 under the EPA's proposed approach and under the two alternatives on which the EPA is also taking comment. The proposed and alternative approaches are discussed in greater detail below.

TABLE 1—COMPARISON OF HCFC–123 CONSUMPTION ALLOWANCE ALLOCATION APPROACHES BETWEEN 2020–2030 (MT)

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Total
Proposal	650	650	650	570	490	410	330	250	170	90	0	4,260
Alternative 1	520	480	450	420	380	350	310	280	250	210	0	3,650
Alternative 2	2,014	2,014	2,014	2,014	2,014	2,014	2,014	2,014	2,014	2,014	0	20,140

(1) Proposal

The agency proposes to issue consumption allowances equal to the 2020 estimated HCFC–123 demand for servicing existing refrigeration and air-conditioning and fire suppression equipment for years 2020 through 2022 and to then decrease the number of allowances issued in each subsequent year by an equal amount each year such that there are zero allowances issued in 2030. In effect, this proposal would meet the estimated, full servicing demand in 2020 with newly imported HCFC–123 and the estimated, full servicing demand in 2030 with reclaimed HCFC–123. Under this proposal, the EPA would allocate 650 MT[18] for the years 2020 through 2022 to ensure adequate supply for servicing both existing air-conditioning and fire suppression equipment. Currently the reclamation market primarily services the refrigeration and air conditioning sector. The EPA believes that initially providing three years of flat allocations would allow time for the reclamation market to enter the fire suppression sector. This is the maximum estimated HCFC–123 demand for servicing refrigeration, air-conditioning, and fire suppression equipment in 2020 as discussed in the *2019 Draft Servicing Tail Report.*

The EPA could use an equal yearly decrease approach beginning in 2023 but start at a higher or lower allocation. Specifically, the EPA could use a starting allocation in the years 2020 through 2022 of up to 1,200 MT (24 ODP-weighted MT), which is the current average annual consumption of HCFC–123 in 2012 through 2017 (83 FR 19757). The agency could also use a lower starting allocation for years 2020 through 2022 of between 650 MT (the proposed starting allocation) and 520 MT (the starting allocation in the first alternative discussed below). The agency requests comment on the full range of possible starting allocations for this option.

The EPA proposes to reduce the allocation annually beginning in 2023 by an equal amount each year to bring allocations down to zero by 2030. This approach balances the various near and longer term needs by fostering a stable supply of HCFCs to be used for servicing throughout the allocation period and past the phaseout date. Gradually reducing HCFC allowances fosters transition and recycling/reclamation and is consistent with the EPA's approach in previous HCFC allocation rules (see 74 FR 66412, December 15, 2009; 76 FR 47451, August 5, 2011; 78 FR 20004, April 3, 2013; and 79 FR 64254, October 28, 2014). During previous ODS phaseouts, decreasing the allocation has provided equipment owners with the proper market signal to foster transition to alternatives and to increase the incentive for recovery and reclamation.

Consistent with our obligations as a party to the Montreal Protocol, and the use limitation in CAA section 605(a) regarding refrigeration and air-conditioning equipment, the EPA is not proposing to issue HCFC–123 allowances for use in fire suppression or refrigeration and air-conditioning equipment manufactured on or after January 1, 2020. The EPA notes that new fire suppression and refrigeration and air-conditioning equipment may be manufactured with recovered and recycled/reclaimed HCFCs in 2020 and beyond. Section 605(a) of the CAA does not restrict the use of recycled/reclaimed HCFC–123. For instance, as explained in the *2019 Draft Servicing Tail Report* available in the docket, the fire suppression sector has a long history of using recovered and recycled/reclaimed ODS for both servicing and new equipment. For example, there has been continuing demand for halons in newly-manufactured fire suppression equipment since the 1994 halon phaseout in the United States. This demand for halons has been satisfied with recycled/reclaimed halons. Any demand for HCFC–123 for charging and servicing fire suppression equipment manufactured on or after January 1, 2020 must also be met by recycled/reclaimed HCFC–123 or HCFC–123 that was stockpiled prior to 2020.

Following the November 2018 Montreal Protocol adjustment, the EPA revised the *2018 Draft Servicing Tail Report* to disaggregate estimated demand for fire suppression to show estimated demand for servicing compared to demand for new equipment. The EPA consulted with industry on the estimate of future market demand for HCFC–123 fire suppression applications. Over the past several years, total demand (the manufacture of new equipment and the servicing of existing equipment) has varied, but the average has been approximately 260 MT per year. The EPA expects the servicing demand for fire suppression servicing to be between 35 to 90 MT based on projections[19] from the Vintaging Model and feedback from industry.

Starting the allocation levels below the estimated demand for servicing both fire suppression and refrigeration and air-conditioning equipment, even though the amount reclaimed is expected to be significant, could lead to insufficient quantities of recycled/

[17] 76.2 ODP-weighted metric tons is the equivalent of 3,810 MT of HCFC–123.

[18] 13 ODP-weighted MT.

[19] EPA. 2019. The U.S. Phaseout of HCFCs: Projected Servicing Demands in the U.S. Air Conditioning, Refrigeration, and Fire Suppression Sector (2020–2030), Table 5.

reclaimed HCFC–123 to meet fire suppression demand, as indicated in the *2019 Draft Servicing Tail Report.* As such, the EPA does not think it would be prudent to reduce the allocation further to account for the complete amount of expected reclamation in the early years. Conversely, if the EPA allocated a higher amount than demand, more virgin HCFC–123 may be imported, reducing the need for recovered and reclaimed HCFC–123. As a point of comparison, the EPA allocated 100% of the HCFC–123 baseline (2,014 MT, Alternative 2 in Table 1) for the years 2015 through 2019. In those years HCFC–123 could be used to manufacture new equipment as well as service existing equipment. Allowance holders did not use their full allocation for HCFC–123 during those years and often used the inter-pollutant transfer mechanism to convert their HCFC–123 allowances into HCFC–22 allowances. After January 1, 2020, there is no other market for transfers.

The EPA seeks comment on all aspects of this proposed allocation including the proposed number of allowances to be issued for 2020. The agency requests comment on the rationale explained above for its proposal to allocate 650 MT HCFC–123 consumption allowances for 2020 through 2022; whether the starting allocation in 2020 should be higher or lower; the proposal to decrease this allocation by a constant amount each year after 2022; and whether this proposal would meet demand for HCFC–123 during the years 2020 through 2029. The EPA also requests comment on the expected servicing demand for fire suppression equipment, which is based on projections from the Vintaging Model and feedback from industry. The EPA is taking comment on whether the proposed allocation would strand any equipment in 2020 through 2029, and what the potential cost impacts may be for any stranded equipment. The agency also requests comment on whether there is a significant cost difference to users between reclaimed and virgin HCFC–123. Commenters should provide as much detail, with as much quantitative reasoning (*e.g.,* benefits, market effects, etc.), as possible. When developing a final rule, the EPA will consider any comments received on the starting allocation number and the proposal to decrease the allocation by a constant amount each year.

(2) Alternatives

The EPA is also seeking comment on two alternative approaches the EPA considered for determining how many HCFC–123 consumption allowances to issue. The first alternative approach would be to issue allowances equal to the total modeled demand each year from 2020 through 2029 (which includes servicing of existing equipment and the manufacture of new equipment using reclaimed HCFC–123) minus the low end of the projection for reclamation each year from 2020 through 2029. This contrasts with the proposed approach which, as explained above, would neither consider demand for the manufacture of new equipment using reclaimed HCFC–123 nor directly decrease allocations based on projections for reclamation. The EPA's low-end estimate for reclamation is 300 MT in 2020, rising by 10 MT per year to 390 MT in 2029. See Table 8 of the *2019 Draft Servicing Tail Report* for more discussion of estimated reclaim. In Table 1, above, the first alternative presents the allocations that would result from applying this approach.

Setting the initial allocation at total estimated demand in 2020 minus the low-end projections for reclamation would reflect current total HCFC–123 market conditions and allow companies to continue consuming HCFC–123 at a rate consistent with demand to ensure adequate supply. Decreasing the allocations gradually over time would potentially guard against consumption levels that are significantly higher than demand. This approach would also account for continued manufacture of fire suppression equipment using HCFC-based fire suppression agent to the extent recycled/reclaimed HCFC–123 is available. While this approach would start at a lower allocation in 2020 than the proposed approach and would allocate less HCFC–123 overall in 2020 through 2029, it would give more time for industry to transition given the slower decrease in the allocation level over time, it would also result in a larger drop between 2029 and 2030 compared to the proposed approach. This could result in a situation where HCFC–123 equipment owners wait until the end of the regulatory period to transition or are unprepared for the 2030 phaseout.

While the EPA estimates that the level of reclaimed HCFC–123, at 300 MT per year, will be higher than the estimated demand for new fire suppression equipment, the agency expects that much of this reclaimed material will be sold into the refrigeration and air-conditioning market given current business relationships. Based on industry feedback, the EPA has tentatively concluded that reclaimed HCFC–123 is currently sold exclusively into the refrigeration and air-conditioning market. Thus, it might not be immediately available for fire suppression. More availability of virgin HCFC–123 would allow time for the market for recycled/reclaimed HCFC–123 to shift towards new fire suppression equipment, as consumption of HCFC–123 under the Montreal Protocol is only for servicing equipment.

The EPA seeks comment on this first alternate approach. The EPA requests comment on accounting for the anticipated continued manufacture of fire suppression equipment using reclaimed HCFC–123. The EPA also requests comment on using the low end or the high end of the estimate for reclamation, or a point in between. Using the current high end of the expected reclamation estimate would equate to an allocation of approximately 470 MT in 2020, 220 MT in 2025, and 20 MT in 2029. The EPA also seeks comment on whether it should start at a higher amount in 2020 (up to 1,200 MT) consistent with current average consumption of HCFC–123, or a lower amount consistent with the high end of the expected reclamation estimate provided in Table 9 of the *2019 Draft Servicing Tail Report.* Commenters should provide as much detail, with as much quantitative reasoning (*e.g.,* benefits, market effects, etc.), as possible.

Lastly, the EPA is seeking comment on a second alternative approach under which, as shown in Table 1 above, the EPA would issue 2,014 MT of HCFC–123 consumption allowances for each year for the years 2020 through 2029. This is equal to 100 percent of the aggregate consumption baseline allowances for HCFC–123 and is the maximum allocation allowed under section 605(c) of the CAA. This approach would allocate approximately half of the annual consumption cap allowed under the Montreal Protocol. Specifically, this allocation would equal 40.3 ODP-weighted MT compared to 76.2 ODP-weighted MT allowed during each year between 2020 through 2029. This approach could be warranted given the relatively low ODP of HCFC–123 (0.02) and the long lifetime of equipment using HCFC–123.

The agency believes this approach would provide significantly more allowances than are needed to meet demand for HCFC–123. The existing regulatory prohibition on producing or importing HCFC–123 for most uses, including in the manufacture of refrigeration and air-conditioning and fire suppression equipment as of January 1, 2020 will significantly reduce the demand for HCFC–123. However, this approach would be consistent with

the EPA's past approach of issuing the maximum allocation for HCFC–123 during the 2015–2019 control periods. This option does not account for recycling or reclamation and might lead to higher consumption than demand for HCFC–123. This situation risks decreased incentive to reclaim refrigerant at the end of life and during servicing, potentially resulting in higher emissions. It also would not incorporate specific reductions to foster reclamation and recycling or the transition to alternatives. The EPA anticipates it may also significantly curtail the existing market in the refrigeration and air-conditioning sector, since the only remaining market for reclaimed HCFC–123 would be for the manufacture of new fire suppression equipment. This approach would also result in an abrupt decrease in allowances in 2030 when the allocation would decrease from 2,014 MT to zero, which is inconsistent with past practice of fostering a smooth transition to alternatives. The EPA welcomes comment on this alternative approach of issuing 2,014 MT in each year. Commenters should provide as much detail, with as much quantitative reasoning (*e.g.,* benefits, market effects, etc.), as possible.

B. De Minimis Exemption

The EPA is proposing to create a *de minimis* exemption from the use prohibition in CAA section 605(a) to allow virgin HCFC–123 to be used for the manufacture of chillers that meet specific criteria through December 31, 2020. This proposal aims to address a unique situation that has arisen because certain construction projects that ordered HCFC–123 chillers for installation in 2019 are behind schedule and the chillers may not be installed by the end of 2019. The EPA understands that many of the chillers and the virgin HCFC–123 to charge them are already on site at these construction projects and that companies purchased virgin HCFC–123 for charging these chillers given the expectation that they would be installed in 2019. However, due to construction delays, the final steps in the manufacture of these chillers (including charging with refrigerant) may not occur until after January 1, 2020. CAA section 605(a) prohibits the introduction into interstate commerce or use of any class II substance as a refrigerant unless such substance is used as a refrigerant in appliances manufactured before January 1, 2020. To address this unique circumstance, the EPA is proposing to create a *de minimis* exemption to allow virgin HCFC–123 to be used for the manufacture of chillers that meet specific criteria through December 31, 2020. This exemption would only apply if the HCFC–123 chiller unit and other components were ready for shipment to a construction location and the components were specified for installation under a building permit or contract dated on or before the date of signature of the proposed rule, the HCFC–123 was imported prior to 2020 and is in the possession of the entity that will complete the manufacture of the appliance, and all refrigerant added to that appliance after December 31, 2020 is used, recovered, or recycled/reclaimed. This proposal is based on the information currently available to the agency. We will consider all comments on the merits of this proposal and its potential impacts before deciding whether to take final action to create such a *de minimis* exemption.

(1) Background

As described in Section III of this notice, the CAA restricts introduction into interstate commerce and use of HCFCs over time with limited exceptions. The CAA prohibits the use of HCFCs to manufacture new appliances effective January 1, 2020, unless the HCFCs are used, recovered, and recycled. The CAA also phases out production and consumption of HCFCs, with an interim milestone in 2015 and the full phaseout in 2030. Additionally, the Montreal Protocol phases out the production and consumption of HCFCs as of January 1, 2020, while allowing a limited amount of new production and consumption for servicing existing refrigeration and air-conditioning appliances, as well as other uses described in Section III. The EPA codified the CAA use and interstate commerce restrictions related to refrigeration and air-conditioning appliances at 40 CFR part 82, subpart A in prior rulemakings.

As defined in the regulations, the term manufactured [20] ''for an appliance, means the date upon which the appliance's refrigerant circuit is complete, the appliance can function, the appliance holds a full refrigerant charge, and the appliance is ready for use for its intended purposes; . . .'' Appliances used in commercial refrigeration, such as large chillers, and industrial process refrigeration typically involve more complex installation processes, which may require custom-built parts, and typically are manufactured on-site. Appliances, such as these, that are field charged or have the refrigerant circuit completed on-site, regardless of whether additional refrigerant is added or not, are manufactured at the point when installation of all the components and other parts are completed, and the appliance is fully charged with refrigerant and able to operate.

Recently, the EPA learned that a limited number of HCFC–123 chillers specified for installation in 2019 may not be fully manufactured prior to January 1, 2020. The key uncharged components, in particular the chiller units themselves, were ready for shipment to the construction location in the first half of 2019. The agency understands that chiller manufacturers ceased factory operations for making new HCFC–123 chiller units at the end of April 2019. However, for some delayed projects, even though the units and refrigerant may already be on-site, the final steps to manufacture the appliance, in particular charging the chiller with refrigerant, may not occur until 2020. Thus, if no regulatory relief is provided, the virgin HCFC–123 could not be used to charge these chillers even if it has already been purchased and is on site.

(2) Proposed *De Minimis* Exemption

To provide flexibility to complete the manufacture of HCFC–123 chillers from components that are ready for shipment to a construction location, the EPA is proposing to create a *de minimis* exemption to the use prohibition in 605(a). This exemption would allow HCFC–123 to be used for the initial charging of certain chillers manufactured between January 1, 2020 and December 31, 2020 provided they meet specific conditions. The proposed exemption would only apply if the HCFC–123 chiller unit and components are ready for shipment to a construction location and the components were specified for installation under a building permit or contract dated on or before the date of signature of the proposed rule, the HCFC–123 was imported prior to 2020 and is in the possession of an entity involved in the manufacture of the appliance, and all refrigerant added to that appliance after December 31, 2020 is used, recovered, or recycled/reclaimed.

The EPA has implied authority to propose a *de minimis* exemption from the section 605(a) use restriction. The United States Court of Appeals for the District of Columbia Circuit has recognized that ''[u]nless Congress has been extraordinarily rigid, there is likely a basis for an implication of *de minimis* authority to provide exemption when the burdens of regulation yield a gain of trivial or no value.'' *Alabama Power Co.*

[20] The definition of ''manufactured'' can be found at § 82.3. See also 74 FR 66439.

v. *Costle,* 636 F.2d 323, 360–61 (D.C. Cir. 1980).

In *Alabama Power,* the Court held that ''[c]ategorical exemptions from statutory commands may . . . be permissible as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered *de minimis.* It is commonplace, of course, that the law does not concern itself with trifling matters, and this principle has often found application in the administrative context. Courts should be reluctant to apply the literal terms of a statute to mandate pointless expenditures of effort.'' *Id.* (internal citations omitted). In an earlier case cited by the court in *Alabama Power,* the court described the doctrine as follows: ''The 'de minimis' doctrine that was developed to prevent trivial items from draining the time of the courts has room for sound application to administration by the Government of its regulatory programs . . . The ability, which we describe here, to exempt *de minimis* situations from a statutory command is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design.'' *District of Columbia* v. *Orleans, 406 F.2d 957, 959 (1968).*

In this respect, the *Alabama Power* opinion observed in a footnote that the *de minimis* principle ''is a cousin of the doctrine that, notwithstanding the 'plain meaning' of a statute, a court must look beyond the words to the purpose of the act where its literal terms lead to 'absurd or futile' results.'' *Alabama Power* at 360 n. 89 (citations omitted). To apply an exclusion based on the *de minimis* doctrine, ''the agency will bear the burden of making the required showing'' that a matter is truly *de minimis* which naturally will turn on the assessment of particular circumstances. *Id.* The *Alabama Power* opinion concluded that ''most regulatory statutes, including the CAA, permit such agency showings in appropriate cases.'' *Id.*

A notable limitation on the *de minimis* doctrine is that it does not authorize the agency to exclude something based on a cost-benefit analysis. As the court explained, this ''implied authority is not available for a situation where the regulatory function does provide benefits, in the sense of furthering the regulatory objectives, but the agency concludes that the acknowledged benefits are exceeded by the costs.'' *Id.* The court held that any ''implied authority to make cost-benefit decisions must be based not on a general doctrine but on a fair reading of the specific statute, its aims and legislative history.'' *Id.*

Courts have continued to recognize that authority to create *de minimis* exemptions may be implied where ''the burdens of regulation yield a gain of trivial or no value.'' *Envtl. Def. Fund Inc.* v. *EPA,* 82 F.3d 451, 455 (D.C. Cir. 1996) (internal quotation marks omitted) *see also e.g., Ass'n of Admin Law Judges* v. *FLRA,* 397 F.3d 957, 961–62 (D.C. Cir. 2005).

The EPA believes it has authority to provide flexibility by creating a *de minimis* exemption to the 605(a) use prohibition. Section 605(a) is not extraordinarily rigid and is ambiguous as it does not speak directly to the circumstance presented here. In addition, providing flexibility is consistent with the statutory intent.

The EPA does not view section 605(a) as ''extraordinarily rigid.'' Title VI of the CAA can generally be summarized into three principal areas: The phaseout of the production and import of ODS (section 602–607); the reduction of emissions of ODS via various means such as required servicing practices, restrictions on sale and distribution of products, and consumer education (section 608–611); and the transition to alternatives that reduce overall risk to human health and the environment (section 612). Section 605 specifically addresses the phase-out of production and consumption of class II substances. For class II substances, section 605 established specific restrictions beginning in 2015 on use, introduction into interstate commerce and production, while establishing a complete phaseout of HCFCs in 2030. Congress' overall approach to the class II phaseout was generally less rigid than its approach to the class I phaseout, given the longer timeframes and the presence of only one intermediate reduction step (see section 605(b)). Given this context, the EPA does not view section 605(a) as ''extraordinarily rigid.''

The EPA finds that section 605(a) is ambiguous as it does not speak directly to the circumstance presented here. Section 605(a) does not explicitly address whether virgin HCFC–123 may be used in a chiller where all the chiller components were ready for shipment to a construction site before January 1, 2020 but where the initial charge is not completed until after January 1, 2020. Because the statute does not specify when manufacture is complete, it does not unambiguously prohibit the use of virgin HCFC–123 for the initial charge of chillers where all the chiller components were ready for shipment before January 1. 2020. Thus, the EPA has authority to resolve the ambiguity through regulation and determine whether the use prohibition should apply in this circumstance.

The EPA views the proposed *de minimis* exemption as consistent with statutory intent. The proposed flexibility would ensure the orderly phaseout of ODS and be consistent with the past practice of preventing the stranding of existing appliances without being counter to the three principle areas of Title VI described previously. First, it would not contribute to additional production and consumption of HCFCs and thus would not inhibit the United States from reaching the CAA phaseout date of 2030 or complying with the Montreal Protocol. Second, these chillers would continue to be subject to the servicing practices and labeling requirements applicable to all ODS appliances. Third, it would not slow the transition to alternatives. As discussed below, the components to assemble these chillers have already been made ready for shipment and they have been purchased for installation. While these chillers may one day be retrofitted to an alternative, such as R–514A, Title VI does not require the retrofitting of existing equipment.

In addition, rigid application of CAA section 605(a) in the unique circumstances presented here would ''yield a gain of trivial or no value.'' *Envtl. Def. Fund Inc.* v. *EPA,* 82 F.3d 451, 455 (D.C. Cir. 1996) (internal quotation marks omitted). The EPA believes that there would be no environmental benefit associated with rigidly applying 605(a). First, because the HCFC–123 used to initially charge these chillers must have been imported prior to 2020, existing allowances would have to have been expended. There would therefore not be any increase in U.S. consumption compared to the current allowed level of consumption for 2019. Second, this exemption would not encourage the manufacture of additional HCFC–123 chiller units because factory operations for making them have already ceased and the exemption would not permit such operations for additional units.

The number of chillers is also anticipated to be small. Based on consultations with industry, the EPA understands that the manufacture of up to five percent of the chillers expected to be installed in 2019 could be delayed beyond January 1, 2020. The EPA expects the number of HCFC–123 chillers to be affected is 33. As detailed in the *2019 Draft Servicing Tail Report,* the EPA assumes an average charge size for an HCFC–123 commercial chiller is approximately 445 kg. Thus, the EPA

estimates about 15 MT of HCFC–123 could be needed to complete the manufacture of chillers in 2020 if the proposed exemption is finalized. This would equate to about 0.4 percent of all HCFCs allocated in 2019.

Because the EPA has implemented the HCFC phaseout under the CAA using a ''worst first'' approach, this final step in the phaseout means that the HCFCs that remain, like HCFC–123, have the lowest ozone-depleting potential of all HCFCs. Specifically, the ODP of HCFC–123 is 0.02. Thus, the 15 MT of HCFC–123 anticipated to be used to initially charge these chillers equates to only 0.3 ODP-weighted metric tons. Comparing again to the consumption allowances allocated for 2019, this time on an ODP-weighted basis, this use would be only 0.02 percent of what was allocated in 2019.

Beyond the HCFC–123 needed for the initial charge, the EPA has also analyzed whether this proposed exemption could increase the servicing demand for HCFC–123 in the years 2020 through 2029 compared to not providing this proposed flexibility. As an initial matter, the modeled servicing demand described in the *2019 Draft Servicing Tail Report* includes the demand from the appliances affected by this exemption. The report assumes that chillers expected to be manufactured in 2019 are manufactured in that year. Because the chillers that would be affected by this proposed exemption were anticipated to be manufactured in 2019, they would not increase expected demand. This exemption would not alter the requirement that used, recovered, or recycled/reclaimed HCFC–123 be used for all subsequent servicing events on these chillers. Further, HCFC–123 chillers have very low leak rates, and thus the amount of replacement refrigerant would be low. Therefore, the EPA does not anticipate that future servicing demand will affect the market for reclaimed HCFC–123 in a manner that the EPA has not already considered when proposing allowance allocation amounts for 2020–2029.

The proposed exemption also contains numerous constraints that limit its potential impact. The proposed exemption from the 605(a) prohibition on use in appliances manufactured before January 1, 2020 would apply only for one year and only in a limited set of circumstances. It would apply only if the refrigerant used to manufacture the appliance was in the possession of an entity involved in the manufacture of the appliance and imported prior to January 1, 2020. In addition, any servicing of the equipment after December 31, 2020 would need to be done with HCFC–123 that is used, recovered, or recycled/reclaimed. Further, the exemption would not allow for the manufacture of additional chillers beyond those for which the components had already been made ready for shipment to a construction location and the components were specified for installation under a building permit or contract dated on or before the date of signature of the proposed rule.

The proposed *de minimis* exemption is also consistent with past EPA practice in this program. The EPA, on past occasions, has provided limited flexibility around use restrictions and phaseout dates. Existing regulations have typically prevented the stranding of appliances and past investments while phasing out controlled substances. For example, a concern similar to the one at issue here came to the EPA's attention in 2009 when commenters requested a limited waiver from a regulatory prohibition on manufacturing HCFC–22 appliances that was to begin in 2010 (74 FR 66412, 66440–41, December 15, 2009). Commenters identified scenarios in which HCFC–22 appliances had been scheduled for use in projects, such as construction projects, prior to January 1, 2010 but for a variety of reasons their manufacture could not be completed prior to January 1, 2010. The EPA agreed to grant flexibility by providing an exemption from the regulatory deadline to allow HCFC–22 to be used as refrigerant in appliances manufactured between January 1, 2010 and December 31, 2011 if their components were manufactured prior to January 1, 2010 and were specified in a building permit or contract dated before January 1, 2010 for use on a project. The EPA explained that providing flexibility would not result in additional consumption of HCFCs, because companies had previously produced or imported the HCFCs for use in the manufacture of appliances, and it did not affect long-term projections on servicing needs because this equipment was already planned to be installed in the previous year (74 FR 66441).

The EPA also previously created a *de minimis* exemption from the statutory prohibition on the use of previously-imported virgin HCFCs. In a 2014 rule, the EPA created an exemption from the 605(a) use prohibition to provide limited flexibility regarding the use of HCFCs for sectors other than refrigeration and air-conditioning and fire suppression. For example, the EPA allowed continued use of a small amount of material that was previously produced and/or imported using the appropriate allowances and in inventory prior to the CAA's 2015 use restriction for solvents. The EPA determined that the continued use of previously produced/imported material was consistent with past practices, that production and consumption would not be higher than that already allowed for and that the environmental effect would be limited. (79 FR 64254, October 28, 2014).

The EPA also recognizes that in the circumstances presented here, there could be negative impacts if the agency did not provide flexibility. Without the proposed flexibility, chiller manufacturers would not be able to use virgin HCFC–123 to initially charge and install new equipment even though that virgin HCFC–123 may already be on-site. Granting flexibility would allow the installation to continue using the HCFC–123 available and prevent further delay of the installation.

For the reasons described above, the EPA is proposing to create a *de minimis* exemption to the 605(a) use restriction and to revise 40 CFR 82.15(g)(5)(iii) to allow virgin HCFC–123 to be used for the initial charging of certain chillers manufactured between January 1, 2020 and December 31, 2020 provided they meet specific conditions. The proposed exemption would only apply if the HCFC–123 chiller unit was ready for shipment to a construction location and the components were specified for installation under a building permit or contract dated on or before the date of signature of the proposed rule, the HCFC–123 was imported prior to 2020 and is in the possession of an entity that will complete the manufacture of the appliance, and any service on the appliance after December 31, 2020 is done using refrigerant that is used, recovered, or recycled/reclaimed. In sum, the proposed exemption would apply only in limited instances where projects have begun but due to delays have not yet been completed prior to January 1, 2020. The EPA believes this would address concerns that were expressed by stakeholders, would not result in an environmental effect, and is consistent with statutory intent.

The EPA is taking comment on this proposal to establish an exemption to allow limited flexibility for the manufacture of chillers with HCFCs past January 1, 2020. Specifically, the EPA is requesting comment on several aspects of the proposal, including:

- Whether there is enough availability of reclaimed material for the initial charge of chillers whose manufacture is delayed until 2020 and whether rushed installations would

result in unintended emissions of HCFCs;

- Whether the EPA has appropriately assessed the environmental effects of providing or not providing flexibility, such as whether up to five percent of chiller installations may be delayed;
- Whether factory operations for making uncharged HCFC–123 chiller equipment have ceased in the United States as of May 1, 2019;
- Whether HCFC–123 chillers will in fact be stranded in the absence of this proposed exemption;
- Whether any additional conditions would be appropriate to further narrow the scope of the exemption; and
- Whether the agency has authority to establish a *de minimis* exemption in this situation.

C. Addition of Fire Suppression Servicing Uses to the HCFC Phaseout Schedule

The EPA is proposing to modify the regulations in 40 CFR part 82 consistent with CAA section 605 and the November 2018 adjustment to Article 2F of the Montreal Protocol that allows for the continued production and consumption of HCFCs for servicing fire suppression equipment manufactured before January 1, 2020. Specifically, the EPA is proposing to modify §§ 82.16(e) and 82.15(g) to allow for HCFC–123 to be produced and imported, as well as introduced into interstate commerce and used, during the years 2020 through 2029, to service fire suppression equipment existing on January 1, 2020,[21] so long as it is being used as a streaming agent listed as acceptable for use or acceptable subject to narrowed use limits for nonresidential applications in accordance with the SNAP regulations.

The EPA is proposing to modify § 82.16(e)(2) to permit the production and import of HCFC–123 for servicing fire suppression equipment manufactured before January 1, 2020. While the agency is proposing to include the term ''production'' in this regulatory change, as stated above, this action does not propose to allocate production allowances for HCFC–123 given the lack of production in the United States. Section 82.16(e) establishes limits on the production and import of HCFC–123 starting on January 1, 2020. It provides that HCFC–123 may not be produced or imported for any purposes other than the listed permissible uses. The proposed revision would add to the list of permissible uses the following: Use as a fire suppression streaming agent listed under the SNAP program as acceptable for use or acceptable subject to narrowed use limits for nonresidential applications. This revision would allow for this additional use in the years 2020 through 2029.

The EPA is also proposing to add a new paragraph after § 82.15(g)(4) to ensure consistency with the proposed change to § 82.16(e)(2). Section 82.15(g) establishes limits on the introduction into interstate commerce and use of certain HCFCs at certain dates in accordance with the worst-first approach discussed previously. Section 82.15(g)(4)(i) establishes limits that apply to many HCFCs including HCFC–123 and HCFC–124, effective January 1, 2015.[22] The EPA is proposing a new paragraph after § 82.15(g)(4) that repeats the limits in § 82.15(g)(4)(i) but may be helpful in clarifying the permissible uses of HCFC–123 and HCFC–124 produced or imported after January 1, 2020. Consistent with the restrictions on production and import in the Montreal Protocol (as modified through the adjustment adopted in 2018) and § 82.16, with regard to fire suppression, HCFC–123 produced or imported after January 1, 2020, may only be used for servicing fire suppression equipment manufactured before January 1, 2020. Existing inventories of HCFC–123 produced or imported prior to January 1, 2020, may continue to be used to manufacture and service new fire suppression equipment after January 1, 2020. This change would ensure that the regulations are clear and consistent between §§ 82.15 and 82.16, and, as a practical matter, would add no additional limitations to those in § 82.16.

These proposed revisions, if finalized, would provide flexibility consistent with the November 2018 adjustment to the phaseout schedule for HCFCs in the Montreal Protocol. The United States was a proponent of adjusting the phaseout schedule to allow for the continued production and consumption of HCFCs to service existing fire suppression equipment for years 2020 through 2029. The EPA's analysis indicates that in theory, the United States could meet its own domestic fire suppression needs with alternatives and recycled/reclaimed HCFC–123, absent competing demands from other sectors. Past phase-outs, such as the halon phaseout, demonstrated that the availability of recycled/reclaimed and stockpiled material provides flexibility for users of ODS long after the phaseout date. However, recycled/reclaimed HCFC–123, which is currently being sold predominately into the refrigeration and air-conditioning market,[23] may not be immediately available to the fire suppression sector. The EPA is concerned that reclaimers and distributors would need to adjust current distribution and sales practices to ensure that reclaimed material is available for fire suppression. At least in the near term this could affect the availability and price of HCFC–123. Given that a lack of HCFC–123 based fire suppression agents could present a safety issue, especially for applications where there is not an approved alternative clean agent, such as for Aircraft Rescue and Fire Fighting (ARFF) vehicles, allowing continued consumption of HCFC–123 for the years 2020 through 2029 for servicing existing fire suppression equipment is prudent. This is also consistent with the EPA's long-standing policy of working to avoid the premature retirement of existing ODS-based equipment while fostering the transition to alternatives.

The EPA notes that the November 2018 adjustment adopted by the Parties to the Montreal Protocol also contains an essential use provision and adds other uses under the Article 2F cap, namely solvent applications in rocket engine manufacturing and topical medical aerosol applications for the specialized treatment of burns. The EPA is only proposing regulatory changes that would allow production and consumption for the servicing of fire suppression equipment manufactured before 2020. The EPA does not currently have any information indicating a need in the United States for the additional flexibilities added to Article 2F; for that reason, the EPA has not assessed their practicality or its authority to implement them under the CAA, and we are not proposing any action on them at this time.

D. Revisions to Labeling Requirements

This section presents the EPA's proposal to adjust the current labeling requirements to reflect the proposed change to 40 CFR part 82, subpart A, which would allow the use of newly-imported HCFC–123 for servicing fire suppression equipment manufactured before January 1, 2020. The proposed changes to §§ 82.15 and 82.16 in subpart A are discussed in Section III.B of this notice. Revising the existing labeling requirements in 40 CFR part 82, subpart

[21] This proposal would expand the permitted uses under §§ 82.15 and 82.16 which also allow for use and introduction into interstate commerce, as well as production and consumption, of HCFCs for use as a refrigerant in equipment manufactured before January 1, 2020.

[22] Section 82.15(g)(4)(i) applies to all HCFCs not governed by paragraphs § 82.15(g)(1) through (g)(3).

[23] Based on conversation with industry.

E to reflect the limited ability to use HCFC–123 for fire suppression servicing would increase awareness of individuals servicing fire suppression equipment about the restriction on HCFC–123 use and support compliance with the proposed revisions to subpart A. In proposing to revise the current labeling requirements, the EPA is relying on authority under section 605(c) to issue regulations phasing out the production and consumption and restricting the use of class II substances that may be needed for compliance. To further support awareness of these new requirements, the EPA intends to conduct outreach initiatives for technicians, distributors, and service providers.

If the proposed change to subpart A is finalized, HCFC–123 imported on or after January 1, 2020 could be used to make Halotron® I, a fire suppression agent produced with HCFC–123, and could be used to service fire suppression equipment manufactured before January 1, 2020. It could not, however, be used in the manufacture of new equipment on or after January 1, 2020 or to service equipment manufactured after January 1, 2020. Only Halotron® I produced with HCFC–123 that is reclaimed or was imported prior to 2020 may be used for those purposes. Labeling of products manufactured with or containing HCFCs has been required under CAA Section 611 since 2015, and the EPA has not seen a movement away from these fire suppression agents due to current labeling requirements. Similarly, the EPA does not expect a proposed addition to the existing labeling requirement would cause a movement away from Halotron® I. The EPA identified this addition as the lowest cost option to ensure the United States meets its international obligation that newly-produced HCFC–123 only be used to service existing equipment, since this would only modify the text of the existing label to provide more information to technicians. Thus, in addition to adding a labeling requirement, users will need to be able to know the date of manufacture of fire suppression equipment. They will also need to be able to distinguish fire suppression agents that may be used only for servicing equipment manufactured before January 1, 2020 from fire suppression agents that may be used for manufacturing new equipment or servicing equipment regardless of the date of manufacture.

The EPA believes that users will be able to identify the date of equipment manufacture using existing methods as is the case with refrigeration and air-conditioning equipment. However, without additional labeling of containers of fire suppression agents that contain HCFC–123, namely Halotron® I, it may not be possible for users to distinguish containers that may only be used to service fire suppression equipment manufactured before January 1, 2020 from other containers. Therefore, the EPA is proposing to modify the current labeling requirements codified at 40 CFR part 82 subpart E for such containers. The EPA is proposing to conclude that such modified labeling is necessary to ensure that users will have enough information to determine which containers of fire suppression agent may be used in which equipment, in order to comply with the proposed revisions to the HCFC phaseout regulations. The existing CAA section 611 label is on reclaimed and virgin product. This proposal would modify only labels of product containing virgin HCFC. The EPA is also taking comment on whether to modify the current labeling requirements for containers of fire suppression agents that contain HCFC–123 that is either reclaimed or was imported before 2020, and if there are any other low-cost ways to distinguish containers for servicing fire suppression equipment.

To the EPA's knowledge, the only HCFC used in a fire suppression agent is HCFC–123, and it is only used in an agent sold under the name Halotron® I. Clean agents like Halotron® I do not leave a residue, and are commonly used in applications such as data centers, clean rooms, and aircraft where high-value or life-saving equipment will not be damaged by its use, thereby minimizing economic damages from a fire (*e.g.,* shorter equipment downtime or lower costs to repair). There are three main fire suppression streaming end uses where clean agents are used in the United States: (1) Hand-held portables; (2) 150-pound wheeled units; and (3) ARFF vehicles.

As per the National Fire Protection Association (NFPA) and DOT regulations at 49 CFR 180.250, all portable fire extinguishers must be maintained in a fully charged operable condition and undergo hydrostatic testing. NFPA is a codes and standards organization accredited by the American National Standards Institute established to minimize the risk and effects of fire by establishing criteria for building, processing, design, service, and installation around the world. Fire extinguishers, which include portable hand-held devices and wheeled units, are recommended to undergo maintenance to ensure that an extinguisher will operate effectively and safely in the event of fire.[24] Equipment should be recharged after being used to extinguish a fire for it to be usable again. Technicians who conduct hydrostatic testing, perform inspections, or recharge fire suppression equipment after a discharge may need additional information to aid in distinguishing between the permissible uses of specific containers of Halotron® I.

The EPA is proposing to modify the existing label required by section 611 of the CAA for certain containers of fire suppression agent. Section 611 requires containers of ODS to have a label and demonstrates that Congress recognized that labeling requirements may be needed to effectively implement the phaseout. In 1993, the EPA established the labeling requirements for both class I and class II substances in 40 CFR part 82, subpart E (58 FR 8136, February 1, 1993). Containers in which ODS are stored or transported must bear a clearly legible and conspicuous warning label that can be read by consumers before they can be introduced into interstate commerce. Section 611 provides specific language for the label: ''Warning: Contains [insert name of substance], a substance that harms public health and environment by destroying ozone in the upper atmosphere.'' This is reflected in the implementing regulations at § 82.106. According to CAA section 611, the label must be ''clearly legible and conspicuous.'' Labels generally should be within the principal display panel, the warning statement should be in sharp contrast to any background upon which it appears, and if there is any outer package for the container (*e.g.,* cylinder, isotank, or other container), labels should be on the outside packaging. Specific requirements on the size, text, and location of the label are provided in §§ 82.106–82.110.

The EPA is proposing to modify the required labeling of all containers of fire suppression agent made with HCFCs imported on or after January 1, 2020. The EPA believes that Halotron® I is the only fire suppression agent that uses HCFCs that would be manufactured after 2020. Containers of Halotron® I must currently be labeled per § 82.102(a) because they contain a class II substance. The EPA is proposing to modify the current required label for all containers of Halotron® I made with HCFC–123, imported on or after January 1, 2020, by adding the following sentence: ''Do not use to service

[24] National Fire Protection Association. (2018) ''Standards for Portable Fire Extinguishers'' available at: *https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=10.*

equipment manufactured on or after January 1, 2020.'' The EPA believes that this information may be necessary for technicians to determine which containers of Halotron® I may or may not be used to service new fire suppression equipment after 2020, thereby aiding compliance with applicable regulations. Technicians would still need to locate the manufacture date on all fire extinguishers or ARFF vehicles to determine which container of Halotron® I may be used to service the equipment. The EPA is requesting comment on this proposal.

The EPA is also requesting comment on whether it should also require a modified label for containers of Halotron® I made with recycled/reclaimed HCFC–123 or HCFC–123 imported before 2020. While there would be limited additional cost, this could help technicians distinguish between specific containers of Halotron® I. A second sentence could therefore be added to the existing label for containers of Halotron® I made with recycled/reclaimed HCFC–123 or HCFC–123 imported before 2020 that reads ''Not restricted to use in servicing pre-2020 equipment.'' Additionally, the EPA is requesting comment on whether there is another low-cost way to distinguish containers for servicing fire suppression equipment, such as having all containers labeled ''Virgin material may not be used to service equipment manufactured on or after January 1, 2020,'' and then include additional labeling on containers that distinguish ''virgin'' vs. ''reclaimed'' material. This may result in a cost of about $3,000 to the industry.

The agency intends to develop outreach materials in concert with the final rule and distribute them to appropriate stakeholders to ensure industry awareness of the servicing requirements. The EPA believes that there are existing methods to determine the date of manufacture of fire suppression equipment, as follows.

DOT fire extinguisher regulations at 49 CFR 173.309 require that each fire extinguisher be tested before initial shipment and marked to indicate the year of the test. Technicians could use this date as a guide for determining servicing with Halotron® I. The agency recommends that technicians inspect the date on hand-held and wheeled fire extinguishers to determine if they were manufactured before or after January 1, 2020.

For servicing ARFF vehicles, the EPA recommends that technicians inspect the manufactured date on the vehicle. For class I–III all-wheel drive commercial vehicles, vehicle identification numbers (VINs) are required by DOT per 49 CFR 565. VINs are located on the lower right-hand corner of the windshield. For smaller class IV and V vehicles, a Vehicle Information Data Plate must be in the cab of the vehicle and contain all the information in the ''Aircraft Rescue and Fire-Fighting Vehicle Tilt Table Certification'' per NFPA 414, including the make and model year.[25] Locating the year the vehicle was manufactured would aid the technician in determining whether a container of Halotron® I can be used for servicing.

The EPA requests comment on whether individuals servicing fire suppression equipment can readily identify the date the equipment was manufactured and whether the EPA's understanding of the location of this information is accurate. The EPA also takes comment on ways technicians can identify the manufacture date of fire suppression equipment and whether manufacturers and service technicians typically reuse Halotron® I cylinders to hold recovered fire suppression agent or imported HCFC–123. The EPA is taking comment on whether the manufacture of Halotron® I can designate cylinders for use in servicing existing equipment.

E. Allocation of HCFC–124 Production and Consumption Allowances

This section presents the EPA's proposed approach for determining the amount of HCFC–124 production and consumption allowances to be issued for the years 2020 through 2029. HCFC–124 is minimally used as a refrigerant. It is a component in refrigerant blends such as R–401A, which is used in industrial process and transport refrigeration equipment. It is also used as a stand-alone refrigerant in some niche applications that reach high condensing temperatures. It is not currently used for fire suppression.

As previously noted, under section 605(b)(1) and (c) of the CAA, it is unlawful for any person to produce or consume any class II substance in an annual quantity greater than the quantity of such substance produced or consumed by such person during the baseline year. This would equate to a maximum production amount of 4,029 MT (89 ODP-weighted MT) and a maximum consumption amount of 2,396 MT (53 ODP-weighted MT). Over the past five years, consumption has been approximately 250 MT per year and reclamation has been minimal. Based on recent sales data from the California Air Resources Board, the EPA estimates that annual demand for HCFC–124 is between 100 to 200 MT for servicing refrigeration and air-conditioning equipment nationally. More information on anticipated demand for HCFC–124 is in the *2018 Draft Servicing Tail Report.*

Given the small projected need for HCFC–124 beyond 2019 and the continued use of certain refrigerant blends containing HCFC–124, the agency is proposing to issue HCFC–124 production and consumption allowances in the years 2020 through 2029 consistent with the level of demand in the *2018 Draft Servicing Tail Report.* Based on Vintaging Model estimates, along with industry feedback on anticipated demand, uses of HCFC–124, and the use of HCFC–124 allowances in recent years, the EPA is proposing to allocate 200 MT for the first three years and then gradually decrease over the next seven years by an equal amount each year, as shown in Table 2. The EPA's goal is to ensure that servicing needs can be met, while also encouraging recovery and reuse and transition to alternatives. The EPA believes providing consistent allocations for the first three years would assist in establishing an inventory of HCFC–124 to be used for servicing throughout the allocation period and past the phaseout date for the expected lifetimes of all existing equipment. The EPA does not want to strand existing equipment because of an inadequate supply of HCFC–124. This proposed allocation supports this goal because it accounts for allowed end uses of HCFC–124 that may not be captured by the Vintaging Model (*e.g.,* use of niche refrigerant blends containing HCFC–124 to service equipment manufactured before 2020). The EPA is taking comment on this approach.

The EPA is also taking comment on whether, to ensure adequate supply, the agency should issue 200 MT annually beginning in 2020 without any decrease (Alternative in Table 2). Without significant reclamation of HCFC–124, it may be preferable to err toward a higher allocation. This is a small quantity in the broader context and would not have significant environmental effects given the low ODP (0.022) of HCFC–124.

[25] National Fire Protection Association. (2018) ''Standards for Aircraft Rescue and Fire-fighting Services at Airports'' available at: *http://arco-hvac.ir/wp-content/uploads/2018/04/NFPA-403-Std-Aircrft-Rscu-Fire-Ftg-Srvs-at-Airprts-2018.pdf.*

TABLE 2—COMPARISON OF HCFC–124 PRODUCTION AND CONSUMPTION ALLOWANCE ALLOCATION OPTIONS BETWEEN 2020–2030

[MT]

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Cumulative
Proposal	200	200	200	175	150	125	100	75	50	25	0	1,300
Alternative: No Annual Decrease	200	200	200	200	200	200	200	200	200	200	0	2,000

The EPA is requesting comment on all aspects of this proposal, as well as whether to issue 200 MT or some other number of allowances per year without any decline or waiting until 2023 before starting to decrease allowances. Commenters should provide as much detail, with as much quantitative reasoning (*e.g.,* benefits, market effects, etc.), as possible.

F. Changes To Transfer of Allowance Provisions in Section 82.23

This section presents the EPA's proposal to prohibit the transfer of allowances for phased out HCFCs to allowances for HCFC–123 and HCFC–124. The proposal would prohibit calendar-year inter-pollutant transfers into ODS that are already phased out of production and consumption. This proposal responds to stakeholder inquiries about inter-pollutant transfers to phased out HCFCs. HCFC–123 and HCFC–124 are the only remaining HCFCs that can be produced or imported in the years 2020 through 2029, with limited exceptions. As such, the EPA is proposing to issue allowances for only these two substances. Production and import of HCFC–141b, HCFC–225ca, and HCFC–225cb have already been phased out and production and import of HCFC–22 and HCFC–142b are phased out starting in 2020. Demand for some of these HCFCs, particularly HCFC–22, will continue beyond 2020. This could create an incentive for HCFC–123 and HCFC–124 allowance holders to attempt to convert their allowances into allowances for phased out HCFCs, such as HCFC–22.

Under CAA section 607, the EPA has issued regulations at § 82.23 which provide for both inter-pollutant and inter-company transfers of allowances for class II ODS under certain conditions. In an inter-pollutant transfer, an allowance holder converts allowances for one class II ODS into allowances for another class II ODS (§ 82.23(b)). The EPA is concerned about the potential for allowance holders to attempt inter-pollutant transfers that would be inconsistent with the established chemical-by-chemical phaseout.

The EPA views § 82.16 as effectively prohibiting this practice by prohibiting production and import of HCFCs that have already been phased out. Section 82.16(b)–(e) prohibits individuals from producing or importing certain HCFCs that have been phased out, with limited exceptions. For example, production and import of HCFC–22 and HCFC–142b are prohibited in 2020, with limited exceptions that are not considered to be United States consumption under the CAA or Montreal Protocol. These provisions do not explicitly prohibit the transfer of HCFC–123 or HCFC–124 allowances into allowances for a phased out ODS even though the entity would be violating § 82.16(e)(1) if it produced or imported that phased out ODS for any purpose other than the few listed exceptions, such as for use in a process resulting in its transformation.

Given the EPA has already received several inquiries about whether inter-pollutant transfers from HCFC–123 or HCFC–124 to HCFC–22 will be allowed after the phaseout of HCFC–22, the EPA is proposing to explicitly prohibit calendar-year inter-pollutant transfers of HCFC–123 and HCFC–124 to phased out HCFCs in § 82.23(b) to ensure clarity for the regulated community. Section 82.23(d) already prohibits permanent inter-pollutant transfers of baseline allowances, so there is no additional change needed in that paragraph. The proposed change to § 82.23(b) would not have a practical effect on the ability of allowance holders to legally produce or import phased out ODS given the prohibition in § 82.16. However, the proposed change would minimize confusion and reduce the likelihood that an allowance holder attempts to request an inter-pollutant transfer of HCFC–123 or HCFC–124 allowances to phased out HCFCs. Inter-pollutant transfers between HCFC–123 and HCFC–124 may continue so long as the newly produced or imported HCFC–123 and HCFC–124 are for an allowed use, such as for servicing refrigeration and air-conditioning appliances manufactured before January 1, 2020.

The EPA is soliciting comments on the proposed prohibition on calendar-year inter-pollutant transfers into ODS that are already phased out of production and consumption to improve the clarity of the regulations at § 82.23.

IV. Updates to Other Provisions of the Production and Consumption Control Program

This section presents the EPA's proposal to update several other provisions in 40 CFR part 82, subpart A—Production and Consumption Controls. To decrease the burden of ODS reporting and increase the accuracy of reports, the EPA is proposing to require that certain reports, import petitions, and certifications of intent to import ODS for destruction be submitted electronically through CDX. To reduce the reporting burden, the EPA is proposing to update the reporting regulations, consolidate reporting elements, and harmonize reporting requirements for class I and class II substances. The EPA is also proposing changes to the recordkeeping provisions for QPS uses of methyl bromide to increase awareness of the existing use restrictions and to amend the regulatory text for readability. In addition, to better monitor imports into the United States and to facilitate imports of ODS for destruction, the EPA is proposing changes to provisions related to imports of ODS.

A. Electronic Reporting

The EPA began allowing electronic reporting as an option for most types of reported information under this program in 2008 (73 FR 15520). The EPA provided electronic reporting forms and instructions to assist entities in fulfilling reporting requirements in §§ 82.13, 82.20, and 82.24 but did not require their use and allowed the submission of hard-copy forms. Upon receipt of the reports, the EPA either enters the data manually or imports it electronically via CDX into the ODS Tracking System. Manual entry of data provided in hard copy is time consuming for the agency as well as a potential source of error. On July 1, 2018 the EPA launched a new electronic platform for the ODS Tracking System along with revised and streamlined electronic forms. The EPA is proposing to require the use of the agency's CDX to submit reports electronically and is proposing a compliance date for this

requirement that is 30 days after the effective date of the final rule, to ensure that stakeholders have adequate time to register in CDX. To achieve this, the EPA would update the definition of ''Administrator'' in § 82.3, define ''Central Data Exchange'' in § 82.3, add a new section at § 82.14 with instructions on the process for electronic reporting, and revise provisions at §§ 82.13(c) and 82.24(a)(1) to indicate that reporters must comply with the requirement to report electronically through CDX 30 days after the effective date of the final rule.

Currently, the definition of ''Administrator'' instructs submitters to mail all reports and petitions to import ODS. The EPA is proposing to amend the definition of ''Administrator'' to require electronic reporting for the reports and petitions that are available in CDX, which includes the majority of reports under subpart A, as well as the import petitions and the Certification of Intent to Import ODS for Destruction, a new process which the EPA is proposing to create, as discussed further in Section IV.D of this notice. The EPA is also proposing to revise §§ 82.13, 82.23, and 82.24 to clarify that where a form is electronically available in CDX it must be submitted electronically through that tool. The EPA is also proposing to add the definition of ''Central Data Exchange'' and provide instructions on how to register in CDX and submit information electronically in a new section at § 82.14. Each entity must establish an account in CDX in order to prepare, transmit, certify, and submit reports and submissions.

CDX is the EPA's electronic system for environmental data exchange and serves as the EPA's main mechanism for receiving and exchanging electronic information reported via the internet. CDX provides the capability for submitters to access their data using web services. CDX enables the EPA to work with stakeholders to enable streamlined electronic submission of data via the internet. All information sent via CDX is transmitted securely to protect CBI. A reporting entity may register for a CDX account or gain access to an existing CDX account at *https://cdx.epa.gov,* as discussed further below.

The ODS Tracking System is a secure database that serves as the primary vehicle for tracking the production and consumption of ODS in the United States. The ODS Tracking System allows producers, importers, and exporters of class I (excluding methyl bromide) and class II substances to submit quarterly and annual reports electronically. The ODS Tracking System maintains the data submitted to the EPA and helps the agency to: (1) Maintain oversight over total production and consumption of ODS in the United States; (2) monitor compliance of individual companies with domestic limits and restrictions on production, imports, and transfers and with specific exemptions from the phaseout; (3) enforce against entities illegally importing without allowances; and (4) assess and report on compliance with the United States production and consumption caps established under the Montreal Protocol, as implemented through the CAA.

Providing a system to facilitate electronic reporting is consistent with the EPA's E-Enterprise initiative to reduce transaction costs and burdens for the regulated community by leveraging technologies. Eliminating paper-based submissions in favor of electronic reporting, including use of the revised Microsoft Excel reporting forms, and CDX, is part of broader government efforts to move to modern electronic methods of information gathering. One of the objectives of E-Enterprise is to reduce paperwork burden for the regulated community by offering electronic reporting, optimized operations, and advanced real-time monitoring tools. For more information on the EPA's E-Enterprise efforts please visit: *https://www.epa.gov/e-enterprise.*

Section 603 of the CAA grants the EPA the authority to issue certain regulations on the monitoring and reporting of ODS. The EPA may also use the information gathering authority under CAA section 114(a) to carry out the provisions of Title VI, including the production and consumption controls, and may require anyone who is subject to Title VI, or who may have information necessary to carry out Title VI, to make such reports as may reasonably be required. It is reasonable to require electronic reporting for the reasons set forth in this notice. Using electronic reporting enables more efficient data transmittal and reduces errors through built-in validation procedures. It reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the agency. It also promotes efficiency in communications and cost savings in submissions and correspondence. Additional support for electronic reporting comes from the Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504), which states that Executive agencies are to provide ''(1) for the option of the electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.'' The EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3), published in the **Federal Register** on October 13, 2005 (70 FR 59848), provides that any requirement in title 40 of the CFR to submit a report directly to the EPA can be satisfied with an electronic submission that meets certain conditions once the agency has published a notice in the **Federal Register** announcing that the EPA is prepared to receive certain documents in electronic form. See 40 CFR 3.2(a). For more information about CROMERR, go to *https://www.epa.gov/cromerr.*

The EPA designed the electronic reporting forms with input from stakeholders to reduce effort and allow submitters to paste transaction-level data into the form from other spreadsheets. They contain built-in validations, drop-down lists, and auto-populated cells to reduce errors from data entry. Once the form is complete, users generate a comma separated value (CSV) file and submit the Microsoft Excel report, CSV file, and any required supporting attachments via CDX. Refer to the EPA's website for additional information on electronic form submission: *https://www.epa.gov/ods-phaseout/ods-recordkeeping-and-reporting.* The web-based tool, as appropriate, also allows the user to choose ''Print,'' ''Save,'' or ''Transmit through CDX.'' The reporting tool encrypts the file and electronically submits it through CDX. The user can also check the status of their submissions at any time via CDX. Upon successful receipt of the submission by the EPA, the status of the submissions will be flagged as completed. The CDX inbox is currently used to notify the users of any correspondence related to user registration.

Under this proposal, entities generally would be required to submit the first quarter reports for the 2020 reporting year, due April 1, 2020, through CDX. Other reports that are available for submission through CDX, including import petitions and certifications of intent to import ODS for destruction, also would be required to be submitted electronically through CDX starting April 1, 2020. The EPA believes this would give the regulated community enough time to register in CDX and familiarize themselves with the revised electronic reporting forms and format. If this rule is finalized as proposed, reporting entities would be required to register and electronically submit most reports and petitions through CDX. Specifically, for production, import, export, destruction, transformation, transfers, and trades of ODS entities must use specified forms to allow for

submission through CDX. Some reports are not required to be submitted through CDX and would continue to be submitted to the EPA in hardcopy. These are low-volume reports for which the EPA has not released an electronic form, and include the laboratory use certifications and applications for critical use exemptions for methyl bromide. The OMB control number for this information collection request (ICR) and these forms is 2060–0170. The following electronic forms were released on July 1, 2018 and are available at *https://www.epa.gov/ods-phaseout/ods-recordkeeping-and-reporting* and through CDX:

—Class I Producer Quarterly Report (EPA Form 5900–151);
—Class I Importer Quarterly Report (EPA Form 5900–150);
—Class I Exporter Annual Report (EPA Form 5900–149);
—Class I Laboratory Supplier Quarterly Report (EPA Form 5900–153);
—Second-Party Transformation Annual Report (EPA Form 5900–147);
—Second-Party Destruction Annual Report (EPA Form 5900–148);
—Class II Producer Quarterly Report (EPA Form 5900–202);
—Class II Importer Quarterly Report (EPA Form 5900–200);
—Class II Exporter Quarterly Report (EPA Form 5900–199);
—Class II Trades (EPA Form 5900–205);
—Class II Request for Additional Consumption Allowances (EPA Form 5900–201).
—Methyl Bromide Producer Quarterly Report (EPA Form 5900–141);
—Methyl Bromide Importer Quarterly Report (EPA Form 5900–144);
—Methyl Bromide Exporter Quarterly Report (EPA 5900–140);
—Distributor of QPS Methyl Bromide Quarterly Report (EPA Form 5900–155); and
—Methyl Bromide Pre-2005 Stocks Annual Report (EPA Form 5900–142).

Petitioners currently have the option of using CDX to submit petitions. The current CDX process guides users through a series of drop downs, fillable fields, and uploads of PDF attachments using an electronic webform. The EPA is proposing to require reporting entities importing ODS for reuse or destruction to submit their reports through CDX because it would enable more efficient data transmittal and would reduce errors, as it has built-in validation procedures. For instance, missing information in a required field would prevent the petitioner from submitting the petition until all fields are completed. Thus, the EPA and entities would expect to benefit from electronic reporting by receiving complete submissions in a system that allows for secure electronic communication.

The EPA estimates that entities submitting ODS reports who have not yet registered in CDX would incur a one-time burden associated with registration. Most entities have already registered with CDX to voluntarily submit electronic ODS Tracking System forms or for other agency regulatory programs. The EPA estimates 20 respondents would need to incur the one-time CDX registration burden. Based on the EPA's CROMERR (ICR number 2002.07; OMB Control No. 2025–0003), the EPA assumes that entities would spend fifteen minutes per employee to register with CDX and complete LexisNexis identity proofing. Furthermore, the EPA assumes that an average of two technical staff members would need to register for each company, resulting in 20 minutes of burden per entity.

The EPA estimates that only those entities who have not yet registered in CDX would incur a one-time burden for this change. Based on the number of entities that are already reporting through CDX, the EPA expects more than 90% of reporting entities were reporting electronically at the start of 2019. Thus, the EPA estimates initial CDX registration and electronic signature costs incurred in the first year would be $2,000 because most entities have previously registered in CDX and are reporting electronically. The EPA estimates the annual costs savings to reporters to be $4,000 per year for electronic reporting.

As discussed in the supporting statement for the accompanying ICR available in the docket to this rule, the EPA also expects to reduce its own burden as the result of receiving electronic submissions and communicating electronically with entities. The agency resources and time requirements to review and process data would decrease, and document storage and retrieval would require fewer resources. The electronic submission of data through CDX would allow for the direct import of data into the ODS Tracking System. This would reduce the time the agency spends manually entering data into the ODS Tracking System from paper forms as well as reduce the potential for human error that exists when data are entered by hand. Agency personnel would also be able to communicate more efficiently with entities electronically. The conversion to an electronic reporting system as well as the adoption of CDX to facilitate form submission and processing are expected to create long-term burden reductions and increased efficiencies for the EPA. Annual costs to the EPA would be associated with the operation and maintenance of CDX for the data flow.

The EPA seeks comment on its proposal to require electronic reporting for ODS data under 40 CFR part 82, subpart A, with exceptions for a few low-volume forms. In addition, the EPA seeks input on experience to date with electronic reporting of ODS data and whether entities that have already transitioned to electronic reporting have been able to lower their reporting costs, and if so, by how much. The EPA also requests comment on the proposal that the requirement for electronic reporting would begin 30 days after the effective date of any final rule and on whether additional time would be needed to comply with the electronic reporting requirements.

B. Changes to Reporting Requirements in §§ 82.13, 82.23, and 82.24

This section presents the EPA's proposal to consolidate and harmonize ODS reporting elements. The agency has provided the option of electronic reporting for most submissions since 2008 to assist stakeholders in the reporting process. The proposed regulatory changes would reflect current practices by entities that can be designed into electronic forms. The EPA monitors company compliance, in part, through the recordkeeping and reporting regulations at §§ 82.13 and 82.24. The EPA is proposing these updates under CAA sections 603 and 114. Many of these proposed regulatory changes would ease the reporting burden. For example, the EPA is proposing to remove reporting elements in §§ 82.23(a), 82.24(b), and 82.24(c) that require the reporter to calculate values from data already provided. Requiring this of the entity is unnecessary because if finalized as proposed, the requirement to report electronically through CDX means these values can automatically be calculated and populated. This would save reporting entities time in reporting and reduce errors in submissions. The EPA is also proposing to change §§ 82.13(h) and 82.24(d) so that the quantity (rather than the percentage) of used, recycled, or reclaimed class I and class II substances, respectively, would be a required reporting element. This change would improve consistency with the importer reporting requirements and correspond with the way companies report their annual data. It would also streamline the exporter reporting forms by eliminating the need for an entity to calculate a percentage. The EPA is also proposing to remove references to expended and unexpended production and consumption allowances at § 82.13(f)(3)(iv) and (g)(4)(viii), which

likewise can be calculated automatically with the use of electronic reporting forms.

Other proposed regulatory changes would harmonize the requirements for class I and class II substances. For example, the EPA is proposing that the timeframe submitters have to make revisions to forms for class I and class II substances be the same. Currently under § 82.24 class II reporters have 180 days from the end of the applicable reporting period to make revisions while the class I provisions in § 82.13 are silent on the issue. The EPA is proposing to address this omission in the class I regulations by adding a provision that revisions to reports for class I substances under § 82.13 be made within 180 days of the end of the applicable reporting period. This would conform to the current practices followed by entities that make revisions to class I reports and is consistent with the EPA's current practice of allowing such revisions to the reports for class I substances. These changes would also be consistent with the current regulations in § 82.24 for revisions to reports for class II substances.

The EPA is further proposing to amend § 82.24(d)(1) to clarify that exporters who submit a Request for Additional Consumption Allowances (RACA) must still include that export on their quarterly exporter report. Under § 82.20, companies may submit a request for additional consumption allowances if they export class II substances that were previously produced in or imported into the United States using consumption allowances. Currently, the regulatory text at § 82.24(d)(1) excludes from quarterly reporting those RACAs even though exporters do typically include those exports in their quarterly reporting. For ease of review by the EPA and for consistency of reporting by exporters, the agency is proposing that all exports be included in the quarterly export report, even if the EPA had issued additional consumption allowances to the exporter for that export. This proposed change matches current practice, so the agency does not anticipate an increase in burden for the exporter.

The EPA is also proposing to amend the reporting requirements at § 82.13(v) to add the contact information for the source company from which the material was purchased and the laboratories to whom the material is sold. This proposal would allow the EPA to better track the sale of ODS for laboratory purposes through the Class I Laboratory Supplier Report.

Lastly, the EPA is proposing to correct class I reporting requirements for exporters by replacing the term ''Employee Identification Number'' with the correct term ''Employer Identification Number'' in § 82.13(h).

The EPA seeks comment on its proposed regulatory changes to the reporting requirements under 40 CFR part 82, subpart A. The EPA welcomes comment on any other changes that would ease burden on reporters.

C. Changes to Methyl Bromide Provisions in §§ 82.4 and 82.13

The EPA is proposing to amend the existing regulatory provisions related to the QPS exemption for methyl bromide under CAA section 604(d)(5) and ensure that QPS methyl bromide is not used in a manner inconsistent with the exemption. The EPA's regulations implementing CAA section 604(h) set January 1, 2005 as the production and import phaseout date (§ 82.4(b), (d)). Certain exceptions apply, including an exemption for methyl bromide produced or imported for quarantine and preshipment applications. Quarantine applications and preshipment applications are both defined at § 82.3. Briefly, quarantine applications are treatments to prevent the introduction, establishment, and/or spread of quarantine pests (including diseases), or to ensure their official control. These can include commodities entering or leaving the United States or any State (or political subdivision thereof). Preshipment applications are those non-quarantine applications applied within 21 days before export to meet the official requirements of the importing country or existing official requirements of the exporting country. The current recordkeeping and reporting regulations relating to QPS methyl bromide appear at § 82.13 and establish specific requirements for producers, importers, distributors, and applicators, including in some instances requirements for written certifications that the methyl bromide will be used only for QPS applications in accordance with the definitions in § 82.3.

This section discusses three types of proposed changes to the QPS regulations. As a brief overview, first, the EPA is proposing to clarify that it is a violation to sell or use methyl bromide produced under the QPS exemption for any uses other than QPS applications. Second, the EPA is proposing to extend the existing certification requirements to all purchasers of QPS methyl bromide. Third, the EPA is proposing to make non-substantive changes to §§ 82.4 and 82.13 to improve readability, including changes to the naming convention for methyl bromide where appropriate and removal of unnecessary references to ''used'' material.

These proposed changes are, in part, in response to the misuse of QPS methyl bromide by applicators and distributors in the U.S. Virgin Islands and Puerto Rico. As described in the Centers for Disease Control's (CDC) Morbidity and Mortality Weekly Report (MMWR), on March 18, 2015,[26] a U.S. Virgin Islands pest control company, Terminix International USVI LLC, fumigated a condominium complex in St. John with a product containing methyl bromide for the purpose of exterminating household pests. As a result, a family of four suffered acute methyl bromide poisoning resulting in three family members having life-altering illnesses. On March 25, 2015, the U.S. Virgin Islands Department of Planning and Natural Resources issued a stop-use order for methyl bromide to the company that performed the fumigation. A subsequent investigation by the Department of Planning and Natural Resources and the EPA revealed that a previous fumigation with methyl bromide had occurred on October 20, 2014, at the same condominium resort. In total, 37 persons may have been exposed to methyl bromide as a result of the October 2014 and March 2015 fumigations (Kulkarni et al., 2015). Terminix, LP and Terminix, USVI were sentenced to pay a total of $10 million in criminal fines and restitution for violating the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[27] The companies were also ordered to perform community service following an investigation and guilty pleas to their use and application of illegal fumigants in multiple residential locations in the U.S. Virgin Islands.

As a result of the exposures in the U.S. Virgin Islands, as well as documented misuse of QPS methyl bromide in Puerto Rico, and the high health risk potential from mishandling or misuse of QPS methyl bromide, the EPA is proposing to add a regulatory provision at § 82.4(r) to expressly prohibit the sale or use of QPS methyl

[26] 1. Kulkarni, P.A., Duncan, M.A, Watters, M.T., Graziano, L.T., Vaouli, E., Cseh, L.F., Risher, J.F., Orr, M.F., Hunte-Ceasar, T.C., Ellis, E.M. (2015) Severe Illness from Methyl Bromide Exposure at a Condominium Resort-U.S. Virgin Islands, March 2015 *Morbidity Monthly and Weekly Report (MMWR)* Center for Disease Control, 64(28); pg. 763–766. Available at: *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6428a4.htm.*

[27] EPA. (2017). ''Press Release: Terminix Companies Sentenced for Applying Restricted-Use Pesticide to Residences in the U.S. Virgin Islands.'' Available at: *https://www.epa.gov/newsreleases/terminix-companies-sentenced-applying-restricted-use-pesticide-residences-us-virgin.*

bromide for any uses other than QPS applications. The proposed provision would also explicitly state that it is a violation of subpart A to sell or use methyl bromide produced or imported under the QPS exemption for any uses other than QPS applications.

The existing regulations at § 82.13(y)(1) and (z)(2) require certification statements from distributors, applicators, commodity owners, shippers or their agent that methyl bromide ''will be used only for quarantine and preshipment applications.'' Similarly, § 82.13(f)(2)(xviii) and (xix) describe the exempted quantities of methyl bromide as ''produced solely for quarantine and preshipment applications.'' The EPA interprets this existing text as already prohibiting the use of methyl bromide produced or imported under the QPS exemption for any uses other than QPS applications. Although the EPA is proposing to add an express statement of the prohibition at § 82.4(r) to add clarity and enforceability to this prohibition, the EPA does not view this as changing the existing requirements. The proposed prohibition that would appear at § 82.4(r) for the QPS exemption is modelled on the language at § 82.4(n), which contains an express prohibition on using controlled substances produced under the essential use exemption.

Second, to help avoid future exposures stemming from misuse of QPS methyl bromide, the EPA is proposing to extend the existing certification requirements to all purchasers of QPS methyl bromide, including purchasers who purchase for further distribution. Under the existing recordkeeping and reporting requirements at § 82.13(f)(2)(xviii), producers of methyl bromide must maintain certifications that methyl bromide produced for QPS applications has been purchased by distributors or applicators to be used only for QPS applications. Under § 82.13(y), distributors of QPS methyl bromide must certify when they purchase or receive QPS material *from producers and importers* that the controlled substances will be used only for QPS applications. Applicators of QPS methyl bromide must also certify to distributors that the controlled substance will only be used only for QPS applications under the existing regulation at § 82.13(z).

The EPA has identified a gap in this certification chain when the material is sold through multiple distributors before reaching the applicator. When one distributor sells to a second distributor, neither distributor is required to certify or maintain a certification that the material will be used only for a QPS application. The EPA is proposing to revise § 82.13(y) to extend the certification requirement to purchasers who purchase or receive material for further distribution to address this gap.

The proposed extension of the certification requirement would help to ensure that distributors are knowledgeable of the requirements for the sale of QPS methyl bromide. The sales and misapplications of QPS methyl bromide in Puerto Rico and the U.S. Virgin Islands demonstrate that distributors may not have been aware of, or may have ignored, the limitations on the use of this material. The purpose of the requirement when established was to ensure that anyone selling or purchasing QPS methyl bromide signed a certification verifying that they would comply with requirements under Title VI of the CAA (66 FR 37760). Distributors are more likely to make themselves aware of those requirements and be mindful of the fact that QPS methyl bromide can only be used for QPS applications if they are required to sign a certification addressing these requirements and provide it before each purchase. This proposal would fill the gap in the distribution chain and ensure the original intent of the regulation is implemented.

The EPA is therefore proposing to extend the existing requirement that every distributor of QPS methyl bromide certify to the producer or importer from whom they purchased or received the material that quantities purchased or received would be sold only for quarantine applications or preshipment applications to also require such a certification when the material is purchased or received from a *distributor.* Likewise, the existing requirement that such distributors receive from any applicator, to whom they sold or delivered the methyl bromide a certification, prior to delivery of the quantity, stating that the quantity would be used or sold solely for QPS applications in accordance with definitions in subpart A would be extended to sales and deliveries to any *exporter or distributor* under the proposed changes. For exporters, the invoice or sales agreement currently required in § 82.13(h)(2)(viii) is enough for this purpose. The EPA is proposing to make these changes to § 82.13(y).

The EPA is also proposing that the distributor certify that they are *selling* the material for a QPS application rather than certify that it will be *used* for a QPS application, as is required in the existing regulations. This would better align the rule text with the distributor's role. The proper sale of the material is within the distributor's control whereas the use may not be, given that the material may be resold by another distributor and applied by an end user or third-party applicator.

The EPA seeks comment on its proposed addition of § 82.4(r) relating to the prohibition against using QPS methyl bromide for anything other than QPS uses and its proposed changes to the certification requirements for QPS methyl bromide.

The EPA is also proposing edits to § 82.13(h)(2), which contains the recordkeeping requirements for exporters of certain ''types'' of methyl bromide by companies that did not produce the material. The EPA is proposing edits to clarify what is meant by ''type'' of methyl bromide. Specifically, the EPA is proposing to more clearly state that the provision requires reporting of the quantity of methyl bromide exported for transformation, destruction, critical use, and QPS uses. These are the only exempted uses of methyl bromide, and this would match the information requested in the existing reporting forms. The EPA is also proposing to remove the requirement in the existing provision that exporters state how much of the exports are of ''used, recycled or reclaimed material.'' Unlike other ODS, methyl bromide is a product that is registered and controlled under FIFRA and thus is not sold ''used'' or ''recycled'' or ''reclaimed.'' Therefore, these adjectives are not applicable to methyl bromide and this phrase is not needed.

Lastly, the EPA is proposing to replace references to ''class I, Group VI controlled substances'' with ''methyl bromide'' where appropriate for readability throughout §§ 82.4 and 82.13. ''Class I, Group VI controlled substances'' is how methyl bromide is classified under the EPA's regulations in appendix A to subpart A, but methyl bromide is the only compound within this category. Using the common name would improve the readability of the QPS regulations.

The EPA seeks comment on these proposed changes to §§ 82.4 and 82.13 for readability and clarity of the regulations, as well as on the proposed changes to the recordkeeping requirements at § 82.13(h)(2) for exports of certain types of methyl bromide.

D. Changes to Provisions for the Import of Ozone-Depleting Substances in §§ 82.3, 82.4, 82.13, 82.15, and 82.24

Under CAA sections 604, 605, and 606, the EPA restricts the import of ODS consistent with both the CAA and the

Montreal Protocol. As discussed previously in Section II of this notice, importing virgin ODS requires the importer to expend consumption allowances. Controlling the number of allowances and knowing who holds those allowances allows the EPA to ensure that the phaseout obligations under the Montreal Protocol as implemented through the CAA are met. Used ODS [28] can be imported without consumption allowances, and generally without use restrictions, if certain conditions are satisfied. Imports of used ODS are currently regulated under § 82.13(g)(2)–(3) (for imports of used class I substances) and § 82.24(c)(3)–(4) (for imports of used class II substances). The EPA has reviewed the import petition process and is proposing amendments to improve data collection. Such changes would require collection of additional information when additional verification is needed to determine whether the material has been previously used and remove data elements that are currently collected but that are no longer needed. The EPA is also proposing to create a procedure for imports of both used and virgin ODS when they are imported for destruction. This proposal may lead to more used ODS being imported for reuse or destruction because of the less burdensome reporting requirements, which is beneficial for fostering a smooth transition to alternatives and reducing emissions of ODS to the atmosphere. In a recent example, the EPA granted a petition for the import of virgin ODS for destruction. The agency anticipates additional petitions for imports of virgin material may be received by the agency as the global phaseout of HCFCs continues and because the United States has a greater capacity for destruction. Additionally, these proposals would reduce the chance that virgin ODS are imported under the false pretense that it is ''used.''

Anyone wanting to import used ODS must currently submit a petition to the agency and receive a ''non-objection notice'' approving the import. The petition to import a used ODS must contain certain information, which the EPA considers in determining whether the ODS is in fact used. Required information includes: A description of the previous use of the substance; the identity of source facilities from which the material was recovered; a contact person at each source facility; the name, make, and model number of the equipment from which the material was recovered at each source facility; a best estimate of when the material was removed; and an export license from the appropriate government agency from the country of export. See §§ 82.13(g)(2) and 82.24(c)(3). After review, the EPA responds to the petition by issuing either a ''non-objection notice,'' which allows the import to proceed, or an ''objection notice,'' which has the effect of prohibiting the import because a non-objection notice is required for the lawful import of such material.

The EPA established the petition process to import used class I ODS (under CAA sections 603 and 604) in 1998 (63 FR 41626) and in 2003 (68 FR 2819) for class II ODS (under CAA sections 603 and 605) out of concern that some importers were circumventing the production and import controls by importing virgin class I and class II substances that had been intentionally mislabeled as used. The petition process has been effective in addressing this potential problem because the information requirements and the review undertaken by the EPA make it difficult for importers to falsify documents. Sections 604, 605, and 606 of the CAA provide statutory authority for controlling the import of ODS, including the petition process and the proposed changes to that process. Section 603 of the CAA requires reporting of the amount of ODS imported on a quarterly basis or on a basis determined by the Administrator. To the extent that these proposed changes involve recordkeeping and reporting of information, the EPA also relies upon its authority under CAA section 114, which authorizes the EPA to require recordkeeping and reporting in carrying out any provision of the CAA (with certain exceptions that do not apply here). Specifically, the EPA is proposing changes to the recordkeeping and reporting requirements to carry out the import provisions of sections 604, 605, and 606.

Despite the effectiveness of the petition process at providing information that allows the EPA to verify that ODS are used before they are imported, the EPA has identified potential improvements to the process. For example, the current requirements are difficult to satisfy if the imported material comes from a halon bank or other ODS banks. The current regulations exempt only halon 1301 aircraft bottles from the petition process for hydrostatic testing, yet aircraft bottles containing halon 1211 are also imported for such testing. The current petition process also does not distinguish imports of used ODS that are intended to be destroyed from imports of all other used material that are intended to be reclaimed for continued use, though the agency recognizes that the verification requirements do not need to be as rigorous when the ODS are to be destroyed. The existing regulations also do not provide a mechanism to pre-approve the import of virgin material for destruction, resulting in delays at the port of entry while the shipment is verified by the EPA.

i. Changes to the Petition Process To Import Used ODS for Reuse in §§ 82.13 and 82.24

The EPA is proposing changes to the petition process that would generally ease the burden on importers, while still allowing the agency to verify that the material being imported is used. Specifically, the agency is proposing to: Allow, under certain circumstances, submission of an official letter from the appropriate government agency in that country where the material is stored attesting that a class I substance is ''used'' in lieu of detailed equipment-level source information; [29] allow submission of an application for an export license in lieu of the license itself; require that petitions include email addresses in contact information (while removing the requirement to provide fax numbers) and commodity codes for the material; and specifically authorize the agency to request additional information when additional verification is needed before issuing a non-objection notice. In general, the EPA anticipates these changes would increase the availability of used class I substances in the United States and thus help to provide a greater supply of used material for servicing existing equipment, which might otherwise have to be retired before the end of its useful life.

First, the EPA is proposing to amend § 82.13(g)(2) in recognition that banks [30] of halon and other class I ODS overseas are a potential source of used ODS. Since halons were phased out in the United States and other non-Article 5 countries in 1994, many countries and organizations established halon banks where they aggregate and store

[28] Used ODS have been recovered from their intended use systems (*e.g.,* refrigeration and AC equipment) and may include controlled substances that have been, or may be subsequently, recycled or reclaimed. *See* 40 CFR 82.3

[29] The EPA is not proposing similar changes for class II ODS given the production phaseout for these substances is still underway.

[30] The EPA uses the term ''bank'' here to refer to a company-run or nationally government-run facility that collects and stores previously-recovered ODS (*e.g.,* a halon bank) for reuse at a later date, not the ''bank'' of ODS installed in existing equipment and products.

previously used and recovered halon for reuse in fire suppression applications.[31] In most cases the managers of such banks do not have the complete information required by the EPA's petition process especially since the material may have been recovered more than two decades ago. As detailed above, the import petition must currently contain information about the used ODS including the source facility and name, make, and model number of the equipment and from which the material was recovered. Petitioners sourcing class I substances from banks, therefore, rarely have enough records to provide all the information required in the petition process, and as a result the petitions are subject to denial.

The EPA is proposing to waive the requirement for specific source information for halon and other class I substances stored in either a national government ODS bank or a privately-operated bank authorized by a national government to collect and manage ODS if the petitioners include an official letter from the appropriate national government agency of the exporting country attesting that the class I substance(s) proposed for export to the United States is used. The EPA would consider this official letter along with all the other evidence provided in determine whether the material is used. However, providing an official letter does not mean that the EPA would automatically approve the petition. The EPA is proposing to define ''bank'' for clarity in the regulatory text.

Stakeholders have indicated to the agency that this type of change to the petition process would allow U.S. companies to potentially access large reserves of halon held overseas for which source information cannot be obtained. Halons are used for fire protection applications, such as in civil aviation, military, and oil and gas drilling and the continued availability of used halons remains important to many U.S. operations. Industry in the United States has successfully managed the recovery and use of halons since the domestic phaseout of production in 1994 and the EPA anticipates that they will continue to do so. However, as we get further from the phaseout, the available supply of halons decreases.

The Montreal Protocol's Technology and Economic Assessment Panel (TEAP) has provided information on the availability and expected need for halons in the future. The TEAP issued a report in September 2018, noting continued demand for halons, in particular for servicing fire suppression equipment for civilian aviation.[32] Civil aircraft will continue to need halon to meet fire protection requirements for lavatory bottles, handheld extinguishers, engine nacelles, auxiliary power units, and cargo compartments [33] until there is a transition to alternatives for all applications on new aircraft as well as to service the civil aircraft fleet. This proposal would allow halon to be more easily sourced from overseas banks and thus should make more halon available to service aircraft in the United States. In addition, the military and oil and gas drillers continue to need halons for fire suppression applications.

Second, the EPA is proposing to amend the criteria for when the EPA may issue an objection notice to a petition to import a used ODS. When enough information is not provided with the initial petition for a determination, the EPA requests additional information from the petitioner in order to verify that the material was used. The EPA is therefore proposing to clarify that not providing this requested information could be grounds for issuing an objection notice to the petition. As one example of information that may be requested, the EPA may request results of purity sampling of class I or class II substances. The EPA understands that if a halon is used, the purity will typically be much lower (on the order of 90 to 95 percent pure) than if the material is virgin. The EPA may request the results of purity tests in situations where having those results would give the EPA and the company receiving the used ODS information that could confirm, before the material is imported, that the ODS is in fact used. Under this proposal, if petitioners fail to respond to requests from the agency for addition information, the EPA could issue an objection notice.

Other examples of information that the EPA has requested in reviewing petitions to verify the substances is used before issuing a non-objection notice include: A photo of each unit that contained the used ODS, with serial numbers visible; photos of a representative sample of the cylinders, with serial numbers visible; a description of the facility from which the used ODS originates, which includes what is produced at the facility, the location of the facility, and how long the facility has been in the location; a description of each unit from which the used ODS originates; links to websites showing brochures, photographs, and/or descriptions of each different unit from which the used ODS originates; copies of the original, signed work orders authorizing collecting of the used ODS; copies of the paperwork showing that the company completed the work; copies of payment to the company that collected the used ODS for their services, with redactions for confidential or sensitive information such as bank account numbers; copies of business licenses from the government authorizing collection companies to do this type of work; and information on how transport will occur within the exporting country and to the United States. For used ODS from Europe, the EPA has requested a screenshot of the European Commission export license; the name and contact information for the European Commission official who signed the Export License; and copies of all paperwork required for movement within the European Union, such as the ''Notification document for transboundary movement/shipments of waste.'' The EPA is not proposing to collect all such information for each petition and thus is not proposing to revise the regulatory text to require that it be provided in every petition. However, the agency does wish to provide notice to petitioners that it may request additional information to confirm that the ODS is in fact used and is proposing to amend the regulations to make clear that failure to provide such information when requested would be a ground to issue an objection notice. The EPA specifically requests comment on this proposal for an additional ground for denying a petition to import used ODS and on whether the EPA should specifically list the types of information in the regulations that the agency may, on a case by case basis, request from the petitioner after reviewing the initial submission to confirm that the material is used. If the agency were to add a list of specific types of information that it might request on a case-by-case basis, that list could include some or all the information described in the prior paragraphs of this notice that the EPA has requested in reviewing petitions in the past.

Third, the EPA is proposing multiple minor amendments to the petition

[31] Halons were phased out in Article 5 countries in 2010.

[32] UNEP. (2018) Montreal Protocol on Substances on Substances that Deplete the Ozone Layer. Report of the Technology and Economic Assessment Panel. September 2018 Volume 2 Decision XXIX/8 on the Future Availability of Halons and their Alternatives; pg. 1–32. Available at: *https://ozone.unep.org/index.php*.

[33] FAA (2004). ''FAA Halon ARC Final Report Findings & Recommendations'' Halon Replacement Aviation Rulemaking Committee; pg. 1–49. Available at: *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/index.cfm/committee/browse/committeeID/397*.

process to ensure accuracy, faster review, and facilitate the import of used ODS. In particular, the EPA is proposing to update the requested contact information by requiring email addresses and removing fax numbers. The EPA is also proposing to require that the petition for import include the amount of material authorized under the export license or export license application to ensure the petitioned amount is equal to or less than the amount that arrives at the United States port of entry. The EPA is also proposing to require that petitioners provide the commodity code associated with the ODS to be imported. The commodity codes are classifications for goods and services traded among countries. This proposal would match the agency's other import and export requirements in §§ 82.13(g) and (h) and 82.24(c) and (d) and help to ensure that the data are correctly entered in Customs and Border Protection's Automated Commercial Environment and International Trade Data System (ACE/ITDS).

The EPA is also proposing to update the commodity codes for HCFC–123 and HCFC–124 in Appendix K. The U.S. International Trade Commission is responsible for publishing the Harmonized Tariff Schedule of the United States Annotated (HTSA). The HTSA provides the applicable tariff rates and statistical categories for all merchandise imported into the United States. It is based on the international Harmonized System, the global system of nomenclature that is used to describe most world trade in goods. This action updates the commodity codes for HCFC–123 and HCFC–124 in the appendix so that they coincide with those currently in effect and in use by the U.S. International Trade Commission.

In addition, the EPA is proposing to amend §§ 82.13(g)(2) and 82.24(c)(3) to allow importers of class I and class II substances, respectively, to provide an application for an export license in lieu of an actual export license, as is currently required. For example, Canada, the largest exporter of used ODS to the United States, requires the EPA to approve the export before they issue an export license. As such, petitioners are only able to provide the submitted application for an export license with their petition. Considering this, the agency has worked with Canada to accept the submitted application in lieu of the export license. However, there may be other countries that also require approval prior to export, and the EPA wants to ensure all countries receive equal treatment and that all petitioners are aware of this option. As such, the agency desires to formalize the option in the regulations. The EPA is also proposing to require an English translation of the export license application or export license to facilitate the agency's review.

The existing regulations for petitions for imports of used material also require that if the imported substance is intended to be sold as a refrigerant, the petition must include contact information for the U.S. reclaimer who will bring the material to the standard required under CAA section 608 and § 82.152(g), if it is not already reclaimed to those specifications. The EPA is proposing to add ''EPA-certified'' to the description of reclamation facilities in the provisions containing this requirement, §§ 82.13(g)(2)(xiii) and 82.24(c)(3)(xiii). This proposal would highlight the existing expectation for petitions to import used material to be sold as a refrigerant that the reclamation facility that will receive the material in the United States must be EPA-certified. The EPA's reclamation program is described at *https://www.epa.gov/section608/stationary-refrigeration-refrigerant-reclamation-requirements*.

Finally, the agency is proposing to allow flexibility for the timing of the import when the non-objection notices was issued towards the end of the year. The EPA currently requires the import to occur in the same control period (*i.e.,* calendar year) that the non-objection notice was issued. However, this can result in petitioners postponing their requests until the start of the next year. To avoid that unnecessary delay, the EPA is proposing that importers have one year from the date stamped on the non-objection notice to import that shipment.

The EPA is soliciting comments on these proposed changes to the petition process for importing used ODS. The agency is particularly interested in whether streamlining the petition process, including to facilitate imports of material from banks for class I ODS, would affect compliance with the prohibition on import of virgin ODS. The EPA welcomes suggestions from the regulated community on how the petition process may be further streamlined while ensuring compliance.

b. Exemption for Imports of Halon 1211 Aircraft Bottles in § 82.3

To facilitate the import and testing of more types of aircraft halon bottles for hydrostatic testing, the EPA is proposing to extend the definition of ''aircraft halon bottles'' in § 82.3 to also include vessels containing halon 1211. The current regulations in § 82.13(g)(2) exempt aircraft halon bottles that are imported for hydrostatic testing from the import petition process. The EPA has defined ''aircraft halon bottle'' in § 82.3 as a vessel used as a component of an aircraft fire suppression system containing halon 1301.

FAA regulations at 14 CFR 25.851(a)(6) require the presence of halon bottles, or the equivalent, aboard transport category aircraft, and they must be tested under United States Department of Transportation (DOT) regulations in 49 CFR 180.205 and per National Fire Protection Association standards if damaged or discharged (NFPA, 2018a). In particular, such bottles undergo hydrostatic testing, which detects leakage and determines whether the bottles are functioning properly. This testing is important both for safety as well as for detecting and averting emissions of halon, a highly potent ODS.

In 2009, the EPA exempted aircraft fire extinguishing spherical pressure vessels containing halon 1301 (''aircraft halon bottles'') being imported for hydrostatic testing from the import petition requirements (74 FR 10182). The EPA sought comment in that rule on whether to include halon 1211 in the exemption for aircraft halon bottles, and the agency did not receive comment indicating these imports occur. Therefore, the EPA limited the exemption only to aircraft halon bottles containing halon 1301. The 2009 rule reduced the administrative burden on entities when they import aircraft halon bottles for the purpose of maintaining these bottles to commercial safety specifications and standards. More information on the history and the goals of the import petition process and an explanation of why an exemption was warranted for aircraft halon bottles containing halon 1301 can be found in the 2009 rule.

Since that time, the EPA has determined based on import petitions received for halon 1211 and discussions with stakeholders that aircraft halon bottles containing halon 1211 are imported for hydrostatic testing. Thus, the EPA is proposing to extend the exemption created for aircraft bottles containing halon 1301 to those containing halon 1211. This proposed change would be accomplished by adding aircraft bottles containing halon 1211 to the definition of ''aircraft halon bottles'' in § 82.3. The reasons for exempting bottles containing halon 1211 are the same as for bottles containing halon 1301, discussed at 74 FR 10182. For example, this proposed exemption would facilitate proper maintenance of bottles containing halon 1211 and allow transit and testing to

occur more quickly for such bottles. Promoting proper maintenance of these additional fire suppression devices would help ensure the bottles operate correctly to extinguish fires on aircraft. Proper maintenance of the storage vessels also prevents the accidental emission of this high-ODP compound. Lastly, reducing the import petition requirements could also allow hydrostatically tested bottles to be available more readily for aircraft.

The proposed exemption of imports of aircraft bottles containing halon 1211 for hydrostatic testing would only exempt them from the petition process. Recordkeeping and reporting are currently required, and would still be required, for the import and export of aircraft halon bottles. In particular, if the proposed exemption were finalized, importers of such bottles would still need to maintain import records, as set forth in § 82.13(g)(1), submit quarterly reports within 30 days of the end of the applicable quarter in accordance with § 82.13(g)(4), and submit an annual export report 30 days after the end of the calendar year, in accordance with § 82.13(h).

The EPA seeks comment on this proposal and is particularly interested in whether this would affect the ability of technicians, aircraft owners, and fire suppression equipment manufacturers to continue maintaining existing equipment.

c. Changes to Requirements for Imports of ODS for Destruction in §§ 82.3, 82.4, 82.13, 82.15, and 82.24

This portion of the notice discusses two sets of proposed changes to the import process for ODS specifically imported for destruction.[34] First, the EPA is proposing to establish a streamlined approach for importing used ODS for destruction. Second, the EPA is proposing to extend that approach to virgin ODS, as there is currently no mechanism for the EPA to pre-approve import of virgin ODS for destruction.

ODS from decommissioned equipment, unwanted stockpiles, and mixtures that are contaminated and cannot be reclaimed are often imported to the United States for destruction. Facilitating the destruction of ODS is beneficial to the environment since it averts ODS emissions into the atmosphere and thus is consistent with the overarching goal of Title VI to protect stratospheric ozone. The Montreal Protocol's Scientific Assessment Panel estimated that capture and destruction of CFC, halon, and HCFC banks in 2015 could avoid 1.8 million ODP-weighted metric tons of future emission through 2050.[35] It also estimated that if all 2015 halon, CFC, and HCFC banks [36] were destroyed in 2015, the stratospheric chlorine levels at mid-latitude would return to 1980 levels more than six years sooner than in the baseline scenario. The EPA recognizes that there is ongoing commercial demand for certain substances, as discussed earlier in this notice with respect to halons and other ODS. Some ODS may, however, be unwanted and thus susceptible to release; this risk may be higher when they are stored in countries that do not have adequate capability to properly reclaim or destroy them. Creating a process for the import of ODS for destruction would help facilitate the destruction of such ODS and thus reduce the risk of such releases. More information on the destruction facilities that destroy ODS and their technologies is available in the report entitled ''U.S. Destruction in the United States and Abroad.'' Destruction of unwanted ODS in the United States may also generate revenue for domestic destruction facilities.[37]

As discussed earlier in this notice, the EPA's petition processes for the import of used ODS is designed to allow the agency to verify prior use of the material so that virgin ODS are not entering the United States marketplace under the pretense of being ''used.'' Under the current regulations at §§ 82.13(g)(2) and 82.24(c)(4), anyone wishing to import used class I or class II ODS, respectively, for destruction must submit a petition providing the same information as for any other petition to import used ODS. It is then the obligation of the second-party destruction facility to provide a verification report to the importer or producer that the material was destroyed (§§ 82.13(k) and 82.24(e)). Importers are required to keep records on imports for destruction of ODS under §§ 82.13(g)(1) and 82.24(c)(2) and to submit quarterly reports, in accordance with §§ 82.13(g)(4) and 82.24(c)(1). The current regulations contain an exception to the prohibition on import of virgin ODS without consumption allowances in the case of imports for destruction but do not provide a specific process for such imports.

The EPA is proposing to create a new petition process for the import of used and virgin ODS for destruction, called a Certification of Intent to Import ODS for Destruction (''certification''), in §§ 82.13(g)(6) and 82.24(c)(7). Under this process, the importer would submit the certification at least 30 working days before the shipment's departure from the foreign port. After review, the EPA would send either a non-objection notice or an objection notice. The proposed period is shorter than the corresponding period for the import petition process, which is 40 working days from departure, because the certification would contain less information for the EPA to review and verify than in the current process for a petition for import of used ODS. The EPA believes 30 working days would be enough for the EPA to review the certification and that this timeframe would not impede the import. The agency would be authorized to issue an objection notice for any reason it could currently issue an objection notice to a petition to import, such as if the petition provides insufficient information or if it contains false or misleading information. The EPA is also proposing to require that the petitioner submit a destruction verification 30 days after destruction under §§ 82.13(g)(6) and 82.24(c)(7). The EPA is also proposing to require the certification and any supporting documents, including the destruction verification, to be submitted electronically through CDX, for the reasons discussed in Section IV.A of this notice. In particular, the EPA is proposing to add the requirement for electronic submission of these documents via CDX in § 82.14.

The information that would be required in the certification is modeled in large part on the petition to import used ODS. Specifically, the certification would include the following elements, which are similar those required in an import petition: Name, commodity code, and quantity in kilograms of each controlled substance to be imported; source country; intended date of import; shipment importer number; an English translation of the export license (or application for an export license) from the appropriate government agency in the country of export and, if recovered in a country other than the country of export; the quantity in kilograms authorized on the license(s); United

[34] The EPA refers to the import of ODS intended to be destroyed in the United States throughout this notice as ''imports for destruction.''

[35] UNEP. (2014) Scientific Assessment of Ozone Depletion: 2014 World Meteorological Organization Global Ozone Research and Monitoring Project—Report No. 55 pg. 1–416. Available at: *https://www.esrl.noaa.gov/csd/assessments/ozone/2014/report.html*.

[36] As used here, ''banks'' refers to the total ODS that have already been manufactured but not yet released to the atmosphere. This can include ODS contained within closed cell foams, installed in appliances, held in original containers, etc.

[37] EPA. (2018) ''U.S. Destruction in the United States and Abroad'' pg. 1–63. Available at: *https://www.epa.gov/sites/production/files/2018-03/documents/ods-destruction-in-the-us-and-abroad_feb2018.pdf*.

States port of entry for the import; name, address, contact person, phone, and email address of the person responsible for destruction at the facility.

The EPA is proposing to omit the detailed source information that is required in import petitions, as that information is not necessary if the ODS is to be destroyed. The EPA is proposing to collect information from the petitioner about the destruction for the certification process. In particular, the certification would not include the following: Information about all previous source facilities from which the ODS was recovered; a detailed description of the previous use at each source facility and a best estimate or documents indicating when the specific controlled substance was put into the equipment at each source facility; a list of the name, make and model number of the equipment from which the material was recovered at each source facility; contact information of all persons to whom the material was transferred or sold after it was recovered from the source facility; or a description of the intended use of the ODS.

The EPA is proposing to omit these information elements because they are collected for import petitions to verify that the material is used, and the agency believes it is not necessary to verify that ODS is used if it is being imported for destruction. Simplifying the information requirements would decrease the regulatory burden on existing importers who follow the current import petition process to import used ODS for destruction by providing a streamlined regulatory mechanism for such imports. In addition, the current information requirements for petitions to import used ODS has the potential to hinder imports for destruction because petitioners may be unable to provide all the necessary information. Certain elements, such as information about each piece of equipment or each source facility from which the controlled substance was removed, may be particularly difficult for petitioners to provide because used controlled substances intended for disposal are often part of a mixture of chemical waste recovered from a variety of systems and detailed information pertaining to each system may not be available. Although the certification process would in effect relax the information requirements for importing used ODS for destruction compared to the existing import petition process, the EPA believes that this relaxation would benefit the environment because companies wishing to import used ODS into the United States for destruction would be able to do so more easily, and therefore more used ODS would be destroyed. This would be consistent with the overarching goal of Title VI to protect stratospheric ozone.

The EPA is proposing to add provisions §§ 82.13(g)(9) and 82.24(c)(10) to require importers to keep certain records, including records about the destruction of the ODS. In particular, the EPA is proposing that importers of ODS for destruction maintain: A copy of the certificate of intent to import for destruction; a copy of the non-objection notice; a copy of the export license or export license application; Customs and Border Protection (CBP) entry documents for the import that must include the commodity codes; records of that date, amount, and type of controlled substance sent for destruction per shipment; an invoice from the destruction facility verifying shipment was received; and a copy of the destruction verification.

In addition to proposing to create the Certification of Intent to Import ODS for Destruction, the EPA is also proposing to extend the certification to imports of virgin ODS for destruction. While the certification is modeled in large part on the petition to import used ODS, the EPA believes there are also benefits to facilitating the import of virgin ODS for destruction. Currently, virgin ODS that are to be destroyed may be imported without consumption allowances (see §§ 82.4(d) and 82.15(b)). However, there is no regulatory mechanism for the EPA to review and pre-approve those imports. As such, shipments may be held at the border while the EPA determines whether the import is in fact bound for destruction. In some instances, proactive importers have petitioned the agency to import virgin ODS for destruction and the EPA has allowed these imports on a case-by-case basis. However, the absence of a regulatory mechanism for such approvals has created some uncertainty for these imports when they reach the border. Moreover, the EPA believes that establishing regulatory requirements for such imports would help ensure that imports of virgin ODS for destruction are destroyed.

The EPA believes that providing a mechanism to import virgin ODS for destruction would be beneficial to importers and the EPA. Having a transparent process that allows approval occur before the shipment reaches the border would facilitate such imports and reduce potential delays and costs associated with the current approach to imports of virgin ODS for destruction, as well as providing more certainty as to which imports could proceed. In turn, this would encourage imports of unwanted virgin ODS for destruction, potentially avoiding the emission of such ODS. This would be consistent with the overarching goal of Title VI to protect stratospheric ozone. The proposed extension would also close a gap in regulatory provisions for the import of virgin material for destruction. As discussed previously in this notice, the EPA originally established the import petition process for used ODS to verify that virgin ODS was not being imported under the pretext of being used to circumvent the regulatory requirements for expending consumption allowances. In the same way, the EPA believes that a mechanism is needed to verify that virgin ODS imported for destruction will be destroyed and that claims of importing for destruction are not used to circumvent the requirement to expend consumption allowances. In addition, the EPA has historically used the petition process as a mechanism to approve imports for destruction of used material and has applied an analogous but simpler process to imports of virgin material on a case-by-case basis. Based on this experience and these common goals for imports of used and virgin ODS for destruction, the EPA believes that having the same process for imports for destruction of both used and virgin ODS is both feasible and appropriate. Furthermore, establishing a consistent process for used and virgin ODS would simplify the administration of this proposed approach because the same requirements would generally apply regardless of the type of ODS to be imported for destruction. Thus, the EPA is proposing to have the same requirements for both used and virgin ODS in this new proposed process.

As part of this proposal, the EPA would also revise the definitions of ''individual shipment'' and ''non-objection notice'' at § 82.3, both of which currently refer only to the import of used material. The EPA is proposing to amend these definitions by removing references to ''used'' controlled substances, so that ''individual shipment'' and a ''non-objection notice'' may apply to shipments of virgin ODS imported for destruction under a Certification of Intent to Import for Destruction, as well as to shipments of used ODS.

Like the proposal in the import petitions process, the agency is also proposing to allow flexibility for the timing of imports for destruction. In the current petitions process, the EPA requires the import to occur in the same control period (*i.e.,* calendar year) that

the non-objection notice was issued. The EPA is proposing that non-objection notices issued for the Certification of Intent to Import for Destruction for both used and virgin material have a year to import the material. Therefore, once a non-objection notice is issued, the person receiving the non-objection notice would be required to import the individual shipment within a year of the date stamped on the non-objection notice. For instance, a non-objection letter issued on October 1, would not need to be destroyed until September 30 of the following year. This would provide flexibility to imports for destruction that may be operate on a calendar year basis.

The EPA is soliciting comments on its proposal to create the Certification of Intent to Import ODS for Destruction for both used and virgin ODS. The EPA is particularly interested in whether the reduced information elements encourage additional imports of ODS for destruction or reduce burden for importers. The EPA is also interested in the burden of applying the proposed certification process to the import of virgin ODS and providing a year to destroy used or virgin material. The EPA welcomes comment from entities that currently import ODS for destruction or that have considered importing ODS for destruction.

E. Prohibiting the Sale of Illegally Imported Controlled Substances

Based on the EPA's experience with the CFC phaseout, the incentive to illegally import class II substances will increase as the allocation for HCFC–22 reaches zero in 2020. HCFC–22 is the most widely used HCFC in the United States and the EPA anticipates continued demand for HCFC–22 beyond the phaseout in 2020. In addition, there continues to be risk of illegal imports of class I substances. The EPA works closely with CBP to ensure compliance with the phaseout of ODS under CAA sections 604–606. However, recent illegal imports have demonstrated to the agency that additional tools are needed to address the potential for domestic distribution of illegally imported material, as such material would generally be considered consumption. Thus, the EPA is proposing to add to §§ 82.4(s) and 82.15(g)(8) an express prohibition against the sale or distribution, or offer for sale or distribution, of any class I or class II substance, respectively, that the seller knows, or has reason to know, was illegally imported into the United States.[38]

For this proposal, the EPA is relying primarily on its authority under CAA sections 604(c) and 605(c). Section 604(c) directs the Administrator to promulgate regulations to ''insure that the consumption of class I substances in the United States is phased out and terminated'' in accordance with the applicable schedules for the phaseout and termination of production of class I substances under the CAA. Similarly, section 605(c) directs the Administrator to promulgate regulations to ''insure that the consumption of class II substances in the United States is phased out and terminated'' in accordance with the applicable schedules for the phaseout and termination of production of class II substances under the CAA. ''Consumption'' is defined in CAA section 601 as the amount of a substance produced in the United States, plus the amount of that substance imported, minus the amount exported.

As noted above, the EPA remains concerned about the illegal import of ODS. This concern is based largely on the risk that such illegal imports would interfere with the already-completed phaseout of consumption of class I substances and the ongoing phaseout of consumption of class II substances. For example, HCFC–22 that is imported without allowances would generally count toward the United States' consumption cap unless additional action is taken to remove the ODS from the U.S. market (*e.g.,* the illegally imported ODS is destroyed or re-exported in the same year). While there is sufficient space under the HCFC cap currently such that the illegal import would not result in an exceedance of the cap set forth under the Montreal Protocol and CAA, there is be a greater risk that illegal imports not destroyed or re-exported could cause an exceedance following the 2020 stepdown, and more importantly the 2030 phaseout of HCFCs. This is of even greater concern for illegally imported CFCs and other class I ODS, given that the consumption cap for class I ODS is zero.

To address this concern, the EPA is proposing to strengthen its ability to enforce the phaseout of ODS by adding at §§ 82.4(s) and 82.15(g)(8) an express prohibition against the sale or distribution, or offer for sale or distribution, of any class I or class II substance, respectively, that the seller knows, or had reason to know, had been imported into the United States in violation of the import regulations. It would therefore be illegal to sell or distribute any material that the seller knows or had reason to know was imported into the United States without expending the appropriate consumption allowances or otherwise qualifying for an exemption provided for in the regulations (*e.g.,* for transformation or destruction, or for used ODS). The proposed revisions would also explicitly state that every kilogram of illegally imported material sold or distributed, or offered for sale or distribution, constitutes a separate violation.

This proposal would strengthen the EPA's ability to enforce against illegal trade, which in turn helps ensure that consumption remains under the Montreal Protocol and CAA caps. It would increase the EPA's compliance and enforcement options where the agency is not able to identify the importer. For example, this proposal could allow the EPA to pursue investigations where distributors or other sellers of CFCs attempt to sell virgin CFCs in the domestic market knowing that they were imported into the United States after the phaseout of CFCs, which occurred in 1996, without qualifying for any exemption from the consumption phaseout. Actions taken against such distributors would not only address their violations but could also allow the agency to gather the necessary information to identify the smuggler who illegally imported the material in the first place and to pursue compliance and enforcement action against them under existing authorities in §§ 82.4 and 82.15, which could help deter illegal imports. Avoiding illegal imports helps to maintain the complete phaseout of class I ODS and achieve the phaseout of class II ODS, which is consistent with CAA sections 604(c) and 605(c), as well as with the overarching goals of Title VI of the CAA.

Finally, this proposed change would encourage distributors to be more cautious when purchasing ODS that seems suspiciously priced or packaged. Since the phaseout of class I ODS, the EPA has warned distributors of the risk of purchasing black market ODS and provided information on ways to identify illegally-imported material. Distributors and other resellers have numerous ways to identify illegally-imported material. They can look at where the ODS was produced, the brand

[38] The EPA has previously issued restrictions on sale as a means for implementing restrictions on consumption. *See, e.g.,* § 82.3(h) (''No person may sell in the U.S. any Class I controlled substance produced explicitly for export to an Article 5 country''); § 82.3(n)(2) (''Any person selling unused class I controlled substances produced or imported under authority of essential-use allowances or the essential-use exemption for uses other than an essential-use is in violation of this subpart.'').

name the material is being sold under, and the name of the manufacturer. They can also make sure the material meets industry purity standards, ask the seller for documents of prior ownership of the product and a laboratory analysis of the quality, and inspect the packaging for the material since illegally imported refrigerant is sometimes packaged in wrong-size containers or fixed with improper valves. While the incentive to circumvent the import controls will always exist, the EPA hopes that this proposal would help to reduce the market for smuggled ODS, which should also reduce illegal imports.

The agency welcomes comments on these proposed prohibitions against the sale or distribution or offer for sale or distribution of illegally imported controlled substances.

V. Addition of Polyurethane Foam Systems Containing CFCs to the Nonessential Product Ban

The EPA is proposing to add polyurethane foam systems containing CFCs to the existing list of nonessential products under 40 CFR part 82, subpart C. This proposal would prohibit the sale or distribution, or offer for sale or distribution, of any polyurethane foam system containing CFCs in interstate commerce. Historically, CFC–11, CFC–12, and CFC–114 were used as foam blowing agents, but CFC production has been globally phased out since 2010. Nevertheless, recent reports show that the rate of decline in CFC–11 concentrations in the atmosphere, which had been steady, slowed dramatically starting in 2013, and this proposal is in response to those reports. After reviewing the EPA's import restrictions and the nonessential product ban, the agency has identified the potential for sale or distribution, or offer for sale or distribution, of imported polyurethane foam systems [39] containing illegally-produced CFCs. The EPA is not aware that this is currently occurring in the United States but believes that this is a potential gap that can be addressed by amending the list of nonessential products in § 82.66.

Researchers recently discovered that starting in 2013 the concentration of CFC–11 in the atmosphere was not declining as rapidly as it had been in the prior decade.[40] This slowdown is contrary to the modeled decline based on reported global production. In Montzka et al., the modeled concentration was expected to decrease rapidly beginning in 2002, without continued CFC–11 production. However, CFC–11 concentrations did not decline more rapidly each year. Global CFC–11 atmospheric concentrations declined at a constant rate in the decade after 2002. CFC–11 concentrations declined about half as quickly over the past three years compared with the rate measured from 2002–2012. The scale of observations suggests that there may have been unreported production of CFC–11 despite the global phaseout of CFC production in 2010 under the Montreal Protocol. The researchers determined that emissions of CFC–11 began increasing in 2012 and that in the period between 2014 to 2016 emissions were higher than average annual emissions from previous decades. Monitoring data indicate that areas in eastern Asia may be the sources of these elevated emissions. The researchers concluded that damage to the ozone layer could be minor if the source of these emissions can be identified and mitigated, but if not, there would be delays in stratospheric ozone recovery. A subsequent investigation by the Environmental Investigation Agency, a non-governmental environmental organization, indicates that CFC–11 may, in part, be used in foam systems.[41] Additional monitoring data identifies China as the source for much of the CFC–11 emissions.[42]

In response to this finding, the EPA evaluated potential uses of CFCs and whether domestic controls were enough. The EPA wants to ensure that the United States is not inadvertently contributing to demand for CFC production. Except for feedstock applications, production and import of CFCs has been prohibited [43] in the United States since 1996. The nonessential products ban already prohibits sale or distribution, and the offer for sale or distribution, of certain products manufactured with or containing CFCs, including most plastic foam products. The EPA is not aware of any U.S. manufacturer currently using CFC–11 or any other class I substance for polyurethane foam systems. Nonetheless, to ensure that the United States is not inadvertently contributing to demand for CFCs and to avoid potential CFC emissions in the United States, the EPA is proposing to add polyurethane foam systems containing CFCs to the list of nonessential products at § 82.66.

The EPA is also proposing to define ''polyurethane foam systems'' in § 82.62, which is used for thermal insulation. A polyurethane foam system typically consists of two transfer pumps that deliver ingredients (polyisocyanate or isocyanate from one side and a mixture including the blowing agent, catalysts, flame retardants, and stabilizers from the other side) to a metering/mixing device which allows the components to be delivered in the appropriate proportions. The components are then sent to a mixing gun and dispensed as foam directly to a surface such as a roof or tank. These polyurethane foam systems are packaged and sold as complete systems, containing all the ingredients including the polyisocyanate and the blowing agent.

A polyurethane foam system is different from bulk ODS because it is contained in a system and packaged as a product. Under the existing regulations in subpart A, bulk CFCs are included in the definition of a ''controlled substance'' and thus are subject to import controls such as the consumption allowance regime under § 82.4. However, the definition of ''controlled substance'' in § 82.3 excludes ''any such substance or mixture that is in a manufactured product other than a container used for the transportation or storage of the substance or mixture.'' Because the CFCs in polyurethane foam system are contained in a system that is sold as a product, they are not subject to the same import controls as bulk CFCs. If polyurethane foam systems are imported and sold through distribution chains in the United States, they could result in emissions of CFCs during their use. These foam systems are also distinct from a plastic foam product in that the foam product has already been blown. Plastic foam products manufactured with or containing a CFC are currently listed at § 82.66(c) and thus are banned from sale or distribution, or the offer for sale or distribution, in interstate commerce.

The EPA is concerned about the potential sale or distribution, or offer for sale or distribution, of polyurethane foam systems even with the current nonessential product ban on plastic foam products. The proposed addition

[39] These systems are also referred to as polyols, which are defined in Montreal Protocol reports as pre-blended foam chemicals.

[40] Montzka, S.A., Geoff S. Dutton, G.S., Yu, P., Ray, E., Portmann, R.W., Daniel, J.S., Kuijpers, L., Hall1, B.D., Mondeel, D., Siso, C., Nance, J.D., Rigby, M., Manning, A.J., Hu, L., Moore, F., Miller, B.R., and Elkins, J.W. ''An unexpected and persistent increase in global emissions of ozone-depleting CFC–11'' Nature 557; (2018): 413–429.

[41] Environmental Investigation Agency (EIA). (2018) Blowing It: Illegal Production and Use of Banned CFC–11 in China's Foam Blowing Industry. Available at: *https://eia-global.org/reports/20180709-blowing-it-illegal-production-and-use-of-banned-cfc-11-in-chinas-foam-blowing-industry.*

[42] Rigby, M. et al. ''Increase in CFC–11 emissions from eastern China based on atmospheric observations.'' Nature 569.7757 (2019): 546–550.

[43] Historically, limited amounts of CFC production and consumption were authorized domestically for essential uses.

of polyurethane foam systems to the list of nonessential products would result in the prohibitions of the sale or distribution of such products in interstate commerce, and thus would prevent emissions of CFCs in the United States from domestic use of these foam systems.

Section 610 of the CAA, titled ''Nonessential products containing chlorofluorocarbons,'' directs the EPA to issue regulations identifying nonessential products that ''release class I substances into the environment (including any release occurring during manufacture, use, storage, or disposal)'' and ''prohibit[ing] any person from selling or distributing any such product, or offering any such product for sale or distribution, in interstate commerce.'' Section 610(b)(1) and (2) specify that ''[a]t a minimum'' this prohibition shall apply to ''chlorofluorocarbon-propelled plastic party streamers and noise horns'' and ''chlorofluorocarbon-containing cleaning fluids for noncommercial electronic and photographic equipment.'' Section 610(b)(3) provides that the prohibition shall apply to other consumer products determined by the EPA to release class I substances into the environment (including releases during manufacture, use, storage, and disposal) and to be nonessential.

Section 610 further states that in determining whether a product is nonessential, the EPA shall consider the following criteria: ''the purpose or intended use of the product, the technological availability of substitutes for such product and for such class I substance, safety, health, and other relevant factors.'' The CAA requires the EPA to consider each criterion listed in section 610 but does not establish either a ranking or a methodology for comparing their relative importance, nor does it require that any minimum standard within each criterion be met. Thus, section 610 provides the EPA discretion in determining how to consider the listed criteria and the relative weight to give to each. In addition, section 610 gives the EPA latitude to consider ''other relevant factors'' beyond the specific criteria set forth in the statute.

As indicated above, polyurethane foam systems are products that release blowing agent to the environment during use. If CFCs are used as the blowing agent, they would be emitted during the use of such systems. In proposing to list polyurethane foam systems containing CFCs as a nonessential product, the EPA has considered the purpose or intended use of these systems, the technological availability of substitutes, and safety and health considerations. The first criterion, the purpose or intended use, relates to the importance of the product, in terms of benefits to society, specifically whether the product is sufficiently important that the benefits of its continued production outweigh the associated danger from the continued use of a class I ozone-depleting substance in it, or alternatively, whether the product has little benefit, such that even a lack of available substitutes might not prevent the product from being considered nonessential. While foam products, particularly closed-cell rigid polyurethane foams, provide benefits to society, for more than two decades U.S. manufacturers have replaced the use of CFCs in foam production without compromising these benefits.

The intended use of polyurethane foam systems is often for insulation in buildings and residences. While insulation has benefits, such as reducing energy use and costs associated with heating and cooling, in previous rulemakings the EPA's consideration of this criterion has also been informed by consideration of whether use of the class I substance in the product is nonessential (see 58 FR 4474, 66 FR 57514). For example, use of a class I substance in a product may be considered nonessential where substitutes are readily available, even if the product itself is important (see 58 FR 4474, 66 FR 57514). This is reasonable because if the social benefits from a product can be provided by a similar product without use of the class I substance, that tends to support the conclusion that the product using the class I substance is nonessential. U.S. manufacturers successfully transitioned from using class I substances for foam products more than two decades ago meaning that they were able to also replace the use of class I substances in foam blowing systems. Moreover, the same U.S. industry also replaced the use of class II substances in these plastic foam products. There are alternative foam blowing agents that can be used in foam systems as well as alternative methods and products for insulating buildings and residences that do not use class I substances. For instance, there are a variety of insulation types that can be applied throughout the building envelope to save energy and reduce leaks in buildings and homes with a similar R-value as a polyurethane foam system intended for use in insulation. The R-value refers to an insulating material's resistance to conductive heat flow and is measured or rated in terms of its thermal resistance. Alternative non-polyurethane foam insulation products with similar R-values include: Fiberglass, cellulose, and rigid foam boards.

For the criterion of technological availability of substitutes, the EPA considers the existence and accessibility of alternative products or alternative chemicals for use in, or in place of, products releasing class I substances. The EPA has interpreted this criterion to include both currently available substitutes and potentially available substitutes (see 58 FR 4474). There are numerous substitutes for CFCs in polyurethane foam systems that are listed as acceptable under the SNAP program and have been widely used by the foam industry since the mid-1990s. The current list of SNAP approved substitutes is available here: *https://www.epa.gov/snap/substitutes-foam-blowing-agents.* In the initial class I nonessential products rule, the EPA stated that in sectors where the great majority of manufacturers have already shifted to substitutes, the use of a class I substance in that product may very well be nonessential (58 FR 4774). As in previous considerations of this criterion, in this proposal the EPA is examining sectors where the market has previously switched to substitutes. Given the class I nonessential products ban that included plastic foam products was promulgated more than two decades ago and there were also subsequent restrictions on the use of class II substances promulgated under 40 CFR part 82, for polyurethane foam systems, the EPA believes that all U.S. manufacturers have switched from CFCs to non-ODS alternatives such as hydrofluorocarbons, hydrofluoroolefins, hydrocarbons, carbon dioxide, water, and other compounds listed as acceptable substitutes under SNAP in foam blowing.

For the criteria of safety and health, as in prior rules related to the nonessential product ban (see *e.g.,* 66 FR 57514), the EPA interprets these criteria to mean the effects on human health and the environment of products releasing CFCs or their substitutes. As in past rules, in evaluating these criteria, the EPA considers the direct and indirect effects of product use, and the direct and indirect effects of alternatives, such as ozone depletion potential, flammability, toxicity, corrosiveness, energy efficiency, ground-level air hazards, and other environmental factors (see, *e.g.,* 66 FR 57514). The ODPs of CFC–11, CFC–12, and CFC–114 are 1. For the purposes of evaluating other direct and indirect effects for foam systems, the agency does not believe there is a substantive

difference between foam systems and plastic foam products given the former is a precursor for the latter. In developing the class I nonessential products ban, the agency provided information in the docket concerning the known alternatives at that time. Subsequently, alternatives that were already in use as well as additional alternatives for foam-blowing have been evaluated and listed as acceptable under the SNAP program, such as hydrofluorocarbons, hydrofluoroolefins, hydrocarbons, carbon dioxide, and water. The current SNAP list of acceptable substitutes is more expansive than what was in considered in the initial class I nonessential products ban. The range of alternatives includes those that have ODPs ranging from zero to between 0.00024 and 0.00034, significantly lower than the ODP of CFC–11 which is 1, and considers many of the factors identified in the initial class I nonessential products ban. The Montreal Protocol's TEAP also provides a quadrennial global assessment of alternatives for foam blowing including information concerning many of the direct and indirect factors identified above (UNEP, 2014). The EPA considered all these sources of information when deciding whether to propose to add to the list of banned products foam systems that contain phased out CFCs and considered that U.S. industry has already successfully transitioned away from using CFCs.

Considering all three factors together, the EPA proposes to conclude that polyurethane foam systems containing CFCs meet the criteria in section 610 for listing as a nonessential product.

The EPA is requesting comment on its proposal to amend § 82.66(f) to add polyurethane foam systems containing CFCs to the nonessential class I product ban and to add a definition of a ''polyurethane foam system'' to § 82.62. Additionally, the EPA is interested in comments on whether anyone in the United States is using CFCs for foam blowing or is importing foam systems containing CFCs as a blowing agent. While the EPA is not aware of any other CFC-containing products that warrant addition to the list of nonessential products, the EPA seeks comment on whether there are other products using CFCs that could also create demand for imports of illegally-produced CFCs.

VI. Updates to §§ 82.3, 82.104, and 82.270 Related to Destruction

The EPA is proposing to amend certain provisions in 40 CFR part 82, subparts A, E, and H related to the concept of destruction of ODS. Title VI does not state how to treat destruction of ODS in calculating production or consumption; however, the EPA's longstanding regulations address this issue. The regulatory definition of ''production'' at § 82.3 excludes amounts that are destroyed by technologies approved by the Parties to the Montreal Protocol. In addition, amounts imported for destruction are excluded from the import prohibitions at §§ 82.4 and 82.15.

The EPA added a definition of the term ''destruction'' to § 82.3 in 1993. (58 FR 65047–65048). The existing regulatory definition of ''destruction'' includes a limited list of technologies that may be used for destruction. When the EPA established the initial list of destruction technologies the agency also noted that it intended to propose authorizing use of additional destruction technologies through future rulemakings, as such technologies are approved by the Parties (58 FR 65049).

The agency is proposing to update the definition of ''destruction'' in § 82.3 to add destruction technologies that have been approved by the Parties to the Montreal Protocol since the issuance of the 1993 rule. The agency is proposing to add these destruction technologies so that industry in the United States has a greater variety of technological options for the destruction of ODS. All of these technologies are capable of destroying ODS or converting them into byproducts and can be grouped into three broad categories: Incineration, plasma, and other non-incineration technologies. The EPA is proposing to add nitrogen plasma arc, portable plasma arc, argon plasma arc, microwave plasma, and inductively coupled radio frequency plasma to allow for additional plasma technologies to allow for greater industry flexibility for using plasma destruction technologies. Plasma arc technologies are generally designed to be relatively small, compact, and transportable. They consume a large amount of energy in order to generate the plasma but tend to have very high destruction efficiencies and low emissions. The EPA is also proposing to add an additional incineration technology—porous thermal reactor. Porous reactors are high-temperature systems with a porous layer that facilitates the decomposition of ODS and other industrial waste gases. Destruction takes place in an oxidizing atmosphere with a continuous supply of an auxiliary gas. The EPA is also proposing to add four non-incineration technologies, including chemical reaction with hydrogen (H_2) and carbon dioxide (CO_2). Revising the definition of destruction to include these technologies would not affect the applicability of other regulatory requirements relating to use of these technologies. Because one of the non-incineration technologies that the EPA is proposing to add, chemical reaction with H_2 and CO_2, is a conversion technology that converts the ODS into non-ozone depleting constituents that are capable of being reused, the EPA is also proposing to amend the definition of ''destruction'' to modify the statement that that the process must not result in a commercially useful end product. The EPA is also proposing edits to provisions in § 82.104 (Subpart E ''The Labeling of Products Using Ozone-Depleting Substances'') and § 82.270 (Subpart H ''Halon Emissions Reduction'') to conform with the proposed changes in this definition.

The existing regulations define the term ''destruction'' at § 82.3 and § 82.104. The two existing definitions are intended to convey the same meaning but are slightly different. For instance, the definition in § 82.104 refers to a code of good housekeeping contained in a United Nations Environment Programme report while the definition in § 82.3 does not. In addition, both provide a list of destruction technologies approved under decisions of the Parties to the Montreal Protocol. The list at § 82.3 contains seven technologies while the list at § 82.104 contains five.[44] Both lists are out of date in that they fail to include certain technologies that can destroy ODS or converting them into byproducts and have been approved under more recent decisions of the Parties. Similarly, the existing prohibition on disposing of halons in § 82.270 includes an exception for destruction that also provides an outdated list of destruction technologies. The EPA is therefore proposing to harmonize these three definitions of destruction and update the list of destruction technologies to allow the use of more destruction technologies in the United States.

The Parties to the Montreal Protocol have at times requested that the TEAP report to the Parties information on technologies for destroying surplus stocks of ODS based on an assessment of their technical capability to permanently decompose all or a significant portion of the ODS.[45] The

[44] Similarly, the definition of ''completely destroy'' at § 82.104 refers to using ''one of the five'' destruction processes approved by the Parties. The EPA is also proposing to remove that outdated language.

[45] UNEP. (2018) Montreal Protocol on Substances on Substances that Deplete the Ozone Layer. Report of the Technology and Economic Assessment Panel.

Continued

Parties to the Montreal Protocol have approved the use of destruction technologies through various decisions, including Decisions V/26, VII/35, XIV/6, XXII/10, XXIII/12, and at the recent 30th MOP Decision XXX/6. With the proposed revisions to the list of technologies in the definition of ''destruction'' at § 82.3, the EPA's regulations would reflect all technologies approved for ODS destruction under decisions of the Parties. Specifically, the EPA is proposing to add the following destruction technologies to the existing list: Nitrogen plasma arc, portable plasma arc, argon plasma arc, chemical reaction with H_2 and CO_2, inductively coupled radio frequency plasma, microwave plasma, porous thermal reactor, gas phase catalytic dehalogenation, superheated steam reactor, and thermal reaction with methane. An explanation of these technologies appears in the EPA's report on destruction ''ODS Destruction in the United States and Abroad,'' which is available in the docket.

The EPA is also proposing to revise the definition of ''destruction'' in § 82.104 and the prohibition in § 82.270 by removing the outdated lists found in those provisions and adding a cross reference to the list of destruction technologies in § 82.3. This would conform the list of destruction technologies that can be used across subparts A, E, and H. The destruction technologies that would be included the list in § 82.3 under the proposal discussed above in this section are also applicable to these other subparts, although the EPA notes that the listing of municipal waste incinerators in the existing regulations at § 82.3 is limited to the destruction of foams, and thus the added cross reference to § 82.3 in § 82.270 would not make that technology available for the exception for the destruction of halons at § 82.270. The addition of the cross reference to § 82.3 would also simplify updating § 82.104 and § 82.270 in the future. If additional destruction technologies are demonstrated in future to be capable of destroying ODS or converting them into byproducts, the EPA may consider proposing to add those technologies to the definition of ''destruction'' in § 82.3 to further increase the options for ODS destruction in the United States, to the extent consistent with approvals by the Parties and as appropriate. The added cross references would mean that the EPA would only need to revise the list in § 82.3 for the technologies to be approved for destruction under all three provisions.

The EPA is also proposing to amend the definitions of ''destruction'' at §§ 82.3 and 82.104 to modify language regarding commercially useful end products. The current definition contains a restriction that a destruction technology cannot result in a commercially useful product. The EPA is proposing to revise that restriction in part because one of the destruction technologies proposed to be added to the definition of destruction breaks down ODS into substances that have commercial viability. The process ''Chemical Reaction with H_2 and CO_2'' converts fluorinated compounds to hydrofluoric acid, hydrochloric acid, carbon dioxide, chlorine, and water. The reaction technology separates and collects the byproducts at a high purity allowing for them to be sold, potentially improving the economics of using this technology. The EPA does not believe that a process that would otherwise qualify as ''destruction'' should fail to qualify simply because one of the outputs is a commercially useful end product. The EPA is therefore proposing to revise the definition of ''destruction'' so that the mere existence of such an end product does not bar the technology from being included in the definition. The proposed revisions further clarify that the commercial usefulness of the end product is secondary to the act of the ODS destruction. Thus, the EPA's proposed changes to the definition of destruction recognize that while production of a commercially useful end product is not the primary purpose of a destruction process, the destruction process may nevertheless result in a commercially useful product.

The proposed clarification that the usefulness of an end product should be secondary to ODS destruction is intended to maintain a distinction between the terms ''destruction'' and ''transformation.'' The EPA established the definitions of ''destruction,'' ''production,'' and ''transformation'' in the 1993 rule (58 FR 65048–65049). Among other things, the agency excluded from the definition of ''production'': (1) Amounts of controlled substances that are destroyed using approved destruction technologies and (2) the manufacture of a controlled substance that is subsequently transformed. Similarly, the regulatory import prohibitions excluded both amounts destroyed, and amounts transformed. The definition of ''destruction'' noted that it does not result in a commercially useful end product whereas the definition of ''transformation'' noted that it occurs in a process specifically for the manufacture of other chemicals for commercial purposes. Thus, the original distinction in the definitions of these two terms related to whether the process was undertaken to intentionally result in a commercially useful end product or not. The distinction mattered (and is still relevant) because as explained in the 1993 rule, if a portion of the ODS remained after destruction, the destroyed portion could be excluded from production, but the material had to be entirely consumed in the process (except for trace quantities) to qualify for the transformation exclusion (58 FR 65048). The EPA is proposing to remove one aspect of the distinction between these two processes in the original definitions (whether the processes result in a commercially useful end product). The proposed changes to the text would clarify that the usefulness of the product is secondary to the act of destruction. Conversely, transformation is the use of ODS as a feedstock with the goal of manufacturing other chemicals.

Intent has been an important aspect of the distinction between ''destruction'' and ''transformation'' since these definitions were first promulgated. For example, in the 1993 rule establishing the definition of ''destruction,'' in a discussion of whether heat or energy are commercially useful end products, the agency said ''[t]he intent of the destruction process is to destroy the substance, for which a byproduct in the way of heat or energy may be produced, rather than production of an end product being the goal of the destruction activity.'' (58 FR 65049). This discussion recognizes that something useful may incidentally result from destruction. Similarly, the 1993 rule recognized the possibility of a destruction technology converting ODS into other useful substances. In explaining the inclusion of reactor cracking as a destruction technology, the EPA stated ''[s]ince 1983, this process has treated waste gases resulting from the production of CFCs. The gases are converted to hydrofluoric acid, hydrochloric acid, carbon dioxide, chlorine, and water. The two acids *are usable in-house and/or marketable,* and the chlorine is scrubbed, leaving only water vapor, oxygen, and carbon dioxide as waste gases.'' (58 FR 65047, emphasis added).

Consistent with that recognition and with the proposed inclusion of a new destruction technology with commercially useful end products, the EPA believes that the creation of a

April 2018 Volume 2 Decisions XXIX/4 TEAP Task Force Report on Destruction Technologies for Controlled Substances; pg. 1–67. Available at: *http://conf.montreal-protocol.org/meeting/oewg/oewg-40/presession/Background-Documents/TEAP-DecXXIX4-TF-Report-April2018.pdf.*

commercially useful end product should not in itself preclude a technology from being listed in the definition of ''destruction.'' The creation of such an end product does not change whether chemical decomposition occurs. Many destruction processes incinerate the chemicals, but other technologies break down the controlled substance. In breaking down the chemical, it is possible that the result includes a commercially valuable end product that is not a controlled substance. ''Transformation,'' on the other hand, means to use and entirely consume a controlled substance in the manufacture of other chemicals for commercial purposes. The purpose is to create new compounds using the ODS as a feedstock rather than the decomposition of ODS as a waste.

The EPA welcomes comment on the proposal to update and harmonize definitions related to ODS destruction in §§ 82.3, 82.104, and 82.270, including the proposal to add to the list of destruction technologies and amend the definition of ''destruction'' to allow inclusion of destruction technologies that incidentally result in commercially useful end products. The EPA specifically invites comments from entities that destroy ODS or send ODS to facilities for destruction.

VII. Removing Obsolete Provisions in §§ 82.3, 82.4, 82.9, 82.10, 82.12, 82.13, 82.15, 82.16, and 82.24

The EPA is proposing to remove certain provisions that have been made obsolete due to the phaseout of class I ODS or certain class II ODS. Specifically, this notice proposes to remove outdated provisions for class I ODS related to Article 5 allowances, transformation and destruction credits, and transfers of allowances issued prior to the phaseout. The EPA is also proposing to remove definitions and reporting provisions for HCFC–141b exemption allowances and export production allowances.

These changes increase readability and reduce confusion. Removing obsolete provisions would assist the regulated community by making it easier to locate the currently applicable requirements and reduce potential confusion from presentation of requirements that no longer apply. The EPA is not proposing to remove outdated provisions that provide historical context which could assist the reader or that would affect the level of environmental protection provided under subpart A.

The EPA welcomes comments on the proposed removal of these provisions. The agency is particularly interested in any comments indicating these proposed changes may affect current obligations or may be important to the existing requirements.

A. Class I Article 5 Allowances

Before the worldwide phaseout of CFCs and other class I ODS, the EPA historically had provided additional production allowances, known as ''Article 5 allowances,'' for production of certain class I ODS for export to and use by Article 5 countries consistent with the Montreal Protocol.[46] These are countries that were subject to a later production and consumption phaseout schedule than non-Article 5 countries such as the United States. Section 82.9(a) of the existing regulations granted Article 5 allowances until 2010, when the phaseout of these substances was completed in Article 5 countries. Because these provisions no longer have any purpose or effect, the EPA is proposing to remove the schedule for issuing Article 5 allowances found at § 82.9(a) and the corresponding recordkeeping and reporting requirements in § 82.13(f)(2)(v) and (f)(3)(ix). Section 82.9(b) of the existing regulations provides that holders of Article 5 allowances may produce class I controlled substances for export to Article 5 countries and transfer Article 5 allowances. Because there are no more holders of Article 5 allowances, the EPA is proposing to remove these provisions as well.

B. Class I Allowances and Credits Related to Transformation and Destruction

Before the domestic phaseout of class I ODS, the EPA historically had provided additional production allowances in cases where class I ODS were destroyed or transformed. Because these provisions no longer have any purpose or effect, the EPA is proposing to remove these provisions and to remove references to these obsolete allowances in certain other provisions.

Section 82.9(e) of the existing rules contains the provisions related to such allowances, including detailing the information needed in a request for allowances based on having destroyed or transformed a specified quantity of class I ODS. The EPA stopped issuing such allowances in 1996 for all class I controlled substances (except methyl bromide) and in 2005 for methyl bromide. The EPA is proposing to remove § 82.9(e) and related obsolete reporting and recordkeeping requirements in § 82.13(f)(2)(iv), (g)(1)(xv), (g)(4)(xi), and (h)(4)(xi).

Section 82.9(f) authorized persons who were nominated for an essential use exemption to obtain destruction and transformation credits between 1996 and 2000. The EPA established these provisions because of the difference between the phaseout date for class I substances under the CAA and the phaseout date for the same substances under the Montreal Protocol. These provisions include a description of the information needed and the grounds for which the EPA can disallow the request. Section § 82.4(f) addresses production and import with destruction and information credits. The EPA stopped issuing such credits in 2000. Because these provisions no longer have any purpose or effect, the EPA is proposing to remove §§ 82.4(f) and 82.9(f).

C. Class I Consumption Allowances

Before the phaseout of class I ODS, the EPA historically had provided additional consumption allowances where class I ODS were exported, transformed or destroyed, or where an amount of production was transferred from another Party to the Montreal Protocol. Section 82.10 contains provisions related to these additional consumption allowances, including detailing the information needed in a request for them. The EPA stopped issuing those allowances in 1996 for all class I controlled substances (except methyl bromide) and in 2005 for methyl bromide. Because these provisions no longer have any purpose or effect, the EPA is proposing to remove them and reserve § 82.10 in its entirety. The EPA is also proposing to remove references to § 82.10 from the definition of ''consumption allowance'' in § 82.3; § 82.9(c), (e) and (f); § 82.13(h)(1) and (2); and § 82.13(i) as those references are no longer applicable.

D. Transfers of Class I Allowances

The EPA historically had allowed for the transfer of production and consumption allowances for class I substances in various ways. Under section 607 of the CAA, the EPA was required to issue regulations providing for inter-pollutant allowance transfers and allowance transfers between companies. For class I substances, those regulations appear at § 82.12. Due to the class I phaseout, the EPA no longer allocates production or consumption allowances for class I substances. Because these provisions no longer have any purpose or effect, the EPA is proposing to remove provisions related to pre-1996 allowance transfers for class I ODS (and pre-2005 for methyl

[46] For the purposes of the Montreal Protocol, this is called production for basic domestic need.

bromide) found at § 82.12(a)(1) and (b)(1), as any such transfers occurred years ago and these provisions no longer have any purpose or effect.

As discussed in earlier in this section, the EPA is proposing to remove certain provisions governing Article 5 allowances and destruction and transformation credits. The EPA is therefore also proposing to remove provisions allowing for the transfer of Article 5 allowances and destruction and transformation credits found at § 82.12(a)(2), (b)(2)–(5), and (c) as those provisions are longer needed.

E. HCFC–141b Allowances

In 2003, the EPA issued regulations (68 FR 2820, January 21, 2003) to ensure compliance with the first reduction milestone in the HCFC phaseout. In that rule, the EPA established chemical-specific consumption and production baselines for HCFC–141b, HCFC–22, and HCFC–142b for the initial regulatory period ending December 31, 2009. The rule phased out the production and import of HCFC–141b effective January 1, 2003 (see § 82.16(b)). The EPA created a petition process at § 82.16(h) to allow applicants to request ''HCFC–141b exemption allowances'' to produce or import small amounts of HCFC–141b beyond the phaseout. The agency removed § 82.16(h) from the regulations and terminated the HCFC–141b exemption allowance program, effective January 1, 2015 (79 FR 64267, October 28, 2014). At that time, the EPA did not remove definitions and reporting and recordkeeping requirements that pertain only to HCFC–141b exemption allowances.

The EPA is now proposing to remove the definitions in § 82.3 specific to HCFC–141b production or import after the 2003 phaseout, including the definitions of ''Formulator,'' ''HCFC–141b exemption allowances,'' and ''Unexpended HCFC–141b exemption allowances.'' The definitions for HCFC–141b exemption allowances are no longer relevant since the EPA has removed the substantive regulations that these definitions support. For the same reasons, the EPA is proposing to remove references to HCFC–141b in the definition of ''Confer,'' but would retain the remainder of that definition. The EPA is also proposing to remove references and recordkeeping and reporting requirements specifically relating to HCFC–141b exemption allowances. These edits would be made in § 82.24(b)(1)(ix) and (xi); § 82.24(b)(2)(xiv); § 82.24(c)(1)(xi); § 82.24(c)(2)(xvi); and § 82.24(g).

The EPA also created provisions at § 82.18(b) to allow producers to use ''export production allowances'' to produce HCFC–141b for export beyond the phaseout. These allowances ended in 2010 and therefore these provisions have no further purpose or effect. The EPA is proposing to retain the definition of export production allowances and certain references where appropriate to provide context to the reader but remove the recordkeeping and reporting provisions. These edits would be made in § 82.16(e)(1) and (2); § 82.24(b)(1)(iv) and (ix); § 82.24(b)(2)(iv), and (xii); and § 82.24(d)(2).

VIII. Economic Analysis

In total, the EPA estimates that the quantified costs and benefits of this proposal would result in a net savings of $13,000 per year. The agency analyzed the quantitative benefits associated with the overall burden reduction from transitioning to electronic reporting, the streamlined petition process for used ODS, the certification to import ODS for destruction, and costs associated with proposed labeling requirements. For this action, the EPA has provided in the docket technical support documents that consider the costs and the benefits commensurate with changes to ODS phaseout regulations, such as the requirement to use electronic reporting. Further, many of the proposed changes to the ODS phaseout regulations, such as the removal of obsolete requirements, would not result in any new costs or benefits. The quantifiable costs and benefits of this rule primarily result from the proposed revisions to the reporting and recordkeeping requirements and the requirement to use electronic reporting. For the phaseout of ODS, the EPA previously considered the domestic costs and benefits of the United States' phaseout.[47]

The EPA anticipates that electronic reporting would allow for faster review and transmission of submissions to the EPA. Additionally, all information submitted electronically would be linked in an improved tracking system, which would facilitate document management efforts. The intent is that this would allow companies to manage past and future submissions easier. The EPA expects that the estimated burden hours and labor costs would decrease as a result of the complete transition from paper to electronic reporting. Even accounting for the one-time burden for entities that have not yet registered in CDX of $2,000, the electronic reporting would result in an overall burden reduction for respondents of approximately $4,000. Similarly, the estimated agency burden hours and labor costs would also decrease. For example, by requiring electronic reporting the agency would no longer have to manually enter data into the ODS Tracking System.

The streamlined petitions process and new certification to import ODS for destruction would decrease the total estimated respondent burden. There would be a reduction in reporting requirements for imports for destruction relative to the current petition process. Specifically, the number of reporting elements for importers for destruction would be reduced from 13 to 8 and reduce burden hours per response by four hours. The EPA also estimates that exempting halon 1211 used in aircraft bottles from the petition process would reduce the number of responses per respondent by one, as detailed in descriptions of the recordkeeping and reporting burden, including cost savings to the agency, which can be found in the supporting statement for the Information Collection Request available in the docket to this rule.

The EPA estimates that the proposed requirements to redesign the existing labels on containers of Halotron® I would result in a one-time cost between $1,000 to $3,000. Administrative and graphic design labor costs are estimated based on the total amount of hours required to redesign existing labels as well as hourly labor costs. These hourly costs include wages, overhead rates, and fringe rates. Additional information on this analysis is available in the docket.

There are also effects of this rule that the agency has not or cannot quantify. The EPA did not conduct a specific analysis of the benefits and costs associated with prohibiting the sales of QPS methyl bromide for non-QPS purposes, prohibiting sales of polyurethane foam systems, other elements of the proposal, and allocating allowances of HCFC–123 and HCFC–124. Prohibiting both the sales of QPS methyl bromide for non-QPS purposes and the sales of illegally imported ODS is designed to improve compliance with the existing provisions. Costs are unquantifiable as the scale of these sales are unknown but anticipated to be small. The proposed prohibition on sales and distribution of polyurethane foam systems containing CFCs should have no cost. Updating the definition of destruction would allow for the use of

[47] The following documents are available in the docket: ''EPA. 1999. The Benefits and Costs of the Clean Air Act: 1990 to 2010;'' ''EPA. 1992. Regulatory Impact Analysis: Compliance with Section 604 of the Clean Air Act for the Phaseout of Ozone Depleting Chemicals;'' and ''EPA. 1993. Addendum to the 1992 Phaseout Regulatory Impact Analysis: Accelerating the Phaseout of CFCs, Halons, Methyl Chloroform, Carbon Tetrachloride, and HCFCs.''

new destruction technologies that are currently not in use, but the agency is unable to estimate the market for the use of those new technologies if they are adopted. The proposed removal of obsolete provisions is not anticipated to have any material cost or benefit.

For the allocation of HCFC–123 and 124, previous analyses provide information on the costs and benefits of the United States' ODS phaseout, and specifically the phaseout of all HCFCs through 2030, but do not quantify the costs and benefits of each individual phaseout step for each individual chemical. A memorandum summarizing these analyses, including the original regulatory impact analysis for the full phaseout of ODS, is available in the docket.[48] Finalizing this proposed rule would allow for the production and consumption of HCFC–123 and HCFC–124 that would otherwise not be allowed in the absence of this rulemaking under existing regulations. The benefit of issuing allowances consistent with this proposal outweighs the disbenefit associated with no action.

Since the allocation for HCFC–123 is the largest component of this rule, the following discusses the potential costs and benefits of the proposed and alternative allocation levels for HCFC–123. As discussed in the allocation section of this notice, the consumption baseline of the United States under the Montreal Protocol in 2020 for all HCFCs, on an ODP-weighted basis, will be 0.5% of the historic HCFC baseline. This equates to 3,810 MT of HCFC–123. Under section 605(c) of the CAA, the consumption of HCFCs by any person is limited to the quantity consumed by that person during the baseline year. The baseline[49] for HCFC–123 is the aggregated quantity consumed in the baseline years and equates to 2,014 MT. In developing the proposed allocations, the EPA considered the quantities needed to satisfy estimated demand for HCFC–123 to service equipment manufactured before 2020. Lastly, the EPA estimated a range for the amount HCFC–123 that will likely be reclaimed annually, and thus be available to meet part of the servicing demand for HCFC–123. These are summarized in Table 3.

TABLE 3—HCFC–123 SERVICING DEMAND AND ESTIMATED RECLAMATION (MT)

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	Total
Total Estimated Demand	820	790	770	750	720	700	670	650	630	600	7,100
Estimated Reclamation Low	300	310	320	330	340	350	360	370	380	390	3,450
Estimated Reclamation High	350	378	407	436	465	494	523	552	581	610	4,796
Total Need for New Production with Low Reclaim	520	480	450	420	380	350	310	280	250	210	3,650
Total Need for New Production with High Reclaim	470	412	363	314	255	206	147	98	49	0	2,314

The agency's intent is to accomplish the complete phaseout in 2030 in a manner that achieves a smooth transition to alternatives without stranding equipment. This is important because the EPA estimates that 36,000 appliances using HCFC–123 will still be in operation in 2030.[50] At that time, no more HCFC–123 may be produced or imported into the United States.

TABLE 4—PROJECTED NUMBER OF HCFC–123 AC AND REFRIGERATION UNITS IN OPERATION

[1000s of Units]

Equipment type	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Chillers (AC)	47	45	43	41	39	37	35	33	31	29	27
IPR	14	13	13	12	12	11	11	10	10	9	9

The EPA does not want to strand existing equipment because of an inadequate supply of HCFCs, but also must achieve a complete phaseout of production and consumption by 2030. A viable reclamation market is important to support the continued availability of HCFCs after the 2030 phaseout, and during 2020 through 2029 can support the fire suppression market and decrease the need for new production and import. As noted previously, the EPA is requesting comment on the HCFC demand estimates included in the *2019 Draft Servicing Tail Report,* which is included in the docket for this rulemaking.

Table 5 presents the three allocation amounts for HCFC–123 raised for comment in this proposed rule. The agency proposes to issue consumption allowances equal to the 2020 estimated HCFC–123 demand for servicing existing refrigeration and air-conditioning and fire suppression equipment for years 2020 through 2022 and to then decrease the number of allowances issued in each subsequent year by an equal amount each year such that there are zero allowances issued in 2030. Alternative 1 is equal to the estimated demand minus the low end of estimated reclaim. Alternative 2 is 100% of the domestic HCFC–123 consumption baseline, which as discussed previously is the full amount that can be allocated under the CAA.

TABLE 5—COMPARISON OF HCFC–123 CONSUMPTION ALLOWANCE ALLOCATIONS (MT)

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	Total
Proposal	650	650	650	570	490	410	330	250	170	90	4,260

[48] EPA. 2008. ''HCFC Cost Analysis.'' and EPA. 2018. ''Overview of CFC and HCFC Phaseout.''

[49] Baseline from 40 CFR 82.19.

[50] EPA. 2019. *The U.S. Phaseout of HCFCs: Projected Servicing Demands in the U.S. Air Conditioning, Refrigeration, and Fire Suppression Sector (2020–2030).* See Table 3.

TABLE 5—COMPARISON OF HCFC–123 CONSUMPTION ALLOWANCE ALLOCATIONS (MT)—Continued

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	Total
Alternative 1	520	480	450	420	380	350	310	280	250	210	3,650
Alternative 2	2,014	2,014	2,014	2,014	2,014	2,014	2,014	2,014	2,014	2,014	20,140
0.5% of HCFC Consumption Baseline	3,810	3,810	3,810	3,810	3,810	3,810	3,810	3,810	3,810	3,810	38,100

The EPA expects more disbenefits in allocating significantly above projected demand. Because of the limited numbers of allowance holders, the EPA does not expect the price of HCFC–123 to appreciably decrease if the agency allocates 100% of the HCFC–123 baseline (Alternative 2 in Table 5). The disbenefits the EPA is concerned about include near and longer term available supply of reclaimed and recycled HCFC–123, as well as emissions of ODS, given the agency's assumption that all refrigerant produced is eventually emitted into the atmosphere. More allocated allowances would likely suppress the recovery and reclamation market and cause more HCFC material to be vented at the end of the equipments' lifetime. In the near term, this would also have an adverse effect on the availability of reclaimed HCFC–123 for the fire suppression sector because reclamation is the only source of HCFC–123 for the manufacture of new fire suppression equipment; it is projected that the fire suppression sector would need between 170 to 225 MT for the manufacture of new equipment. Thus, if the reclaim market is suppressed from 2020 through 2029, there will be less supply and higher costs for HCFC–123, especially from 2030 onwards when the only supply of HCFC–123 will be from the reclaim market. Based on the *2019 Draft Servicing Tail Report,* HCFC–124 consumption has been approximately 250 MT per year and reclamation has been minimal. Recent sales data from the California Air Resources Board as well as other information indicate that demand for HCFC–124 should be between 100 and 200 MT in 2020. Like HCFC–123, providing HCFC–124 allowances significantly in excess of demand may not foster transition. Thus, the EPA is proposing to allocate 200 MT for the first three years and then gradually decrease over the next seven years by an equal amount each year. The EPA is taking comment on the assumptions and projections in this section.

Regardless of allocation level, for the purposes of analyzing the impact of this proposal on small business, the EPA finds there is no significant impact on a substantial number of small entities (SISNOSE). The EPA performed a sales test to assess the economic impact of a regulatory option on small businesses and compared the results of the sales test. Based on the screening analysis of allowance holders of HCFC–123 and HCFC–124, this proposed rulemaking could be presumed to have no SISNOSE because it is expected to result in a net benefit to small business through the ability to continue producing, importing and/or selling HCFC–123 and HCFC–124. The EPA notes that there are only eight companies total that hold consumption allowances for HCFC–123 and HCFC–124, only two of which are small businesses.

Table 6 summarizes the environmental effect, in ODP-weighted metric tons, of the various HCFC–123 allocation levels over the length of the 2020–2029 regulatory period. For comparison, the EPA estimates total demand for HCFC–123 over the next decade to equal 7,100 MT, or 142 ODP-weighted metric tons. About 70% to 75% of this amount is for servicing existing equipment and can be met with newly-imported HCFCs, and the remainder must be met with reclaimed or recycled HCFCs. Not all allowances may be expended so this does not reflect the actual impact to the stratospheric ozone layer of these three options. However, the EPA does assume that all refrigerant produced is eventually emitted into the atmosphere. Alternative 1 followed by the proposed allocation amounts would have the least impact on the stratospheric ozone layer. For HCFC–124, the EPA estimates total demand over the next decade equal to 1,000 to 2,000 MT, or 22 to 44 ODP-weighted metric tons.

TABLE 6—ENVIRONMENTAL EFFECTS OF THE HCFC–123 AND HCFC–124 ALLOCATION AMOUNTS

[Total of 2020–2029]

	MT	ODP-weighted metric tons
Proposed HCFC–123 Allocation Amount	4,260	85
HCFC–123 Alternative 1	3,650	73
HCFC–123 Alternative 2	20,140	403
Proposed HCFC–124 Allocation Amount	1,300	28.6
HCFC–124 Alternative	2,000	44

IX. Statutory and Executive Order Reviews

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is expected to be an Executive Order 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the EPA's ICR associated with this rulemaking.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The ICR document that the

EPA prepared has been assigned EPA ICR number 1432.34. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

This ICR covers provisions under the Montreal Protocol and Title VI of the CAA that establish limits on total U.S. production, import, and export of ODS. The EPA monitors compliance with the CAA and commitments under the Montreal Protocol through the recordkeeping and reporting requirements established in the regulations at 40 CFR part 82, subpart A. The EPA informs the respondents that they may assert claims of business confidentiality for any of the information they submit. Information claimed as confidential will be treated in accordance with the procedures for handling information claimed as confidential under 40 CFR part 2, subpart B, and will be disclosed to the extent, and by means of procedures, set forth in Subpart B. If no claim of confidentiality is asserted when the information is received by the EPA, it may be made available to the public without further notice to the respondents (40 CFR 2.203).

Respondents/affected entities: Producers, importers, exporters, and certain users of ozone depleting substances; methyl bromide applicators, distributors, and end users including commodity storage and quarantine users.

Respondent's obligation to respond: Mandatory—sections 603(b) and 114 of the CAA.

Estimated number of respondents: 93.

Frequency of response: Quarterly, annually, and as needed.

Total estimated burden: 2,940 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $354,068, includes $346,693 annualized capital and operation & maintenance costs of $7,375.

The ICR addresses the incremental changes to the existing reporting and recordkeeping programs that are approved under OMB control number 2060–0170.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oria_submissions@omb.eop.gov,* Attention: Desk Officer for the EPA. Since OMB is required to decide concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than September 13, 2019. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities potentially subject to increased costs from this action include allowance holders, distributors, applicators, and end users of methyl bromide and importers of ODS. The EPA estimates that the total incremental savings associated with this proposed rule is $13,000 per year in 2018 dollars. Details of this analysis are presented in Section VIII of this notice.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

F. Executive Order 13132: Federalism

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

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to E.O. 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in E.O. 12866. The agency nonetheless has reason to believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Depletion of stratospheric ozone results in greater transmission of the sun's ultraviolet (UV) radiation to the earth's surface. The following studies describe the effects of excessive exposure to UV radiation on children: (1) Westerdahl J, Olsson H, Ingvar C. ''At what age do sunburn episodes play a crucial role for the development of malignant melanoma,'' Eur J Cancer 1994: 30A: 1647–54; (2) Elwood JM Japson J. ''Melanoma and sun exposure: an overview of published studies,'' Int J Cancer 1997; 73:198–203; (3) Armstrong BK, ''Melanoma: childhood or lifelong sun exposure,'' In: Grobb JJ, Stern RS, Mackie RM, Weinstock WA, eds. ''Epidemiology, causes and prevention of skin diseases,'' 1st ed. London, England: Blackwell Science, 1997: 63–6; (4) Whiteman D., Green A. ''Melanoma and Sunburn,'' Cancer Causes Control, 1994: 5:564–72; (5) Heenan, PJ. ''Does intermittent sun exposure cause basal cell carcinoma? A case control study in Western Australia,'' Int J Cancer 1995; 60: 489–94; (6) Gallagher, RP, Hill, GB, Bajdik, CD, et. al. ''Sunlight exposure, pigmentary factors, and risk of nonmelanocytic skin cancer I, Basal cell carcinoma,'' Arch Dermatol 1995; 131: 157–63; (7) Armstrong, DK. ''How sun exposure causes skin cancer: an epidemiological perspective,'' Prevention of Skin Cancer. 2004. 89–116.

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 82

Environmental protection, Air pollution control, Chemicals, Reporting and recordkeeping requirements.

Dated: July 24, 2019.

Andrew R. Wheeler,

Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 82 as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–767q.

■ 2. Amend § 82.3 by:
■ a. Adding. In alphabetical order, definitions for ''bank'' and ''Central Data Exchange;''
■ b. Revising the definitions for ''Administrator,'' ''Aircraft halon bottle,'' ''Confer,'' ''Consumption allowances,'' ''Destruction,'' ''Individual shipment,'' ''Non-Objection notice,'' and ''Production''; and
■ c. Removing definitions for ''Formulator,'' ''HCFC–141b exemption allowances,'' and ''Unexpended HCFC–141b exemption allowances.''

The revisions and additions read as follows:

§ 82.3 Definitions.

* * * * *

Administrator means the Administrator of the United States Environmental Protection Agency or his or her authorized representative. Reports and petitions that are available to be submitted through the Central Data Exchange must be submitted through that tool. Any other reports and communications shall be submitted to Stratospheric Protection Manager, 1200 Pennsylvania Ave. NW, Mail Code: 6205T, Washington, DC 20460.

Aircraft halon bottle means a vessel used as a component of an aircraft fire suppression system containing halon-1301 or halon-1211 approved under FAA rules for installation in a certificated aircraft.

* * * * *

Bank means a facility run by a national government or privately run and authorized by a national government that collects and stores previously-recovered ozone-depleting substances for reuse at a later date.

* * * * *

Central Data Exchange means EPA's centralized electronic document receiving system, or its successors.

* * * * *

Confer means to shift the essential-use allowances obtained under § 82.8 from the holder of the unexpended essential-use allowances to a person for the production of a specified controlled substance.

* * * * *

Consumption allowances means the privileges granted by this subpart to produce and import controlled substances; however, consumption allowances may be used to produce controlled substances only in conjunction with production allowances. A person's consumption allowances for class I substances are the total of the allowances obtained under §§ 82.6 and 82.7 as may be modified under § 82.12 (transfer of allowances). A person's consumption allowances for class II controlled substances are the total of the allowances obtained under §§ 82.19 and 82.20, as may be modified under § 82.23.

* * * * *

Destruction means the expiration of a controlled substance to the destruction and removal efficiency actually achieved, unless considered completely destroyed as defined in this section. Such destruction might result in a commercially useful end product, but such usefulness would be secondary to the act of destruction. Destruction must be achieved using one of the following controlled processes approved by the Parties to the Protocol:

(1) Liquid injection incineration;
(2) Reactor cracking;
(3) Gaseous/fume oxidation;
(4) Rotary kiln incineration;
(5) Cement kiln;
(6) Radio frequency plasma;
(7) Municipal waste incinerators (only for the destruction of foams);
(8) Nitrogen plasma arc;
(9) Portable plasma arc;
(10) Argon plasma arc;
(11) Chemical reaction with H2 and CO2;
(12) Inductively coupled radio frequency plasma;
(13) Microwave plasma;
(14) Porous thermal reactor;
(15) Gas phase catalytic de-halogenation;
(16) Superheated steam reactor; or
(17) Thermal reaction with methane.

* * * * *

Individual shipment means the kilograms of a controlled substance for which a person may make one (1) U.S. Customs entry, as identified in the non-objection letter from the Administrator under §§ 82.13(g)(2), (3), and (5) and 82.24(c)(4) and (6).

* * * * *

Non-Objection notice means the privilege granted by the Administrator to import a specific individual shipment of a controlled substance in accordance with §§ 82.13(g)(2), (3), and (5) and 82.24(c)(3), (4), and (6).

* * * * *

Production means the manufacture of a controlled substance from any raw material or feedstock chemical, but does not include:

(1) The manufacture of a controlled substance that is subsequently transformed;
(2) The reuse or recycling of a controlled substance;
(3) Amounts that are destroyed by the approved technologies in § 82.3; or
(4) Amounts that are spilled or vented unintentionally.

■ 3. Amend § 82.4 by:
■ a. Removing and reserving paragraph (f);
■ b. Revising paragraph (j); and
■ c. Adding paragraphs (r) and (s).

Revisions read as follows:

§ 82.4 Prohibitions for class I controlled substances.

* * * * *

(j)(1) Effective January 1, 1995, no person may import, at any time in any control period, a used class I controlled substance, except for Group II used controlled substances shipped in aircraft halon bottles for hydrostatic testing, without having received a non-objection notice from the Administrator in accordance with § 82.13(g)(2) and (3). A person who receives a non-objection notice for the import of an individual shipment of used controlled substances may not transfer or confer the right to import, and may not import any more than the exact quantity, in kilograms, of the used controlled substance cited in the non-objection notice. Every kilogram of importation of used controlled substance in excess of the quantity cited in the non-objection notice issued by the Administrator in accordance with § 82.13(g)(2) and (3) constitutes a separate violation.

(2) Effective September 13, 2019, no person may import for purposes of destruction, at any time in any control period, a class I controlled substance for which EPA has apportioned baseline production and consumption allowances, without having submitted a certification of intent to import for destruction to the Administrator and received a non-objection notice in accordance with § 82.13(g)(5). A person issued a non-objection notice for the import of an individual shipment of class I controlled substances for destruction may not transfer or confer the right to import, and may not import any more than the exact quantity (in kilograms) of the class I controlled

substance stated in the non-objection notice. For imports intended to be destroyed in the U.S., a person issued a non-objection notice must destroy the controlled substance in the year cited in the non-objection letter, may not transfer or confer the right to import, and may not import any more than the exact quantity (in kilograms) of the class I controlled substance stated in the non-objection notice. Every kilogram of import of class I controlled substance in excess of the quantity stated in the non-objection notice issued by the Administrator in accordance with § 82.13(g)(5) constitutes a separate violation of this subpart.

* * * * *

(r) *Quarantine and preshipment exemption.* No person may sell or use methyl bromide produced or imported under the quarantine and preshipment exemption for any purpose other than for quarantine applications or preshipment applications as defined in § 82.3. Each kilogram of methyl bromide produced or imported under the authority of the quarantine and preshipment exemption and sold or used for a use other than quarantine or preshipment is a separate violation of this subpart.

(s) Effective September 13, 2019, no person may sell or distribute, or offer for sale or distribution, any class I substance that they know, or have reason to know, was imported in violation of this section, except for such actions needed to re-export the controlled substance. Every kilogram of a controlled substance imported in contravention of this paragraph that is sold or distributed, or offered for sale or distribution, constitutes a separate violation of this subpart.

■ 4. Amend § 82.9 by:

■ a. Removing and reserving paragraphs (a), (b), (e), and (f); and

■ b. Revising paragraph (c) introductory text.

The revision reads as follows:

§ 82.9 Availability of production allowances in addition to baseline production allowances for class I controlled substances.

* * * * *

(c) A company may increase or decrease its production allowances, including its Article 5 allowances, by trading with another Party to the Protocol according to the provision under this paragraph (c). A company may increase or decrease its essential-use allowances for CFCs for use in essential MDIs according to the provisions under this paragraph (c). A nation listed in appendix C to this subpart (Parties to the Montreal Protocol) must agree either to transfer to the person for the current control period some amount of production or import that the nation is permitted under the Montreal Protocol or to receive from the person for the current control period some amount of production or import that the person is permitted under this subpart. If the controlled substance is produced under the authority of production allowances and is to be sold in the United States or to another Party (not the Party from whom the allowances are received), the U.S. company must expend its consumption allowances allocated under § 82.6 and § 82.7 in order to produce with the additional production allowances.

* * * * *

§ 82.10 [Removed and reserved]

■ 5. Remove and reserve § 82.10.

■ 6. Amend § 82.12 by:

■ a. Revising paragraph (a)(1) introductory text; and

■ b. Removing and reserving paragraphs (a)(2), (b) and (c).

The revision reads as follows:

§ 82.12 Transfers of allowances for class I controlled substances.

(a) * * *

(1) After January 1, 2002, any essential-use allowance holder (including those persons that hold essential-use allowances issued by a Party other than the United States) (''transferor'') may transfer essential-use allowances for CFCs to a metered dose inhaler company solely for the manufacture of essential MDIs. After January 1, 2005, any critical use allowance holder (''transferor'') may transfer critical use allowances to any other person (''transferee'').

* * * * *

■ 7. Amend § 82.13 by:

■ a. Revising paragraphs (a), (c), (f)(2)(xvii)–(xxii), (f)(3)(xiii)–(xvii), (g)(1)(xi), (xv), (xvii)–(xxi), (g)(2)(i)–(iv), (vi), (viii)–(xiii), (g)(3)(i)(A), (g)(3)(vii), (g)(4)(xv)–(xviii), (h)(1) introductory text, (h)(1)(ii)–(iii), (h)(2) introductory text, (h)(2)(ii)–(v), (viii), (v), (w)(2), (y), (z), (aa);

■ b. Removing and reserving paragraphs (f)(2)(iv), (v), and (xvi), (f)(3)(iv), (ix), (g)(2)(xiv), (g)(4)(vii), (xi), (i); and

■ c. Adding paragraphs (g)(2)(xv) and (g)(5)–(9).

The revisions and additions read as follows:

§ 82.13 Recordkeeping and reporting requirements for class I controlled substances.

(a) Unless otherwise specified, the recordkeeping and reporting requirements set forth in this section take effect on January 1, 1995. For class I, Group VIII controlled substances, the recordkeeping and reporting requirements set forth in this section take effect on August 18, 2003. For critical use methyl bromide, the recordkeeping and reporting requirements set forth in this section take effect January 1, 2005.

* * * * *

(c) Unless otherwise specified, reports required by this section must be submitted to the Administrator within 45 days of the end of the applicable reporting period. Starting [DATE 30 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], reports that are available for submission through the Central Data Exchange must be submitted electronically through that tool. Revisions of reports that are required by this section must be submitted to the Administrator within 180 days of the end of the applicable reporting period, unless otherwise specified.

* * * * *

(f) * * *

(2) * * *

(xvii) For methyl bromide, dated records of the quantity of controlled substances produced for quarantine and preshipment applications and quantity sold for quarantine and preshipment applications;

(xviii) Written certifications that quantities of methyl bromide produced solely for quarantine and preshipment applications were purchased by distributors or applicators to be used only for quarantine applications and preshipment applications in accordance with the definitions in this subpart; and

(xix) Written verifications from a U.S. purchaser that methyl bromide produced solely for quarantine and preshipment applications, if exported, will be exported solely for quarantine applications and preshipment applications upon receipt of a certification in accordance with the definitions of this subpart and requirements in paragraph (h) of this section.

(xx) For methyl bromide, dated records such as invoices and order forms, and a log of the quantity of controlled substances produced for critical use, specifying quantities dedicated for pre-plant use and quantities dedicated for post-harvest use, and the quantity sold for critical use, specifying quantities dedicated for pre-plant use and quantities dedicated for post-harvest use;

(xxi) Written certifications that quantities of methyl bromide produced for critical use were purchased by distributors, applicators, or approved

critical users to be used or sold only for critical use in accordance with the definitions and prohibitions in this subpart. Certifications must be maintained by the producer for a minimum of three years and;

(xxii) For methyl bromide, dated records such as invoices and order forms, and a log of the quantity of controlled substances produced solely for export to satisfy critical uses authorized by the Parties for that control period, and the quantity sold solely for export to satisfy critical uses authorized by the Parties for that control period.

(3) * * *

(xiii) The amount of methyl bromide sold or transferred during the quarter to a person other than the producer solely for quarantine and preshipment applications;

(xiv) A list of the quantities of methyl bromide produced by the producer and exported by the producer and/or by other U.S. companies, to a Party to the Protocol that will be used solely for quarantine and preshipment applications and therefore were not produced expending production or consumption allowances; and

(xv) For quarantine and preshipment applications of methyl bromide in the United States or by a person of another Party, one copy of a certification that the material will be used only for quarantine and preshipment applications in accordance with the definitions in this subpart from each recipient of the material and a list of additional quantities shipped to that same person for the quarter.

(xvi) For critical uses of methyl bromide, producers shall report annually the amount of critical use methyl bromide owned by the reporting entity, specifying quantities dedicated for pre-plant use and quantities dedicated for post-harvest use, as well as quantities held by the reporting entity on behalf of another entity, specifying quantities dedicated for pre-plant use and quantities dedicated for post-harvest use along with the name of the entity on whose behalf the material is held; and

(xvii) A list of the quantities of methyl bromide produced by the producer and exported by the producer and/or by other U.S. companies in that control period, solely to satisfy the critical uses authorized by the Parties for that control period; and

* * * * *

(g) * * *

(1) * * *

(xi) The quantity of imports of used, recycled or reclaimed class I controlled substances;

* * * * *

(xv) Dated records of the quantity of controlled substances imported for an essential use;

* * * * *

(xvii) Dated records of the quantity of methyl bromide imported for quarantine and preshipment applications and quantity sold for quarantine and preshipment applications;

(xviii) Written certifications that quantities of methyl bromide imported solely for quarantine and preshipment applications were purchased by distributors or applicators to be used only for quarantine and preshipment applications in accordance with the definitions in this subpart; and

(xix) Written verifications from a U.S. purchaser that methyl bromide imported solely for quarantine and preshipment applications, if exported, will be exported solely for quarantine and preshipment applications upon receipt of a certification in accordance with the definitions of this Subpart and requirements in paragraph (h) of this section.

(xx) For methyl bromide, dated records such as invoices and order forms, of the quantity of controlled substances imported for critical use, specifying quantities dedicated for pre-plant use and quantities dedicated for post-harvest use, and the quantity sold for critical use, specifying quantities dedicated for pre-plant use and quantities dedicated for post-harvest use, and;

(xxi) Written certifications that quantities of methyl bromide imported for critical use were purchased by distributors, applicators, or approved critical users to be used or sold only for critical use in accordance with the definitions and prohibitions in this subpart. Certifications must be maintained by an importer for a minimum of three years.

(2) Petitioning—Importers of Used, Recycled or Reclaimed Controlled Substances. For each individual shipment over 5 pounds of a used controlled substance as defined in § 82.3, except for imports intended for destruction and Group II used controlled substances shipped in aircraft halon bottles for hydrostatic testing and imports intended for destruction, an importer must submit directly to the Administrator, at least 40 working days before the shipment is to leave the foreign port of export, the following information in a petition:

(i) Name, commodity code, and quantity in kilograms of the used controlled substance to be imported;

(ii) Name and address of the importer, the importer ID number, and the contact person's name, email address, and phone number;

(iii) Name, address, contact person, email address, and phone number of all previous source facilities from which the used controlled substance was recovered or the government agency storing the controlled substance;

(iv) A detailed description of the previous use of the controlled substance at each source facility and a best estimate of when the specific controlled substance was put into the equipment at each source facility, and, when possible, documents indicating the date the material was put into the equipment; or an official letter from the exporting country that the controlled substance is used;

* * * * *

(vi) Name, address, contact person, email address, and phone number of the exporter and of all persons to whom the material was transferred or sold after it was recovered from the source facility;

* * * * *

(viii) A description of the intended use of the used controlled substance, and, when possible, the name, address, contact person, email address, and phone number of the ultimate purchaser in the United States;

(ix) Name, address, contact person, email address, and phone number of the U.S. reclamation facility, where applicable;

(x) If someone at the source facility recovered the controlled substance from the equipment, the name, email address, and phone number of that person;

(xi) If the imported controlled substance was reclaimed in a foreign Party, the name, address, contact person, email address, and phone number of any or all foreign reclamation facility(ies) responsible for reclaiming the cited shipment;

(xii) An English translation of the export license, or application for an export license, from the appropriate government agency in the country of export and, if recovered in another country, the export license from the appropriate government agency in that country, and quantity authorized for export in kilograms on the export license(s);

(xiii) If the imported used controlled substance is intended to be sold as a refrigerant in the U.S., the name, address, and email address of the EPA-certified U.S. reclaimer who will bring the material to the standard required under section 608 (§ 82.152(g)) of the CAA, if not already reclaimed to those specifications.

* * * * *

(xv) If the used controlled substance is stored by a foreign national

government in a bank of used class I controlled substances, or by a privately-operated bank authorized by the foreign national government to collect and store class I controlled substances, an official letter from the appropriate government agency in that country where the material is stored may be provided in lieu of the information required in subparagraphs (iii) through (vi) of this paragraph.

(3) * * *

(i) * * *

(A) If the Administrator determines that the information is insufficient, that is, if the petition lacks or appears to lack any of the information required under § 82.13(g)(2) or other information that may be requested during the review of the petition necessary to verify that the controlled substance is used;

* * * * *

(vii) A person receiving the non-objection notice is permitted to import the individual shipment only within one year of the date stamped on the non-objection notice.

* * * * *

(4) * * *

(xv) The amount of methyl bromide sold or transferred during the quarter to a person other than the importer solely for quarantine and preshipment applications;

(xvi) A list of the quantities of methyl bromide exported by the importer and or by other U.S. companies, to a Party to the Protocol that will be used solely for quarantine and preshipment applications and therefore were not imported expending consumption allowances; and

(xvii) For quarantine and preshipment applications of methyl bromide in the United States or by a person of another Party, one copy of a certification that the material will be used only for quarantine and preshipment applications in accordance with the definitions in this subpart from each recipient of the material and a list of additional quantities shipped to that same person for the quarter.

(xviii) For critical uses of methyl bromide, importers shall report annually the amount of critical use methyl bromide owned by the reporting entity, specifying quantities dedicated for pre-plant use and quantities dedicated for post-harvest use, as well as quantities held by the reporting entity on behalf of another entity, specifying quantities dedicated for pre-plant use and quantities dedicated for post-harvest use along with the name of the entity on whose behalf the material is held.

* * * * *

(5) Certification of Intent to Import for Destruction. For each individual shipment of a class I controlled substance imported with the intent to destroy that substance, an importer must submit electronically to the Administrator, at least 30 working days before the shipment is to leave the foreign port of export, the following information:

(i) Name, commodity code, and quantity in kilograms of each controlled substance to be imported,

(ii) Name and address of the importer, the importer ID number, and the contact person's name, email address, and phone number;

(iii) The U.S. port of entry for the import, the expected date of shipment and the vessel transporting the chemical. If at the time of submitting the certification of intent to import for destruction the importer does not know the U.S. port of entry, the expected date of shipment and the vessel transporting the chemical, and the importer receives a non-objection notice for the individual shipment in the petition, the importer is required to notify the Administrator of this information prior to the U.S. entry of the individual shipment;

(iv) Name, address, contact person, email address, and phone number of the responsible party at the destruction facility;

(v) An English translation of an export license, or application for an export license, from the appropriate government agency in the country of export, and quantity authorized for export in kilograms on the export license(s);

(vi) A certification of accuracy of the information submitted in the certification.

(6) For each individual shipment of a class I controlled substance imported with the intent to destroy that substance, an importer must submit to the Administrator a copy of the destruction verification within 30 days after destruction of the controlled substance(s).

(7)(i) Starting on the first working day following receipt by the Administrator of a certification of intent to import a class II controlled substance for destruction, the Administrator will initiate a review of the information submitted under paragraph (c)(6) of this section and take action within 30 working days to issue either an objection-notice or a non-objection notice for the individual shipment to the person who submitted the certification of intent to import the class II controlled substance for destruction.

(ii) The Administrator may issue an objection notice if the petition lacks or appears to lack any of the information required under this subparagraph or for the reasons listed in § 82.24(c)(4)(i)(B)–(E).

(iii) In cases where the Administrator does not object to the petition, the Administrator will issue a non-objection notice.

(iv) To pass the approved class II controlled substances through U.S. Customs, the non-objection notice issued by EPA must accompany the shipment through U.S. Customs.

(v) If for some reason, following EPA's issuance of a non-objection notice, new information is brought to EPA's attention which shows that the non-objection notice was issued based on false information, then EPA has the right to:

(A) Revoke the non-objection notice;

(B) Pursue all means to ensure that the class II controlled substance is not imported into the U.S.; and

(C) Take appropriate enforcement actions.

(8) A person receiving the non-objection notice is permitted to import the individual shipment only within one year of the date stamped on the non-objection notice.

(9) A person receiving a non-objection notice from the Administrator for a certification of intent to import class I controlled substances for destruction must maintain the following records:

(i) A copy of the certificate of intent to import for destruction;

(ii) The EPA non-objection notice;

(iii) A copy of the export license or export license application;

(iv) U.S. Customs entry documents for the import that must include one of the commodity codes from Appendix K to this subpart;

(v) The date, amount, and type of controlled substance sent for destruction, per shipment;

(vi) An invoice from the destruction facility verifying the shipment was received; and

(vii) A copy of the destruction verification from the destruction facility.

(h) * * *

(1) For any exports of class I controlled substances (except methyl bromide) not reported under paragraph (f)(3) of this section (reporting for producers of controlled substances), the exporter who exported a class I controlled substance (except methyl bromide) must submit to the Administrator the following information within 45 days after the end of the control period in which the unreported exports left the United States:

(i) * * *

(ii) The exporter's Employer Identification Number;

(iii) The type and quantity of each controlled substance exported including the quantity of controlled substance that is used, recycled or reclaimed.

* * * * *

(2) For any exports of methyl bromide not reported under paragraph (f)(3) of this section (reporting for producers of controlled substances), the exporter who exported methyl bromide must submit to the Administrator the following information within 45 days after the end of each quarter in which the unreported exports left the United States:

(i) * * *

(ii) The exporter's Employer Identification Number;

(iii) The quantity of methyl bromide exported by use (transformation, destruction, critical use, or quarantine and preshipment);

(iv) The date on which, and the port from which, the methyl bromide was exported from the United States or its territories;

(v) The country to which the methyl bromide was exported;

* * * * *

(viii) The invoice or sales agreement containing language similar to the Internal Revenue Service Certificate that the purchaser or recipient of imported methyl bromide intends to transform those substances, the destruction verifications (as in paragraph (k) of this section) showing that the purchaser or recipient intends to destroy the controlled substances, or the certification that the purchaser or recipient and the eventual applicator will only use the material for quarantine and preshipment applications in accordance with the definitions in this subpart.

* * * * *

(v) Any distributor of laboratory supplies who purchased controlled substances under the global essential laboratory and analytical use exemption must submit quarterly the quantity of each controlled substance purchased by each laboratory customer or distributor whose certification was previously provided to the distributor pursuant to paragraphs (w) of this section, the contact information for the source company from which material was purchased, and the laboratories to whom the material is sold.

(w) * * *

(2) The name, email address, and phone number of a contact person for the laboratory customer;

* * * * *

(y) Every distributor of methyl bromide who purchases or receives a quantity produced or imported for quarantine or preshipment applications under the exemptions in this subpart must comply with the following recordkeeping and reporting requirements:

(1) Every distributor of quarantine and preshipment methyl bromide must certify to the producer, importer, or distributor from whom they purchased or received the controlled substance that quantities purchased or received will be sold only for quarantine applications or preshipment applications in accordance with the definitions in this subpart.

(2) Every distributor of quarantine and preshipment methyl bromide must receive from an applicator, exporter, or distributor to whom they sell or deliver the controlled substance a certification, prior to delivery, stating that the quantity will be used or sold solely for quarantine applications or preshipment applications in accordance with definitions in this subpart.

(3) Every distributor of quarantine and preshipment methyl bromide must maintain the certifications as records for 3 years.

(4) Every distributor of quarantine and preshipment methyl bromide must report to the Administrator within 45 days after the end of each quarter, the total quantity delivered to applicators or end users for quarantine applications and preshipment applications in accordance with definitions in this Subpart.

(z) Every applicator of methyl bromide who purchases or receives a quantity produced or imported solely for quarantine or preshipment applications under the exemptions in this subpart must comply with the following recordkeeping and reporting requirements:

(1) Recordkeeping—Applicators. Every applicator of methyl bromide produced or imported for quarantine and preshipment applications under the exemptions of this subpart must maintain, for every application, a document from the commodity owner, shipper or their agent requesting the use of methyl bromide citing the requirement that justifies its use in accordance with definitions in this subpart. These documents shall be retained for 3 years.

(2) Reporting—Applicators. Every applicator who purchases or receives methyl bromide that was produced or imported for quarantine and preshipment applications under the exemptions in this subpart shall provide the distributor of the methyl bromide, prior to shipment, with a certification that the methyl bromide will be used only for quarantine applications or preshipment applications as defined in this subpart.

(aa) Every commodity owner, shipper or their agent requesting an applicator to use methyl bromide that was produced or imported solely for quarantine and preshipment applications under the exemptions of this subpart must maintain a record for 3 years, for each request, certifying knowledge of the requirements associated with the exemption for quarantine and preshipment applications in this subpart and citing the requirement that justifies its use. The record must include the following statement: ''I certify knowledge of the requirements associated with the exempted quarantine and preshipment applications published in 40 CFR part 82, including the requirement that this letter cite the treatments or official controls for quarantine applications or the official requirements for preshipment requirements.''

* * * * *

■ 8. Add § 82.14 to read as follows:

§ 82.14 Process for electronic reporting.

(a) Submissions of reports that are available to be submitted through the Central Data Exchange, import petitions, and certifications of intent to import ODS for destruction and any related supporting documents must be submitted electronically to EPA via the Central Data Exchange.

(b) You can register and access the Central Data Exchange as follows:

(1) Go to EPA's Central Data Exchange website at *https://cdx.epa.gov* and follow the links for the submission of ozone-depleting substances.

(2) Call EPA's Central Data Exchange Help Desk at 1–888–890–1995.

(3) Email the EPA's Central Data Exchange Help Desk at *HelpDesk@epacdx.net*.

■ 9. Amend § 82.15 by:

■ a. Redesignating paragraphs (g)(5) and (g)(6) as (g)(6) and (g)(7), respectively; and

■ b. Adding paragraphs (b)(3), (g)(5) and (g)(8).

The additions read as follows:

§ 82.15 Prohibitions for class II controlled substances.

* * * * *

(b) * * *

(3) Effective [date 30 days after effective date of final rule], no person may import for purposes of destruction, at any time in any control period, a class II controlled substance for which EPA has apportioned baseline production and consumption allowances, without having submitted a certification of intent to import for destruction to the Administrator and received a non-objection notice in accordance with

§ 82.24(c)(6). A person issued a non-objection notice for the import of an individual shipment of class II controlled substances for destruction may not transfer or confer the right to import, and may not import any more than the exact quantity (in kilograms) of the class II controlled substance stated in the non-objection notice. For imports intended to be destroyed in the U.S., a person issued a non-objection notice must destroy the controlled substance in the year cited in the non-objection letter, may not transfer or confer the right to import, and may not import any more than the exact quantity (in kilograms) of the class II controlled substance stated in the non-objection notice. Every kilogram of import of class II controlled substance in excess of the quantity stated in the non-objection notice issued by the Administrator in accordance with § 82.24(c)(6) constitutes a separate violation of this subpart.

* * * * *

(g) * * *

(5) (i) Effective January 1, 2020, no person may introduce into interstate commerce or use HCFC–123 or HCFC–124 (unless used, recovered and recycled) for any purpose other than for use in a process resulting in its transformation or its destruction; for use as a refrigerant in equipment manufactured before January 1, 2020; for use as a fire suppression streaming agent listed as acceptable for use or acceptable subject to narrowed use limits for nonresidential applications in accordance with the regulations at subpart G of this part to the extent permitted under paragraph (ii) of this subsection; for export to Article 5 Parties under § 82.18(a); as a transshipment or heel; or for exemptions permitted under paragraph (f) of this section.

(ii) HCFC–123 that was produced or imported after January 1, 2020 may be used as a fire suppression streaming agent only to service equipment manufactured before January 1, 2020. HCFC–123 that was produced or imported prior to January 1, 2020 (or used, recovered and recycled) may be used as a fire suppression streaming agent in equipment manufactured before or after January 1, 2020.

(iii) Notwithstanding the prohibition on use in paragraph (g)(5)(i) of this section, the use of HCFC–123 as a refrigerant in equipment manufactured between January 1, 2020 and December 31, 2020 is permitted if the conditions of this paragraph are met. The HCFC–123 must be in the possession of an entity that will complete the manufacture of the appliance and imported prior to January 1, 2020. The appliance components must be ready for shipment to a construction location prior to July 24, 2019 and be specified in a building permit or a contract dated before July 24, 2019 for use on a particular project. All HCFC–123 used to service such appliances on or after January 1, 2021 must be used, recovered, or recycled/reclaimed.

* * * * *

(8) Effective [DATE 30 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], no person may sell or distribute, or offer for sale or distribution, any class II substance that they know, or have reason to know, was imported in violation of this section, except for such actions needed to re-export the controlled substance. Every kilogram of a controlled substance imported in contravention of this paragraph that is sold or distributed, or offered for sale or distribution, constitutes a separate violation of this subpart.

10. Amend § 82.16 by revising the tables in paragraph (a) and revising paragraph (e).

§ 82.16 Phaseout schedule of class II controlled substances.

(a) *Calendar-year Allowances.* (1) In each control period as indicated in the following tables, each person is granted the specified percentage of baseline production allowances and baseline consumption allowances for the specified class II controlled substances apportioned under § 82.17 and § 82.19:

TABLE 1 TO PARAGRAPH (a) CALENDAR-YEAR HCFC PRODUCTION ALLOWANCES

Control period	Percent of HCFC–141b	Percent of HCFC–22	Percent of HCFC–142b	Percent of HCFC–123	Percent of HCFC–124	Percent of HCFC–225ca	Percent of HCFC–225cb
2003	0	100	100				
2004	0	100	100				
2005	0	100	100				
2006	0	100	100				
2007	0	100	100				
2008	0	100	100				
2009	0	100	100				
2010	0	41.9	0.47	0	125	125	125
2011	0	32	4.9	0	125	125	125
2012	0	17.7	4.9	0	125	125	125
2013	0	30.1	4.9	0	125	125	125
2014	0	26.1	4.9	0	125	125	125
2015	0	21.7	0.37	0	5	0	0
2016	0	21.7	0.32	0	5	0	0
2017	0	21.7	0.26	0	5	0	0
2018	0	21.7	0.21	0	5	0	0
2019	0	21.7	0.16	0	5	0	0
2020	0	0	0	0	8	0	0
2021	0	0	0	0	8	0	0
2022	0	0	0	0	8	0	0
2023	0	0	0	0	7	0	0
2024	0	0	0	0	6	0	0
2025	0	0	0	0	5	0	0
2026	0	0	0	0	4	0	0
2027	0	0	0	0	3	0	0
2028	0	0	0	0	2	0	0
2029	0	0	0	0	1	0	0
2030	0	0	0	0	0	0	0

TABLE 2 TO PARAGRAPH (a) CALENDAR-YEAR HCFC CONSUMPTION ALLOWANCES

Control period	Percent of HCFC–141b	Percent of HCFC–22	Percent of HCFC–142b	Percent of HCFC–123	Percent of HCFC–124	Percent of HCFC–225ca	Percent of HCFC–225cb
2003	0	100	100				
2004	0	100	100				
2005	0	100	100				
2006	0	100	100				
2007	0	100	100				
2008	0	100	100				
2009	0	100	100				
2010	0	41.9	0.47	125	125	125	125
2011	0	32	4.9	125	125	125	125
2012	0	17.7	4.9	125	125	125	125
2013	0	18	4.9	125	125	125	125
2014	0	14.2	4.9	125	125	125	125
2015	0	7	1.7	100	8.3	0	0
2016	0	5.6	1.5	100	8.3	0	0
2017	0	4.2	1.2	100	8.3	0	0
2018	0	2.8	1	100	8.3	0	0
2019	0	1.4	0.7	100	8.3	0	0
2020	0	0	0	32.3	8	0	0
2021	0	0	0	32.3	8	0	0
2022	0	0	0	32.3	8	0	0
2023	0	0	0	28	7	0	0
2024	0	0	0	24	6	0	0
2025	0	0	0	20	5	0	0
2026	0	0	0	16	4	0	0
2027	0	0	0	12	3	0	0
2028	0	0	0	8	2	0	0
2029	0	0	0	4	1	0	0
2030	0	0	0	0	0	0	0

* * * * *

(e)(1) Effective January 1, 2020, no person may produce HCFC–22 or HCFC–142b for any purpose other than for use in a process resulting in their transformation or their destruction, for export under § 82.18(a) using unexpended Article 5 allowances, or for exemptions permitted in § 82.15(f). Effective January 1, 2020, no person may import HCFC–22 or HCFC–142b for any purpose other than for use in a process resulting in their transformation or their destruction, or for exemptions permitted in § 82.15(f).

(2) Effective January 1, 2020, no person may produce HCFC–123 for any purpose other than for use in a process resulting in its transformation or its destruction, for use as a refrigerant in equipment manufactured before January 1, 2020, for export under § 82.18(a) using unexpended Article 5 allowances, or for exemptions permitted in § 82.15(f). Effective January 1, 2020, no person may import HCFC–123 for any purpose other than for use in a process resulting in its transformation or its destruction, for use as a refrigerant in equipment manufactured before January 1, 2020, for use as a fire suppression streaming agent in equipment manufactured before January 1, 2020 listed as acceptable for use or acceptable subject to narrowed use limits for nonresidential applications, or for exemptions permitted in § 82.15(f).

* * * * *

■ 11. Amend § 82.23 by

■ a. Removing and reserving paragraph (a)(i)(F); and

■ b. Adding paragraphs (b)(1)(i) and (ii).

The addition reads as follows:

§ 82.23 Transfers of allowances of class II controlled substances.

* * * * *

(b) * * *

(1) * * *

(i) Effective January 1, 2020, a person (transferor) may only convert allowances for one class II controlled substance for which EPA has issued allowances under § 82.16 to another class II controlled substance for which EPA has issued allowances under § 82.16.

(ii) [Reserved].

* * * * *

■ 12. Amend § 82.24 by:

■ a. Revising paragraphs (a)(1), (b)(2)(iv), (c)(3)(i)–(iii), (vi), (viii)–(xiii), (c)(4)(i)(A), (c)(4)(vii), and (d)(1) introductory text;

■ b. Removing and reserving paragraphs (b)(1)(iv), (ix), and (xi), (b)(2)(xii) and (xiv), (c)(1)(vi) and (xi), (c)(2)(xvi), (d)(2), and (g); and

■ c. Adding paragraphs (c)(6)–(10).

The revisions and addition read as follows:

§ 82.24 Recordkeeping and reporting requirements for class II controlled substances.

(a) * * *

(1) Reports required by this section must be submitted to the Administrator within 45 days of the end of the applicable reporting period, unless otherwise specified. Starting [date 30 days after effective date of final rule], reports that are available for submission through the Central Data Exchange must be submitted electronically through that tool.

* * * * *

(b) * * *

(2) * * *

(iv) Dated records of the quantity (in kilograms) of class II controlled substances produced with Article 5 allowances;

* * * * *

(c) * * *

(3) * * *

(i) The name, commodity code and quantity (in kilograms) of the used class II controlled substance to be imported;

(ii) The name and address of the importer, the importer ID number, the contact person, email address, and phone number;

(iii) Name, address, contact person, email address, and phone number of all previous source facilities from which

the used class II controlled substance was recovered;

* * * * *

(vi) Name, address, contact person, email address, and phone number of the exporter and of all persons to whom the material was transferred or sold after it was recovered from the source facility;

* * * * *

(viii) A description of the intended use of the used class II controlled substance, and, when possible, the name, address, contact person, email address, and phone number of the ultimate purchaser in the United States;

(ix) The name, address, contact person, email address, and phone number of the U.S. reclamation facility, where applicable;

(x) If someone at the source facility recovered the class II controlled substance from the equipment, the name, email address, and phone number of that person;

(xi) If the imported class II controlled substance was reclaimed in a foreign Party, the name, address, contact person, email address, and phone number of any or all foreign reclamation facility(ies) responsible for reclaiming the cited shipment;

(xii) An English translation of an export license, or application for an export license, from the appropriate government agency in the country of export and, if recovered in another country, the export license from the appropriate government agency in that country, and quantity authorized for export in kilograms on the export license(s);

(xiii) If the imported used class II controlled substance is intended to be sold as a refrigerant in the U.S., the name, address, and email address of the EPA-certified U.S. reclaimer who will bring the material to the standard required under subpart F of this part, if not already reclaimed to those specifications.

(4) * * *

(i) * * *

(A) If the Administrator determines that the information is insufficient, that is, if the petition lacks or appears to lack any of the information required under paragraph (c)(3) of this section or other information that may be requested during the review of the petition necessary to verify that the controlled substance is used;

* * * * *

(vii) A person receiving the non-objection notice is permitted to import the individual shipment only within one year of the date stamped on the non-objection notice.

* * * * *

(6) Certification of Intent to Import for Destruction. For each individual shipment of a class II controlled substance imported with the intent to destroy that substance, an importer must submit electronically to the Administrator, at least 30 working days before the shipment is to leave the foreign port of export, the following information:

(i) Name, commodity code, and quantity in kilograms of each controlled substance to be imported,

(ii) Name and address of the importer, the importer ID number, and the contact person's name, email address, and phone number;

(iii) The U.S. port of entry for the import, the expected date of shipment and the vessel transporting the chemical. If at the time of submitting the certification of intent to import for destruction the importer does not know the U.S. port of entry, the expected date of shipment and the vessel transporting the chemical, and the importer receives a non-objection notice for the individual shipment in the petition, the importer is required to notify the Administrator of this information prior to the U.S. entry of the individual shipment;

(iv) Name, address, contact person, email address, and phone number of the responsible party at the destruction facility;

(v) An English translation of an export license, or application for an export license, from the appropriate government agency in the country of export, and quantity authorized for export in kilograms on the export license(s);

(vi) A certification of accuracy of the information submitted in the certification.

(7) For each individual shipment of a class II controlled substance imported with the intent to destroy that substance, an importer must submit to the Administrator a copy of the destruction verification within 30 days after destruction of the controlled substance(s).

(8) (i) Starting on the first working day following receipt by the Administrator of a certification of intent to import a class II controlled substance for destruction, the Administrator will initiate a review of the information submitted under paragraph (c)(6) of this section and take action within 30 working days to issue either an objection-notice or a non-objection notice for the individual shipment to the person who submitted the certification of intent to import the class II controlled substance for destruction.

(ii) The Administrator may issue an objection notice if the petition lacks or appears to lack any of the information required under this subparagraph or for the reasons listed in § 82.24(c)(4)(i)(B)–(E).

(iii) In cases where the Administrator does not object to the petition, the Administrator will issue a non-objection notice.

(iv) To pass the approved class II controlled substances through U.S. Customs, the non-objection notice issued by EPA must accompany the shipment through U.S. Customs.

(v) If for some reason, following EPA's issuance of a non-objection notice, new information is brought to EPA's attention which shows that the non-objection notice was issued based on false information, then EPA has the right to:

(A) Revoke the non-objection notice;

(B) Pursue all means to ensure that the class II controlled substance is not imported into the U.S.; and

(C) Take appropriate enforcement actions.

(9) A person receiving the non-objection notice is permitted to import the individual shipment only within one year of the date stamped on the non-objection notice.

(10) A person receiving a non-objection notice from the Administrator for a certification of intent to import class II controlled substances for destruction must maintain the following records:

(i) A copy of the certificate of intent to import for destruction;

(ii) The EPA non-objection notice;

(iii) A copy of the export license or export license application;

(iv) U.S. Customs entry documents for the import that must include one of the commodity codes from Appendix K to this subpart;

(v) The date, amount, and type of controlled substance sent for destruction, per shipment;

(vi) An invoice from the destruction facility verifying the shipment was received; and

(vii) A copy of the destruction verification from the destruction facility.

(d) * * *

(1) Reporting—Exporters. For any exports of class II controlled substances not reported under paragraph (b)(2) of this section (reporting for producers of class II controlled substances), each exporter who exported a class II controlled substance must submit to the Administrator the following information within 30 days after the end of each quarter in which the unreported exports left the U.S.:

* * * * *

■ 13. Revise Appendix K to read as follows:

Appendix K to Subpart A of Part 82—Commodity Codes From the Harmonized Tariff Schedule for Controlled Substances and Used Controlled Substances

Description of commodity or chemical	Commodity code from harmonized tariff schedule
Class II:	
HCFC-22 (Chlorodifluoromethane)	2903.71.0000
HCFC-123 (Dichlorotrifluoroethane)	2903.72.0020
HCFC-124 (Monochlorotetrafluoroethane)	2903.79.1000
HCFC-141b (Dichlorofluoroethane)	2903.73.0000
HCFC-142b (Chlorodifluoroethane)	2903.74.0000
HCFC-225ca, HCFC-225cb (Dichloropentafluoropropanes)	2903.75.0000
HCFC-21, HCFC-31, HCFC-133, and other HCFCs	2903.79.9070
HCFC Mixtures (R-401A, R-402A, etc.)	3824.74.0000
Class I:	
CFC-11 (Trichlorofluoromethane)	2903.77.0010
CFC-12 (Dichlorodifluoromethane)	2903.77.0050
CFC-113 (Trichlorotrifluoroethane)	2903.77.0020
CFC-114 (Dichlorotetrafluoroethane)	2903.77.0030
CFC-115 (Monochloropentafluoroethane)	2903.77.0040
CFC-13, CFC-111, CFC-112, CFC-211, CFC-212, CFC-213, CFC-214, CFC-215, CFC-216, CFC-217, and other CFCs	2903.77.0080
CFC Mixtures (R-500, R-502, etc.)	3824.71.0100
Carbon Tetrachloride	2903.14.0000
Halon 1301 (Bromotrifluoromethane)	2903.76.0010
Halon, other	2903.76.0050
Methyl Bromide	2903.39.1520
Methyl Chloroform	2903.19.6010

■ 14. Amend § 82.62 by adding, in alphabetical order, the definition for ''polyurethane foam systems'' to read as follows:

§ 82.62 Definitions.

* * * * *

Polyurethane Foam System means an item consisting of two transfer pumps that deliver ingredients (polyisocyanate or isocyanate from one side and a mixture including the blowing agent, catalysts, flame retardants, and/or stabilizers from the other side) to a metering/mixing device which allows the components to be delivered in the appropriate proportions.

* * * * *

■ 15. Amend § 82.66 by:

■ a. Revising paragraphs (d)(2)(vi) and (e); and

■ b. Adding paragraph (f).

The revisions and addition read as follows:

§ 82.66 Nonessential Class I products and exceptions.

* * * * *

(d) * * *

(2) * * *

(vi) Document preservation sprays which contain CFC-113 as a solvent, but which contain no other CFCs, and/or document preservation sprays which contain CFC-12 as a propellant, but which contain no other CFCs, and which are used solely on thick books, books with coated or dense paper and tightly bound documents;

(e) Any air-conditioning or refrigeration appliance as defined in CAA 601(l) that contains a Class I substance used as a refrigerant; and

(f) Any polyurethane foam system that contains any CFC.

■ 16. Amend § 82.104 by revising paragraphs (c) and (h) introductory text to read as follows:

§ 82.104 Definitions.

* * * * *

(c) *Completely destroy* means to cause the destruction of a controlled substance by one of the destruction processes approved by the Parties and listed in § 82.3 of subpart A at a demonstrable destruction efficiency of 98 percent or more or a greater destruction efficiency if required under other applicable federal regulations.

* * * * *

(h) *Destruction* means the expiration of a controlled substance to the destruction efficiency actually achieved, unless considered completely destroyed as defined in this section. Such destruction might result in a commercially useful end product but such usefulness would be secondary to the act of destruction. Destruction must be achieved using one of the controlled processes approved by the Parties and listed in the definition of *destruction* in § 82.3 of subpart A.

* * * * *

■ 17. Amend § 82.106 by revising paragraph (a) to read as follows:

§ 82.106 Warning statement requirements.

(a) Effective January 1, 2020, each container of fire suppression agent containing HCFC-123 produced or imported after that date shall bear the following warning statement, meeting the requirements of this subpart for placement and form:

WARNING: Contains [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere. Do not use to service equipment manufactured on or after January 1, 2020.

* * * * *

■ 18. Amend § 82.270 by revising paragraph (e) introductory text to read as follows:

§ 82.270 Prohibitions.

* * * * *

(e) Effective April 6, 1998, no person shall dispose of halon except by sending it for recycling to a recycler operating in accordance with NFPA 10 and NFPA 12A standards, or by arranging for its destruction using one of the controlled processes approved by the Parties and listed in the definition of *destruction* in § 82.3 of subpart A.

* * * * *

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Part V

Department of Transportation

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, 172, et al.
Hazardous Materials: Adoption of Miscellaneous Petitions To Reduce Regulatory Burdens; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, 172, 173, 178, 179, and 180

[Docket No. PHMSA–2017–0120 (HM–219C)]

RIN 2137–AF33

Hazardous Materials: Adoption of Miscellaneous Petitions To Reduce Regulatory Burdens

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This rulemaking responds to numerous petitions for rulemaking submitted by the regulated community that request PHMSA address a variety of provisions, including but not limited to those addressing packaging, hazardous communication, and incorporation by reference documents. PHMSA proposes amendments to the Hazardous Materials Regulations to update, clarify, improve the safety of, or provide relief from various regulatory requirements. The proposed amendments include adopting a phase-out schedule for certain railroad tank cars used to transport materials poisonous by inhalation, allowing the continued use of certain portable and mobile refrigerator systems commonly used in the produce industry, incorporating an industry standard that can help to enhance the production of oil and gas wells, and incorporating an updated consensus standard which applies to the existing market for fireworks; as well as additional proposed amendments derived from PHMSA's petition for rulemaking process.

DATES: Comments must be submitted by October 15, 2019. To the extent possible, PHMSA will consider late-filed comments as a final rule is developed.

ADDRESSES: You may submit comments by identification of the docket number (PHMSA–2017–0120 (HM–219C)) by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Dockets Management System; U.S. Department of Transportation, Dockets Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* To U.S. Department of Transportation, Dockets Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and docket number for this notice at the beginning of the comment. All comments received will be posted without change to the Federal Docket Management System (FDMS), including any personal information.

Docket: For access to the dockets to read background documents (including the Preliminary Regulatory Impact Analysis (PRIA)) or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (see **ADDRESSES**).

FOR FURTHER INFORMATION CONTACT: Steven Andrews or Candace Casey at (202) 366–8553 at the Office of Hazardous Materials Standards, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

Abbreviations and Terms

AAR Association of American Railroads
ACC American Chemistry Council
ADR European Agreement Concerning the International Carriage of Dangerous Goods by Road
AESC Association of Energy Service Companies
APA American Pyrotechnics Association
ASME American Society of Mechanical Engineers
ASME BPVC ASME Boiler and Pressure Vessel Code
ATCCRP Advanced Tank Car Collaborative Research Program
CPC Casualty Prevention Circular
CEQ Council on Environmental Quality
CGA Compressed Gas Association
COSTHA Council on Safe Transportation of Hazardous Articles
DGTA Dangerous Goods Trainers Association
DOT Department of Transportation
EPA Environmental Protection Agency
GVWR Gross Vehicle Weight Rating
HMR Hazardous Materials Regulations
HMT Hazardous Materials Table (49 CFR 172.101)
IAEA International Atomic Energy Agency
IBC Intermediate Bulk Container
IBR Incorporation by Reference
ICAO International Civil Aviation Organization
ICAO Technical Instructions ICAO Technical Instructions for the Safe Transport of Dangerous Goods
IIAR International Institute of Ammonia Refrigeration
IMDG Code International Maritime Dangerous Goods Code
IME Institute of Makers of Explosives
JPG Jet Perforating Gun
MAWP Maximum Allowable Working Pressure
MTC Manual of Tests and Criteria
NPRM Notice of Proposed Rulemaking
OMB Office of Management and Budget
PHMSA Pipeline and Hazardous Materials Safety Administration
PIH Poison Inhalation Hazard
PRD Pressure Relief Device
PRIA Preliminary Regulatory Impact Analysis
PSI Pounds per Square Inch
PSIG Pounds per Square Inch Gauge
RCRA Resource Conservation and Recovery Act
RID European Agreement Concerning the International Carriage of Dangerous Goods by Rail
RIPA Reusable Industrial Packaging Association
RSI Railway Supply Institute
TDG Transport of Dangerous Goods
TPED Transportable Pressure Equipment Directive
TTMA Truck Trailer Manufacturers Association
UN Model Regulations United Nations Recommendations on the Transport of Dangerous Goods: Model Regulations
Unified Agenda Unified Agenda of Federal Regulatory and Deregulatory Actions
UNSCOE TDG United Nations Sub-Committee of Experts on the Transport of Dangerous Goods

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I. Background

The Administrative Procedure Act requires Federal agencies to give interested persons the right to petition an agency to issue, amend, or repeal a rule (*See* 5 U.S.C. 553(e)). PHMSA's rulemaking procedure regulations (*See*

49 Code of Federal Regulations (CFR) 106.95) allows persons to ask PHMSA to add, revise, or delete a regulation by filing a petition for rulemaking containing adequate support for the requested action. In this NPRM, PHMSA (also ''we'' or ''us'') proposes to amend the HMR in response to petitions for rulemaking submitted by shippers, carriers, manufacturers, and industry representatives. These proposed revisions are intended to reduce regulatory burdens while maintaining, or enhancing, the existing level of safety. We discuss the petitions and proposals in detail in Section II of this NPRM. In this NPRM, PHMSA proposes to:

- Prohibit after December 31, 2020, the use of rail tank cars with shells or heads constructed of non-normalized steel used for transportation of poison-by-inhalation (PIH) materials.
- Harmonize the limited quantity exceptions for more than 100 entries for corrosive materials in the HMT.
- Revise § 173.302(b)(2) to allow a minimum height of 12 mm (0.47 inches) for a proper shipping name marked on a portable tank with a capacity of less than 3,785 L (1,000 gallons).
- Revise § 173.28(c)(1)(i) to add the words ''substantially removed'' in the context of cleaning metal drums for reuse and clarifying the requisite cleaning standard.
- Revise § 173.5b to allow for the continued use of Portable and Mobile Refrigerator Systems placed into service prior to 1991 that are rated to a minimum service pressure of 250 pounds per square inch (psig).
- Incorporate by reference updated versions of multiple CGA publications.
- Remove the reference to Special Provision 103 in § 172.101 from Column (7) for four HMT entries to allow them to be shipped as safety devices.
- Revise the HMT entry for ''UN0503, Safety Devices, pyrotechnic'' to allow the shipper to use the exceptions provided in § 173.166(d).
- Remove the words ''manufactured before September 1, 1995'' from § 180.417(a)(3) to allow for an alternative report for cargo tanks manufactured after September 1, 1985.
- Revise the basis weight tolerance provided in § 178.521 from ±5 percent to ±10 percent from the nominal basis weight reported in the initial design qualification test report for paper shipping sacks.
- Revise § 173.308(d)(3) to harmonize with the IMDG Code by removing the requirement for a closed transport container to have the warning mark ''WARNING—MAY CONTAIN EXPLOSIVE MIXTURES WITH AIR—KEEP IGNITION SOURCES AWAY WHEN OPENING'' when transporting lighters.
- Make the ''interim'' rail tank car specifications the ''final'' specifications for the transportation of PIH materials.
- Prohibit after December 31, 2027, the use of certain rail tank cars for the transportation of PIH materials.
- Allow for all waste materials to be managed in accordance with the lab pack exception and associated paragraphs in § 173.12 irrespective of whether they meet the definition of a hazardous waste per the EPA or the RCRA.
- Incorporate by reference the 2017 version of the ASME BPVC Sections II (Parts A and B, C and D), VIII (Division 1), and IX into the HMR.
- Revise §§ 171.23, 173.302, and 173.304 to permit the import of filled pi-marked foreign pressure receptacles for intermediate storage, transport to point of use, discharge, and export as well as the import of certain pi-marked foreign pressure receptacles filling, intermediate storage, and export.
- Revise the language in § 173.166 to clarify the term ''recycle'' by adding the word ''metal'' in front of ''recycling.''
- Correct § 171.7(r) to include the address of the IME and to incorporate the IME/Association of Energy Service Companies (AESC) JPG Standard, also known as the ''*Guide to Obtaining DOT Approval of Jet Perforating Guns using AESC/IME Perforating Gun Specifications,*'' Ver. 02, dated September 1, 2017 as material incorporated by reference.
- Update to the January 1, 2018 version of the APA Standard 87–1, ''*Standard for Construction and Approval for Transportation of Fireworks, Novelties, and Theatrical Pyrotechnics*'', which is currently incorporated by reference in § 171.7(f) of the HMR.

II. Review of Proposed Amendments

1. Phase-Out of Non-Normalized Tank Cars Used To Transport PIH Materials

In its petition (P–1646), AAR requested that PHMSA consider an amendment to prohibit the use of rail tank cars with shells or heads constructed of non-normalized steel for transportation of PIH materials. In its petition, AAR states that the use of pressurized tank cars constructed from non-normalized steel for rail transportation of PIH materials poses an unnecessary risk to the public. AAR adds that non-normalized steel is susceptible to brittle fractures at lower temperatures, and brittle fractures are far more likely to result in a catastrophic failure and instantaneous release of a car's entire contents than ductile fractures. While a slow release of contents generally has time to dissipate in the atmosphere, AAR notes that an instantaneous release creates a concentrated toxic cloud with potential catastrophic consequences for the nearby population. AAR has required that tank cars built since 1989 and used in PIH service must be constructed of normalized steel.

PHMSA believes the phase-out of these legacy rail tank cars would have a positive impact on safety due to their replacement with more robust tanks cars used for the transportation of PIH materials. On April 7, 2017, AAR adopted CPC–1325, which implemented a phase-out of these non-normalized (legacy) steel tank cars in PIH service by July 1, 2019. On July 27, 2018, AAR revised CPC–1325 and re-issued it as CPC–1336, but kept the July 1, 2019 phase-out deadline for the non-normalized steel tank cars. CPC–1336 is incorporated into the AAR members' railroad interchange rules that railroads require compliance with as a condition of shipping hazardous materials by rail. PHMSA proposes to respond to P–1646 by codifying a phase-out of these non-normalized steel tank cars in the HMR that would take effect as of December 31, 2020. PHMSA proposes this date as a general approximation of when this rulemaking is expected to be finalized. However, the AAR phase-out is expected to go into effect regardless of whether PHMSA adopts July 1, 2019, December 31, 2020, or another date into regulation. As a result, there is no cost associated with PHMSA aligning this date as a regulatory deadline. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in phasing-out these non-normalized rail tank cars used for the transportation of PIH materials. In this NPRM, PHMSA is proposing to revise § 173.31 to phase-out non-normalized steel rail tank cars for the transportation of PIH materials by December 31, 2020.

2. Limited Quantity Shipments of Hydrogen Peroxide

In its petition (P–1658), Steris requested a revision to the HMT for limited quantities of hydrogen peroxide. Specifically, this petition requests that PHMSA harmonize Column (8A) packaging exceptions for limited quantities of ''UN2014, Hydrogen peroxide aqueous solution,'' with the UN Model Regulations. Currently, the HMT does not allow the limited quantity exception for UN2014, while

various other international standards and regulations such as the UN Model Regulations provide for transport of UN2014 in limited quantities, up to 60 percent concentration. Steris argues that harmonizing with the UN Model Regulations would provide economic and logistics consistency in global transport of this material in limited quantities and would facilitate commerce for domestic companies.

The shipment of limited quantities of materials similar to those proposed in this petition is already permitted under the HMR. Therefore, PHMSA believes that expanding the exceptions to these additional materials would not cause a reduction in safety. In addition, because these are exceptions to the HMR, PHMSA would expect cost savings to be achieved if the proposal is finalized. However, due to a lack of national data on these types of shipments, PHMSA was unable to quantify the specific cost savings that would result from this change. A more detailed discussion of this economic analysis of this proposal can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in proposing this revision to the HMT. In this NPRM, PHMSA is proposing to revise Column (8A) of the HMT for ''UN2014, Hydrogen peroxide aqueous solution'' to allow limited quantities packaging exceptions for this material by referencing § 173.152 for exceptions for Division 5.1 oxidizers.

3. Markings on Portable Tanks

In his petition (P–1666), William J. Briner suggested that the HMR be revised, consistent with § 172.302(b)(2) and Section 5.3.2.0.2 of the IMDG Code, to allow a minimum height of 12 mm (0.47 inches) for proper shipping name markings on portable tanks with a capacity of less than 3,000 L (792.52 gallons). The revision would also eliminate confusion about the size of markings on portable tanks, as there is no requirement that they be marked with the proper shipping name under the HMR when they are placarded.

A technical review of this petition found that harmonizing the size of this marking with the IMDG Code would not have a negative effect on safety. While this proposal would allow for smaller markings on portable tanks with a capacity of less than 3,000 L (792.52 gallons), PHMSA is unable to quantify these cost savings as it does not have cost data on the savings gained from using smaller markings and to how many stakeholders they might apply. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in proposing this revision. However, PHMSA believes the size limit of the container should be consistent with the 3,785 L (1,000 gallon) limit currently in this section. In this NPRM, PHSMA is proposing to revise § 172.302(b)(2) to allow that proper shipping name markings on portable tanks with a capacity of less than 3,785 L (1,000 gallons) to be a minimum of 12 mm (0.47 inches).

4. Reconditioning of Metal Drums

In its petition (P–1670), RIPA requested a revision to § 173.28(c)(1)(i) to require that labels be *substantially* removed, rather than simply removed. RIPA believes that a strict reading of the current regulation asks for an impossible standard, as the full removal of coatings and labels (including their adhesive residues) is practically impossible. RIPA justifies this request by noting that current cleaning and surface preparation processes have been generally accepted for the last 60 years and have never been considered a safety issue.

A technical review of the petition found there is no evidence that allowing for minimal amounts of residual glue to remain on a drum after cleaning would have any effect on safety. However, PHMSA asserts that there must be a standard to which the drums are cleaned for the coatings and labels to be considered substantially removed. While this proposal is a relaxation of the requirements in the HMR, PHMSA is unable to quantify these cost savings because it does not have data on the cost differences between ''removed'' and ''substantially removed,'' or to how many firms they might apply. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA found that there is merit to proposing this revision to the HMR. In this NPRM, PHMSA is also proposing to revise § 173.28(c)(1)(i) to allow tightly adhering paint, mill scale, and rust to remain on no more than 10 percent of each unit's surface area.

5. Limited Quantity Harmonization

In its petition (P–1676), URS Corporation requests revisions to Column (8A) of the HMT to allow for the shipment of several hazardous materials to be shipped as limited quantities. Specifically, this petition requests that PHMSA harmonize Column (8A) of the HMT for limited quantities for 45 proper shipping names. Currently, the HMT does not allow the limited quantity exception for the materials listed by the petitioner. URS Corporation indicates that if the limited quantity exception is not added to the HMT as proposed, then there would continue to be confusion about hazardous materials shipments imported into the United States that are prepared as limited quantity shipments under international regulations.

A technical review of the petition identified a total of 114 entries in HMT that are not in alignment with the UN Model Regulations, including all of those listed in the petition. The review found that 64 of the 114 entries diverge from the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods (ICAO Technical Instructions). The ICAO Technical Instructions permit all 64 entries to be shipped as a limited quantity. The shipment of limited quantities of similar materials is already permitted under the HMR, and expanding the exceptions to these additional materials would not cause a reduction in safety. Because these are exceptions to the HMR, PHMSA would expect cost savings to be achieved if the proposal is finalized. However, due to a lack of national data on these types of shipments, PHMSA was unable to quantify the specific cost savings that would result from this change. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA found there is merit to proposing this revision to the HMR. In this NPRM, PHMSA is proposing to revise Column (8A) (exceptions) of the HMT consistent with the UN Model Regulations for 114 identified entries.

6. Mobile Refrigeration Units

In its petition (P–1677), the IIAR requests that PHMSA consider changes to § 173.5b for portable and mobile refrigerator systems commonly used in the produce industry. Specifically, this petition proposes to allow the continued use of mobile refrigeration units placed into service prior to 1991 that meet the 250 pounds per square inch (psig) service pressure specification. PHMSA also issued an enforcement discretion memo on September 28, 2017 allowing the continued use of mobile refrigeration units that are tested to a service pressure of 250 psig.

A technical review of this petition found there should be no reduction in safety by allowing the continued use of mobile refrigeration units that are tested to a service pressure of 250 psig. PHMSA believes allowing the continued use of these mobile refrigeration units would allow the agricultural industry to accrue substantial cost savings. In the

PRIA, PHMSA estimates there would be approximately $1,000,000 in annualized costs savings to the agricultural industry resulting from the continued use of mobile refrigeration units currently in service. A more detailed accounting of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit to allowing the continued use of these mobile refrigeration units, under certain conditions. In this NPRM, PHMSA is proposing to revise § 173.5b to allow the continued used of certain portable and mobile refrigerator systems that meet the 250 psig service pressure specification by removing the prohibition of use of refrigeration systems placed into service before June 1, 1991, specified in paragraph (b)(6).

7. Incorporation by Reference of CGA Standards

Certain CGA standards are incorporated by reference in § 171.7 of the HMR. Multiple petitions to update CGA standards were submitted to PHMSA for review. These petitions include:

- Petition (P–1679)—CGA proposed that PHMSA IBR CGA C–6.3, ''Standard for Visual Inspection of Low Pressure Aluminum Alloy Cylinders, 2013, Third Edition'' [1] into § 171.7 to replace the outdated reference to the First Edition of this standard published in 1991.
- Petition (P–1680)—CGA proposed that PHMSA IBR CGA S–7, ''Method for Selecting Pressure Relief Devices for Compressed Gas Mixtures in Cylinders, 2013, Fifth Edition'' into § 171.7 to replace the outdated reference to the 2005 Fourth Edition of this standard.
- Petitions (P–1684) and (P–1693)—In two separate petitions, Worthington Cylinders and CGA requested that § 171.7 be updated to include the most recent version of the CGA C–11, ''Practices for Inspection of Compressed Gas Cylinders at Time of Manufacture, 2013, Fifth Edition'' and that references to the outdated Third Edition of this standard published in 2001 be removed. These petitions also request modifications to § 178.35(b) and (c) to refer to CGA C–11.
- In petition (P–1694)—CGA proposes that PHMSA IBR C–6.1–2013, ''Standards for Visual Inspection of High Pressure Aluminum Compressed Gas Cylinders'' into § 171.7 of the HMR. This sixth edition of CGA C–6.1–2013 would update and replace current references to the 2002 Fourth Edition.

A technical review of these petitions found that the IBR of revised standards would not result in a reduction in safety and would likely enhance safety. It is important for the HMR to reflect the most recent version of these cylinder IBR documents to ensure the safe transportation of compressed gases. There were no quantifiable cost savings identified with these IBR documents. These IBR revisions are primarily technical in nature and do not have a material effect on the cost of business. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in proposing updates to these IBRs in § 171.7 of the HMR. In this NPRM, PHMSA is proposing to IBR the updated CGA publications in § 171.7 of the HMR.

8. Special Provision for Explosives

In its petition (P–1681), the IME proposed that PHMSA remove Special Provision (SP) 103 from § 172.102, as well as remove references to SP 103 from Column (7) of the HMT for the following entries: ''UN 0361, Detonator assemblies, non-electric, for blasting''; ''UN 0365, Detonators for ammunition''; ''UN 0255, Detonators, electric, for blasting''; and ''UN 0267, Detonators, non-electric, for blasting.''

IME requests this change to harmonize the HMR with the UN Model Regulations, which has no provision capping the net explosive mass that may be involved in a limited propagation of detonators within a package classed as Division 1.4B at 25 grams as described in SP 103. Detonators must only pass the tests prescribed by the UN MTC to be transported (in this case pass the UN Test Series 6 requirements). The manual contains the criteria, test methods, and procedures used for the classification of dangerous goods (*i.e.,* hazardous materials) per the provisions of UN Model Regulations to ensure an appropriate level of safety. Only those detonators that successfully pass tests prescribed for Division 1.4B may be classed in this hazardous materials category. The changes IME requests would align the HMR with the UN Model Regulations.

A technical review of this petition found that the removal of this special provision is necessary to harmonize with the international regulations and would have no effect on safety. Since these special provisions are no longer in wide use, PHMSA does not believe there would be any quantifiable cost savings. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in removing this special provision from the four entries in the HMT. In this NPRM, PHMSA is proposing to remove the references to SP 103 for these four entries in Column (7) of the HMT. Also, because SP 103 is only assigned to these four entries, PHMSA is proposing to delete SP 103 from § 172.102.

9. EX Numbers and Safety Devices

In its petition (P–1683), the Ford Motor Company requested a change to the HMT to remove the word ''None'' and replace with ''166'' in Column (8A) for the proper shipping name ''UN 0503, Safety Devices, pyrotechnic.'' This is a reference to authorized packaging for safety devices found in § 173.166. Ford Motor Company believes this omission prevents the shipper of these devices from applying the requirement to include the EX number on the shipping document as found in § 173.166(c), and does not allow the shipper to use the exceptions provided in § 173.166(d). Ford believes the omission is a typo in the HMT and should be corrected.

PHMSA's technical review of this petition determined, consistent with the Ford Motor Company petition, that the exclusion of ''166'' in Column 8A of HMT for ''UN 0503, Safety Devices, pyrotechnic'' was an oversight from a previous rulemaking. There is no reason from a safety perspective why ''UN 0503, Safety Devices, pyrotechnic'' would not be eligible for shipment as a safety device in accordance with § 173.166. Insufficient data on the number of shipments effected limits PHMSA's ability to quantify potential cost savings. In addition, it is perhaps likely that industry is already taking advantage of the exceptions in paragraph (d)(1) whenever the situation allows, and existing requirements in § 172.320(b) already require the EX number. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA found there is merit to proposing this revision to the HMT. In this NPRM, PHMSA is proposing to remove the word ''None'' from Column (8A) for the proper shipping name ''UN 0503, Safety Devices, pyrotechnic'' in the HMT and replace it with ''166'' to authorize use of packaging requirements for safety devices.

10. Alternative Reports for Cargo Tanks

In its petition (P–1685), Polar Service Systems proposes revising the HMR to allow an alternative report for cargo tanks to replace a missing certificate of compliance for cargo tanks manufactured before September 1, 1995.

[1] Previous edition of this document was titled ''Guidelines for Visual Inspection and Requalification of Low Pressure Aluminum Compressed Gas Cylinders, 1991, First Edition.''

The petition recommends accomplishing this by removing the words ''manufactured before September 1, 1995'' from § 180.417(a)(3). The petitioner indicates that there is currently no provision to allow the use of alternative reports when a certificate of compliance is unavailable for cargo tanks manufactured after September 1, 1995. Some cargo tank manufacturers have gone out of business in the past 20 years, making it impossible for a tank owner to obtain a missing certificate of compliance from the manufacturer.

PHMSA's technical review of the petition found there are existing problems with maintaining the required documentation of Cargo Tanks and Cargo Tank Motor Vehicles (CTMVs) when manufacturers are no longer in business. This is true irrespective of the date to which alternative documentation is allowed in § 180.417. PHMSA does not believe there would be an effect on safety because the same testing and recordkeeping requirements would apply to manufacturers that could take advantage of this proposed revision. Alternatively, in the absence of this proposed change, packages with useful life remaining could be forced out of service. This petition is not expected to result in any material cost to industry. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit to proposing this revision to the HMR. In this NPRM, PHMSA is proposing to revise the language in § 180.417(a)(3) to allow for alternative reports when a manufacturer's certificate is not available regardless of date of manufacture.

11. Weight Tolerances for Paper Shipping Sacks

In its petition (P–1688), the Paper Shipping Sack Manufacturers Association proposes that PHMSA revise the basis weight tolerances for liners and mediums used in the manufacture of multiwall shipping sacks. Specifically, this petition requests that PHMSA revise the basis weight tolerance provided in § 178.521 from ±5 percent to ±10 percent from the nominal basis weight reported in the initial design qualification test report. The petitioner notes that multiwall sacks are manufactured on the same or technically equivalent machines that manufacture the liners for fiberboard boxes. PHMSA revised the basis weight tolerances from ±5 percent to ±10 percent for fiberboard boxes in the HM–219A final rule, published on November 7, 2018 [83 FR 55792].

PHMSA's technical review of this petition found that the paper used to manufacture paper bags is made on the same machines or similar machines as that used to make fiberboard boxes. Given the technical data presented in the petition, which included linerboard drop and dynamic compression tests, PHMSA concluded that a small reduction (or a nearly infinite increase) in basis weight of the paper used in manufacturing fiberboard boxes does not affect performance, it is expected that paper bags will behave similarly. PHMSA estimates the total potential annualized cost savings to the industry of $20,000 to $200,000. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA found there is merit to proposing this revision to the HMR. In this NPRM, PHMSA is proposing to revise § 178.521 to revise the nominal basis weight reported in the initial design qualification test report from ±5 percent to ±10 percent.

12. Markings on Closed Transport Containers

In its petition (P–1690), Matson proposes that PHMSA amend § 173.308(d)(3) to remove the requirement for a warning to be placed on the access door of a closed transport vehicle or a closed freight container when lighters are transported by vessel. Matson notes that a similar warning is not required by the IMDG Code, meaning that the HMR is not harmonized in this respect.

As noted above, this requirement is only in the HMR and is not required in the IMDG Code. PHMSA's technical review of this petition found that harmonizing this section with the IMDG Code would not result in a reduction in safety. PHMSA believes the existing hazard communication requirements (transport documents, container placard, etc.) provide a sufficient level of safety that is consistent with requirements for other Division 2.1 materials. As the petition eliminates a warning marking requirement and provides regulatory clarity through harmonization, we anticipate no associated costs from this proposal. However, PHMSA was unable to quantify any cost savings associated with this petition. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA found there is merit to proposing this revision to the HMR. In this NPRM, PHMSA is proposing to amend the lighter transportation requirement in § 173.308(d)(3) to remove the requirement for vessel transport of a closed transport vehicle or freight container to display the warning mark ''WARNING—MAY CONTAIN EXPLOSIVE MIXTURES WITH AIR—KEEP IGNITION SOURCES AWAY WHEN OPENING'' on the access door.

13. Finalization of the HM–246 Tank Car Standard

In a joint petition (P–1691), AAR, the Chlorine Institute, ACC, the Fertilizer Institute, and RSI request that PHMSA convert certain ''interim'' rail tank car specifications to ''final'' tank car specifications. The subject tank car specifications were issued as part of the January 13, 2009, final rule entitled ''Improving the Safety of Railroad Tank Car Transportation of Hazardous Materials (HM–246),'' (74 FR 1769), which was targeted at improving the safe transportation of PIH materials by rail.

The HM–246 final rule contained interim design standards for rail tank cars transporting PIH materials to be used until a permanent standard could be issued by PHMSA. The final rule prescribed enhanced safety measures for PIH materials transported in rail tank cars, primarily stronger tanks with higher tank test pressures, fittings, tank head-puncture resistance protection and, for some commodities, thermal protection. The HM–246 final rule was the result of industry consensus that an updated standard was necessary to improve accident survivability, even as research continued to develop a long-term PIH tank car specification.

The ATCCRP [2] suggests the HM–246 interim specification provides a significant level of improvement over the legacy designs and there are few additional economical options to improve standards beyond the interim standard. According to the petitioner, PIH tank cars built in compliance with the HM–246 interim standards have performed well in service. In addition, conclusions from the various ATCCRP projects provide scientific support to make the interim specifications permanent. Conclusions resulting from these safety research efforts, as reported by ATCCRP, include:

- The ''interim'' standard designs finalized in 2009 provide significant

[2] The ATCCRP coordinates research efforts to enhance the safety and security of rail tank car shipments of toxic inhalation hazard (TIH) materials. It is a joint effort comprised of shippers of tank cars carrying TIH materials (represented by ACC, the Chlorine Institute, and the Fertilizer Institute); railroads that transport hazardous materials (represented by AAR); and rail tank car builders and lessors (represented by RSI). For more information, see *https://tankcarresourcecenter.com/wp-content/uploads/2017/11/ATCCRP-Research-Background-2016.pdf.*

improvement in accident survivability over the legacy designs, *i.e.,* former specifications; and

• No design feature or material was identified that would provide a significantly greater level of improvement, or would be a reasonable alternative (from an economic or manufacturability standpoint) that should be required industry-wide.

PHMSA's technical review of this petition found that the HM–246 compliant rail tank cars have an established safety record with no major incidents attributed to the design of the tank car. The petitioner's requested changes are not expected to result in any material costs to industry, as the costs of this proposed amendment are already accounted for in the analysis of HM–246 final rule, which adopted the interim tank car standard. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA found there is merit to proposing this revision to the HMR. In this NPRM, PHMSA is proposing to revise §§ 173.314(c) and 173.244(a)(2) of the HMR to make the HM–246 rail tank car specification permanent for the transportation of PIH materials.

14. Phase-Out of Non-HM–246 Compliant Rail Tank Cars

In 2006, after several major PIH rail tank car accidents, AAR began to release a series of CPCs that mandated the use of a safer design for tank cars that transport PIH materials. On March 31, 2008, AAR published CPC–1187 implementing design specifications for tank cars used in PIH service. CPC–1187 also included a 10-year phase-out schedule for tank cars that did not meet the CPC–1187 specification. According to the new AAR standard, non-compliant tank cars would not be accepted for interchange after December 31, 2018.

On April 1, 2008, PHMSA published an NPRM proposing revisions to the HMR to improve the crashworthiness protection of railroad tank cars designed to transport PIH materials. (73 FR 17817). On January 13, 2009, PHMSA issued a final rule establishing the ''Interim HM–246 Standard.'' (74 FR 1769). The Interim HM–246 Standard effectively adopted AAR's CPC–1187 tank car specification for the transportation of PIH materials until further research could be completed on enhanced tank car specifications.

In the NPRM for HM–246, PHMSA considered adopting a phase-out of tank cars that did not meet the proposed standard. However, in the HM–246 final rule, PHMSA decided not to adopt a phase-out schedule for legacy cars stating, ''[a]lthough we continue to believe that an accelerated phase out of these cars is justified, we recognize the voluntary efforts already underway by many fleet owners to phase out these cars, in many cases on schedules more aggressive than the five-year deadline proposed in the NPRM.'' (74 FR at 1777–1778). After PHMSA published the HM–246 final rule adopting an interim tank car standard, AAR suspended CPC–1187 until a new tank car standard could be finalized and suspended the December 2018 retirement deadline for non-compliant tank cars.

As discussed in Section II.13, ''Finalization of the HM–246 Tank Car Standard,'' above, research conducted under the ATCCRP has since demonstrated that the HM–246 interim tank car design provides significant improvements in survivability and in their view, no other design would provide significantly greater level of improvement. However, despite initial indications in 2009 that voluntary efforts would result in an accelerated phase-out of those tank cars in PIH service that failed to comply with the HM–246 interim standard, the industry had not adopted a voluntary phase-out schedule as of December 2016 that would eliminate less safe tank cars from PIH service.

On December 16, 2016, AAR submitted a petition (P–1692) requesting that PHMSA adopt a six-year phase-out for PIH rail tank cars that do not meet the interim HM–246 specification standard as implemented in the HM–246 final rule published on January 13, 2009. AAR argued that collaborative research undertaken by industry and government partners (through ATCCRP) over the last seven years has confirmed that HM–246 specification cars have the highest accident survivability rate over other designs and are the most feasible technology to transport PIH materials.

On April 7, 2017, before PHMSA acted on P–1692, AAR adopted CPC–1325, which implemented a phase-out by July 1, 2023 of any tank car in PIH service that does not comply with the HM–246 interim standard. Prior to AAR's adoption of CPC–1325, the Fertilizer Institute commented to the petition for rulemaking docket (P–1692) [3] that it opposed AAR's implementation of the July 1, 2023, phase-out schedule arguing, among other things, that DOT has sole authority over hazardous materials packaging and that AAR's adoption of the phase-out schedule was done without performing a cost-benefit analysis. As a result, the Fertilizer Institute asserted that the phase-out was being implemented without a full understanding of the extent of its potential costs or benefits. Similar comments were relayed to PHMSA by a group of shipper associations during a January 13, 2017 meeting.[4] AAR met with PHMSA and FRA on August 1, 2017, during which AAR suggested its phase-out schedule did not conflict with DOT regulations and that the phase-out schedule was intended to remove an older, less-safe car design from PIH service.[5] PHMSA sees no need to take a position on these specific arguments, as they are rendered moot by subsequent actions. However, it is with a view towards this history that PHMSA notified AAR on December 7, 2017, that it was accepting P–1692 and would conduct a ''safety and policy review that will aid in determining whether the HMR should mandate a phase-out period and, if so, what period would ensure safety and protect the public interest.'' [6]

On July 27, 2018, AAR revised CPC–1325 and re-issued it as CPC–1336, extending the phase-out schedule for non-HM–246 compliant tank cars from six (July 1, 2023) to ten years (December 31, 2027). On August 15, 2018, the railroads (represented by AAR) and a group of PIH material shippers (represented by ACC, the Chlorine Institute, and the Fertilizer Institute) submitted a joint comment to P–1692 proposing a phase-out date of December 31, 2027, for all non-HM–246 specification rail tank cars. The December 31, 2027, phase-out date would be in lieu of the six-year timeline requested in AAR's original petition. The joint commenters met with PHMSA on September 6, 2018, and urged PHMSA to act quickly in completing a rulemaking that would adopt the petition's proposed 10-year phase-out timeline.[7] The joint commenters contend that codifying the phase-out in the HMR would improve safety and increase market certainty.

PHMSA believes the phase-out of these legacy rail tank cars would have

[3] Docket No. PHMSA–2016–0165, at *www.regulations.gov.*

[4] Attendees included representatives from the Fertilizer Institute, American Chemistry Council, the Chlorine Institute, and the American Petroleum Institute. *https://www.regulations.gov/document?D=PHMSA-2016-0165-0007.*

[5] *https://www.regulations.gov/document?D=PHMSA-2016-0165-0011.*

[6] *https://www.regulations.gov/document?D=PHMSA-2016-0165-0012.*

[7] *https://www.regulations.gov/document?D=PHMSA-2016-0165-0014.*

a positive impact on safety due to their replacement with more robust tanks cars used for the transportation of PIH materials and that regulatory certainty could foster market certainty. PHMSA proposes to respond to P–1692 by codifying the 10-year phase-out schedule in the HMR; however, the phase-out is expected to go into effect under railroad interchange rules regardless of whether PHMSA adopts this date into regulation. As a result, there is no cost associated with PHMSA promulgating this date as a regulatory deadline for the phase-out.

As such, PHMSA believes there is merit in proposing the phasing-out of all non-HM–246 rail tank cars for use in the transportation of PIH materials. In this NPRM, PHMSA proposes to revise § 173.31 to phase-out all non-HM–246 rail tank cars for the transportation of PIH materials by December 31, 2027. PHMSA encourages stakeholder comments assessing the potential impacts of the proposed phase-out and whether the proposed phase-out period in this NPRM is an appropriate timeframe.

15. Allow Non-RCRA Waste To Use Lab Pack Exception

In its petition (P–1695), Veolia requests that PHMSA amend § 171.8 by adding a definition of ''waste material.'' The purpose of this petition is to allow for all waste material, whether or not it meets the definition of a hazardous waste according to the EPA's RCRA, to be managed in accordance with the lab packs exception and associated paragraphs in § 173.12. Currently, lab packs in § 173.12 provide relief for ''waste materials'' that are being offered for disposal and recovery; this has been clarified by PHMSA to only apply to ''hazardous wastes'' as defined by the EPA. Veolia believes this does not reflect the intention of the regulation, and that adding a definition would resolve the issue.

PHMSA's technical review of the petition supports the petitioner's interpretation. When PHMSA codified § 173.12, the intention was to apply it to all waste materials, and was not specific to ''hazardous wastes.'' PHMSA believes that clarifying this intention to include all waste would not lead to a reduction in safety. There are no costs that are expected based on the adoption of this petition. The lab pack exception offers flexibility for transporting waste materials, but does not require changes to business operations or changes to how the waste material is ultimately handled. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in this proposal. In this NPRM, PHMSA is proposing to allow waste materials, irrespective of whether they meet the definition of a EPA/RCRA hazardous waste to be shipped under § 173.12 by adopting a definition of waste material.

16. Incorporation of ASME Code Sections II, VIII, and IX

In its petition (P–1700), Trinity Containers requests that PHMSA IBR the 2017 version of the ASME BPVC, Sections II (Parts A and B, C and D), VIII (Division 1), and IX into the HMR. The ASME BPVC is a standard for the design and construction of boilers and pressure vessels. The petitioner indicates that if changes are not made, ASME Code certificate holders will be in violation of the HMR for manufacturing cargo tanks, non-specification tanks, and implements of husbandry to the ASME Code referenced in § 171.7.

PHMSA's technical review of this petition found that for certificate holders to remain in compliance with ASME, they must follow this latest edition of the ASME Code. Currently, the HMR IBRs the 2015 edition which is already causing issues with compliance if manufacturers or repair facilities choose to use the latest edition of the ASME Code. Adopting the latest version of the ASME Code would ensure that the HMR remains consistent with the best practices used by the industry. A review of PHMSA's Civil Penalty Action Reports between 2015 and 2016 revealed no citations that were like the example provided by the petitioner. This suggests that these types of citations are infrequent, and that the cost-savings associated with this petition would be modest. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in this proposal. Note that ASME Code Section V (nondestructive examination) is incorporated by reference in the HMR but that ASME Code Section II, Parts C and D are not. In this NPRM, PHMSA is proposing to IBR the latest version of the ASME BPVC Sections II (Parts A and B), V, VIII (Division 1), and IX.

17. Import of Foreign Pi-Marked Cylinders

In its petition (P–1701), CGA requests that PHMSA modify §§ 171.23, 173.302, and 173.304 to permit the transportation of filled pi-marked foreign pressure receptacles that comply with applicable ADR requirements. Pi-marked pressure receptacles are currently allowed to be imported through special permits and approvals. P–1701 requests authorization for import, immediate storage, transport to point of use, discharge, and export, as well as the import of empty pi-marked foreign pressure receptacles for filling, immediate storage, and export. In an addendum to the P–1701 petition, Entegris requests additional revisions to §§ 171.23(a) and 173.302(a)(2) to explicitly ensure that the proposed rulemaking is applicable to adsorbed gas packages. The changes to § 171.23(a)(3) requested by Entegris are intended to allow for domestic sourcing as well as import of empty pi-marked pressure receptacles for filling and export.

PHMSA's technical review did not find any evidence to suggest that there would be any changes with respect to risk and safety resulting from this proposed regulatory change. The shipping of pi-marked cylinders has been allowed for many years through special permits. There is limited available market data on the current export of pi-marked cylinders. The information provided by the petitioner suggests that adopting the proposed amendment would not result in a change to the number of pi-marked cylinders that are transported or the risk profile of the cylinder transportation. Cost savings are expected to be minimal, resulting primarily from the potential time savings for industry and governments due to the elimination of the need for a special permit or approval. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in this proposal. In this NPRM, PHMSA is proposing to modify §§ 171.23, 173.302, and 173.304 to permit the import of filled pi-marked foreign pressure receptacles for storage incidental to movement, transport to point of use, discharge, and export. PHMSA is also proposing to permit the transportation of pi-marked foreign pressure receptacles for export, including filling and storage incident to movement. In addition, PHMSA is proposing to revise §§ 171.23(a) and 173.302(a)(2) to explicitly ensure that the proposed authorization for pi-marked cylinders is applicable to adsorbed gas packages. Finally, to align with similar ADR provisions, and increase shipper and carrier awareness of the requirements for pi-marked cylinders, we are proposing to require a notation on the shipping paper following the basic description of the hazardous material certifying compliance with the pi-marked cylinder requirements. PHMSA is also proposing

to IBR the ADR and European Union (EU) ''Directive 2010/35/EU of the European Parliament and of the Council'' into § 171.7 of the HMR.

18. Placement of the Word ''Stabilized'' in Shipping Description

In its petition (P–1706), Evonik requested that PHMSA clarify how the word ''stabilized'' should appear when providing the shipping description for a hazardous material. There is currently disharmony between the IMDG Code and the HMR that causes confusion with respect to materials that required the word ''stabilized'' to appear in the proper shipping name. The HMR does not allow the word ''stabilized'' to appear as part of the proper shipping name. The IMDG Code requires it in certain instances. The petitioner claims that this causes needless discrepancies for international shipments under the IMDG Code.

PHMSA's technical review found that hazardous materials that have some instability but are not specifically identified or classified as self-reactive substances or organic peroxides currently cannot be shipped in compliance with both the HMR and the IMDG Code. This disharmony causes problems with transportation documents.

Amending the HMR to allow the use of the word ''stabilized'' in the proper shipping name may require manufacturers and shippers to cover labor costs related to training and ensuring compliance with this new requirement. To the extent that these costs exist, they are expected to be negligible. This is because affected entities that engage in international commerce are expected to already be aware of the requirement, and would simply need to know that international and domestic shipments of stabilized materials can be treated the same on the shipping paper. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in this proposal. In this NPRM, PHMSA is proposing to revise § 172.101(c) to clarify that the word ''stabilized'' can be added as part of the proper shipping name.

19. Incorporation by Reference of an IME Standard

In its petition (P–1710), IME requested that PHMSA incorporate by reference the IME/AESC JPG Standard, also called the ''*Guide to Obtaining DOT Approval of Jet Perforating Guns using AESC/IME Perforating Gun Specifications,*'' Version 02, dated September 1, 2017. IME notes that JPGs use shaped explosive charges to produce a high-pressure jet that penetrates the liner or casing of a wellbore in order to enhance production of oil and gas wells. Testing of early JPG systems in 2007 suggested the potential for JPGs to improve flow performance by 35 percent. In addition to the IBR, IME proposes that PHMSA include a new § 173.67 to outline exceptions for Division 1.1 JPGs subject to this new IBR material.

The IME JPG Standard has been used since 2008 by PHMSA to aid in the review of EX approval applications for articles meeting the JPG Standard templates as either 1.1D or 1.4D. The standard includes parameters for 13 JPG designs and requires that the individual energetic components (*e.g.,* detonation cord, shaped charges, explosive transfer device, etc.) be individually approved. IBR of this standard into the HMR would help to ensure the safe and efficient transportation of JPGs, and provides adequate safety protocols for the transportation of JPGs.

The economic analysis suggests potential annualized cost savings of approximately $360,000 for manufacturers of JPGs compliant with the IME/AESC Standard. Additional cost savings are expected for both manufacturers and PHMSA due to reduced labor requirements for processing applications for EX approvals. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

Therefore, PHMSA believes there is merit in this proposal. In this NPRM, PHMSA is proposing to incorporate this standard into § 171.7 of the HMR and include a new § 173.67 to outline exceptions for Division 1.1 JPGs subject to this new IBR material.

20. Incorporation by Reference of an APA Standard

In its petition (P–1711), the APA requested PHMSA update references in the HMR to incorporate the new version of APA Standard 87–1, ''*Standard for Construction and Approval for Transportation of Fireworks, Novelties, and Theatrical Pyrotechnics,*'' which is currently incorporated by reference in § 171.7(f)(1) of the HMR. The APA states that this 2001 edition of the standard needs to be updated, because of advances in the fireworks industry over the last 15 years. For consumer fireworks, new devices have been developed including combination devices, and more devices now contain multiple tubes and combinations of effects that were previously limited to single tubes. The petitioner elaborates that these new products do not fit into the existing classification system under the current standard.

The National Fireworks Association (NFA) submitted a letter in opposition to this petition. The NFA is a domestic fireworks trade organization with 1,200 members. In the letter, NFA states that proposed changes have a substantial impact on the fireworks industry and, in particular, small businesses. In the letter of opposition, NFA states that the proposed action ''imposes new restrictions, prohibitions, and specifications that do not exist under the current standard.'' In a letter to its members, NFA provides an explanation of its opposition letter. NFA states that although the revised 87–1A standard has ''many good updates, including new design categories that would make EX approvals easier for some items,'' the updated standard also includes restrictions that are inconsistent with industry practices.

PHMSA is choosing to propose to IBR the new APA standard despite NFA's opposition to the petition. NFA objected to PHMSA accepting the APA petition on the assertion that the APA petition lacked the information described in § 106.100(b) of the HMR. This section only states that PHMSA may require more information to evaluate a petition for rulemaking; it is not required. In the case of P–1711, PHMSA determined that additional information was not necessary to accept the petition for rulemaking. The revised APA 87–1 is expected to provide clarity to the fireworks industry, while maintaining the composition limits developed by PHMSA for classification that are needed to ensure the safe transportation of fireworks. Furthermore, PHMSA's decision to propose IBR the revised APA standards was informed by its review of the explicit requirements for consumer fireworks in APA 87–1A, display fireworks in APA 87–1B, and professional fireworks (classed as articles pyrotechnics) in APA 87–1C. These standards add numerous new devices, expand the permitted chemical list, and focus solely on hazard classification for transportation. However, PHMSA will consider comments on whether we should move forward with incorporating this standard in a final rule. PHMSA estimates that adoption of this petition would provide an annualized cost savings of approximately $270,000 to industry, through expanding the approval process to reduce testing requirements for theatrical pyrotechnics. A more detailed discussion of this economic analysis can be found in the accompanying PRIA.

PHMSA believes there is merit in this proposal. Therefore, PHMSA is proposing to incorporate this updated standard into § 171.7 of the HMR. However, PHMSA is seeking comments on both what is proposed in the APA petition and comments submitted by the NFA on the merits of this proposal. All documents related to this petition can be found in the petition docket at *https://www.regulations.gov/docket?D=PHMSA-2018-0019.*

III. Section-by-Section

Below is a section-by-section description of the changes being proposed in this NPRM.

A. Appendix A to Subpart D, Part 107

Appendix A to Subpart D, of Part 107 sets forth the guidelines PHMSA uses (as of October 2, 2013) in making initial baseline determinations for civil penalties. In this NPRM, PHMSA is proposing to update the references to the APA documents to reflect the proposed new versions of the 87–1 Standard.

B. Section 107.402

Section 107.402 outlines how to submit an application for designation as a certification agency. PHMSA is proposing to update a reference to the APA documents to reflect the proposed new version of the 87–1 Standard in § 107.402(d).

C. Section 171.7

Section 171.7 lists all standards incorporated by reference into the HMR that are not specifically set forth in the regulations. In this NPRM, PHMSA is proposing to IBR the following publications by APA, ASME, CGA, and IME:

1. *European Agreement concerning the International Carriage of Dangerous Goods by Road,* 2017, into § 171.23. The ADR outlines the European regulations concerning the international carriage of dangerous goods by road within the EU, and this publication presents the European Agreement, the Protocol Signatures, the annexes, and the amendments. The ADR can be found at *https://www.unece.org/trans/danger/publi/adr/adr_e.html.*

2. *Directive 2010/35/EU of the European Parliament and of the council,* June 16, 2010, into § 171.23. The aim of Directive 2010/35/EU of the European Parliament and of the Council on Transportable Pressure Equipment (2010 TPED) is to promote the free movement of transportable pressure equipment (TPE) within the European Community (EC). This directive provides for a legal structure whereby TPE can be manufactured, sold, and used throughout the EU. A copy of this directive can be found at *https://eur-lex.europa.eu/eli/dir/2010/35/oj.*

3. CGA C–11, *Recommended Practices for Inspection of Compressed Gas Cylinders at Time of Manufacture,* 2013, Fifth Edition, into § 178.35. The purpose of this publication is to promote safety by outlining inspection requirements of DOT and UN pressure vessels as interpreted and practiced by manufacturers and inspectors. A read-only version of this publication is available for review at *https://portal.cganet.com/IBR_Review.aspx.*

4. CGA C–6.1, *Standards for Visual Inspection of High Pressure Aluminum Compressed Gas Cylinders,* 2002, Fourth Edition, into §§ 180.205 and 180.209. This publication has been prepared as a guide for the visual inspection of aluminum compressed gas cylinders with service pressures of 1800 psig or greater. The publication is general in nature and does not cover all circumstances for each individual cylinder type or lading. A read-only version of this publication is available for review at *https://portal.cganet.com/IBR_Review.aspx.*

5. CGA C–6.3, *Guidelines for Visual Inspection and Requalification of Low Pressure Aluminum Compressed Gas Cylinders,* 2013, Third Edition, into §§ 180.205 and 180.209. This publication has been prepared as a guide for the periodic inspection of aluminum alloy compressed gas cylinders with service pressures of 500 psi or less. This publication is general in nature and will not cover all circumstances for each individual cylinder type or lading. A read-only version of this publication is available for review at *https://portal.cganet.com/IBR_Review.aspx.*

6. CGA S–7, *Method for Selecting Pressure Relief Devices for Compressed Gas Mixtures in Cylinders,* 2013, Fifth Edition, into § 173.301. This method is applicable to the determination of the PRD to use with compressed gas mixtures in cylinders. This method is limited to those compressed gas mixtures with known flammability, toxicity, state, and corrosively. A read-only version of this publication is available for review at *https://portal.cganet.com/IBR_Review.aspx.*

7. ASME *Boiler and Pressure Vessel Code (ASME Code),* 2017 Edition, July 1, 2017 (as follows), into §§ 172.102; 173.3; 173.5b; 173.24b; 173.306; 173.315; 173.318; 173.420; 178.255–1; 178.255–2; 178.255–14; 178.255–15; 178.273; 178.274; 178.276; 178.277; 178.320; 178.337–1; 178.337–2; 178.337–3; 178.337–4; 178.337–6; 178.337–16; 178.337–18; 178.338–1; 178.338–2; 178.338–3; 178.338–4; 178.338–5; 178.338–6; 178.338–13; 178.338–16; 178.338–18; 178.338–19; 178.345–1; 178.345–2; 178.345–3; 178.345–4; 178.345–7; 178.345–14; 178.345–15; 178.346–1; 178.347–1; 178.348–1; 179.400–3; 180.407. The ASME BPVC is a standard that regulates the design and construction of boilers and pressure vessels. The document is written and maintained by volunteers chosen for their technical expertise, and ASME works as an accreditation body and entitles independent third parties such as verification, testing, and certification agencies to inspect and ensure compliance to the BPVC. A read-only version of this publication is available for review at *http://go.asme.org/PHMSA-ASME.*

8. IME/AESC JPG Standard, *Guide to Obtaining DOT Approval of Jet Perforating Guns using AESC/IME Perforating Gun Specifications,* Ver. 02, dated September 1, 2017, into § 173.67. The AESC/IME JPG Standard was developed in 2008 by IME, AESC, and PHMSA to provide an efficient and economical mechanism to obtain explosives approvals of jet perforating guns in compliance with the HMR. Applications that are prepared and submitted using the standard are processed by PHMSA with minimal delay and without the need for expensive and time-consuming testing. A free downloadable copy of this publication can be found at *https://www.ime.org/uploads/public/PHMSA/UpdateJPGStandard(2018.06.12).pdf.*

9. American Pyrotechnics Association (APA) Standards: 87–1A *Standard for the Construction, Classification, Approval and Transportation of Consumer Fireworks,* January 1, 2018 version into § 107.402(d), § 173.59, § 173.64, § 173.65, and Appendix A to Subpart D of Part 107 (Guidelines for Civil Penalties), 87–1B *Standard for the Construction, Classification, Approval, and Transportation of Display Fireworks,* January 1, 2018 version into § 173.64 and Appendix A to Subpart D of Part 107 (Guidelines for Civil Penalties). 87–1C *Standard for the Construction, Classification, Approval, and Transportation of Entertainment Industry and Technical (EI&T) Pyrotechnics,* January 1, 2018 version into § 173.64 and Appendix A to Subpart D of Part 107 (Guidelines for Civil Penalties). APA Standard 87–1A, B, and C is a consensus standard in which fireworks classifications are assigned based upon the weight and type of chemical composition contained for each specific type of device, including specific permissible and

restricted chemicals. A copy of this standard can be found in this rulemaking docket at *https://www.regulations.gov/docket?D=PHMSA-2017-0120*.

D. Section 171.8

Section 171.8 defines terms generally used throughout the HMR that have broad or multi-modal applicability. PHMSA is proposing to add a definition for ''waste material'' to allow wastes that do not meet the EPA/RCRA definition of hazardous waste to be managed in accordance with the lab pack exception and associated paragraphs in § 173.12.

E. Section 171.23

Section 171.23 covers the requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Transport Canada TDG Regulations, or the IAEA Regulations. PHMSA is proposing to revise § 171.23(a)(3) to allow for the use of pressure vessels and pressure receptacles that are marked with a pi mark in accordance with the European Directive 2010/35/EU on transportable pressure equipment (TPED) and that comply with the requirements of Packing Instruction P200, P208 and 6.2.2 of ADR concerning PRD use, test period, filling ratios, test pressure, maximum working pressure, and material compatibility for the lading contained or gas being filled. This proposal would allow for intermediate storage, transport to point of use, discharge, and export of pi-marked cylinder.

F. Section 172.101

The HMT is contained in § 172.101. The HMT lists alphabetically, by proper shipping name, those materials that have been designated hazardous materials for the purpose of transportation. It provides information used on shipping papers, package marking, and labeling, as well as other pertinent shipping information for hazardous materials. In this NPRM, PHMSA is proposing to amend the HMT in the following ways.

PHMSA is proposing to remove reference to SP 103 from Column (7) of the HMT for the following four explosive entries ''UN0361, —Detonator assemblies, non-electric, for blasting''; ''UN0365, —Detonators for ammunition''; ''UN0255, —Detonators, electric, for blasting''; and ''UN0267, —Detonators, non-electric, for blasting.'' PHMSA is also proposing to remove the word ''None'' from Column (8A) for the entry ''UN0503, Safety Devices, pyrotechnic'' and replacing it with a reference to § 173.166 (''166''). Finally, PHMSA is also proposing to revise 114 entries to harmonize the limited quantity exceptions in Column (8A) with the ICAO Technical Instructions and the UN Model Regulations.

G. Section 172.102

Section 172.102 lists special provisions applicable to the transportation of specific hazardous materials. Special provisions contain packaging requirements, prohibitions, and exceptions applicable to particular quantities or forms of hazardous materials. Consistent with the § 172.101 Column (7) revisions to ''UN0361, —Detonator assemblies, non-electric, for blasting''; ''UN0365, —Detonators for ammunition''; ''UN0255, —Detonators, electric, for blasting''; and ''UN0267, —Detonators, non-electric, for blasting,'' in this NPRM, PHMSA is proposing to remove SP 103 as it would no longer apply to any HMT entry.

H. Section 172.302

Section 172.302 describes the general marking requirements for bulk packagings. In this NPRM, PHMSA is proposing to revise the minimum size of the marking requirement on portable tanks in § 172.302(b)(2). This revision would require a minimum marking of 12 mm (0.47 inch) in height. The minimum size requirement would apply to portable tanks with capacities less than 3,785 L (1,000 gallons).

I. Section 173.5b

Section 173.5b authorizes the transportation by highway of residual amounts of Division 2.2 refrigerant gases or anhydrous ammonia contained in non-specification pressure vessels that are components of refrigeration systems. PHMSA is proposing to remove paragraph (b)(6) to indefinitely allow the use of refrigeration systems placed into service prior to June 1, 1991 under specified conditions.

J. Section 173.28

Section 173.28 outlines the requirements for the reuse, reconditioning and re-manufacture of packagings. PHMSA is proposing to modify language in § 173.28(c)(1)(i) to clarify requirements for reconditioning metal drums. PHMSA is proposing to revise § 173.28(c)(1)(i) to read: ''Cleaning to base material of construction, with all former contents and internal and external corrosion removed, and any external coatings and labels sufficiently substantially removed to the extent that tightly adherent paint, mill scale, and rust remain on no more than 10 percent of each unit's surface area.''

K. Section 173.31

Section 173.31 outlines the requirements for shipping hazardous materials in tank cars. In this NPRM, PHMSA is proposing to prohibit the use of tank cars that were manufactured using non-normalized steel for head or shell construction for the transportation of PIH materials after December 31, 2020. PHMSA is also proposing the phase-out of all non-HM–246 compliant tank cars for the transportation of PIH materials by December 31, 2027.

L. Section 173.56

Section 173.56 outlines the definitions and procedures for the classification and approval of a new explosive. PHMSA is proposing to add a reference to a new paragraph in § 173.67, which would apply to exceptions for Division 1.1 JPGs.

M. Section 173.59

Section 173.59 outlines the description of terms for explosives. PHMSA is proposing to update a reference to the APA documents in the definition for consumer firework.

N. Section 173.64

Section 173.64 outlines the exceptions for Division 1.3 and 1.4 fireworks. PHMSA is proposing to update a reference to the APA documents in § 173.64(a)(1) and (3).

O. Section 173.65

Section 173.65 outlines the exceptions for Division 1.4G consumer fireworks. PHMSA is proposing to update a reference to the APA documents in § 173.65(a)(1), (a)(3)(i), and (a)(4)(iv).

P. Section 173.67

PHMSA is proposing to add a new § 173.67 to outline exceptions for Division 1.1 JPGs.

Q. Section 173.151

Section 173.151 outlines exceptions for Class 4 materials. PHMSA is proposing to edit the limited quantities provisions in this section to present limited quantities in appropriate SI units in liters in addition to kilograms.

R. Section 173.244

Section 173.244 outlines the requirements for bulk packaging for certain pyrophoric liquids, dangerous when wet (Division 4.3) materials, and poisonous liquids with inhalation hazards (Division 6.1). PHMSA is proposing to modify the list of

authorized tank car specifications in the table of PIH materials (§ 173.244(a)(2)) by replacing the last specification delimiter ''I'' with ''W'' to reflect the change of the interim tank car standard to a permanent standard.

S. Section 173.302

Section 173.302 outlines the requirements for the filling of cylinders with nonliquefied (permanent) compressed gases or adsorbed gases. In this NPRM, PHMSA is proposing to revise § 173.302(a)(1) to refer to exceptions in § 171.23(a)(3) for the importation of pi-marked cylinders. PHMSA is also proposing to revise § 173.302(a)(2) to allow adsorbed gases the exceptions provided in § 171.23(a)(3).

T. Section 173.304

Section 173.304 outlines the requirements for the filling of cylinders with liquefied compressed gases. In this NPRM, PHMSA is proposing to revise § 173.304(a) to refer to exceptions in § 171.23(a)(3) for the importation of pi-marked cylinders.

U. Section 173.308

Section 173.308 outlines the requirements for the shipment of lighters. In this NPRM, PHMSA is proposing to delete § 173.308(d)(3), which requires a closed transport vehicle or closed freight container being transported by vessel to contain the marking, ''WARNING—MAY CONTAIN EXPLOSIVE MIXTURES WITH AIR—KEEP IGNITION SOURCES AWAY WHEN OPENING.''

V. Section 173.314

Section 173.314 outlines the requirements for transporting compressed gases in tank cars and multi-unit tank cars. PHMSA is proposing to modify the table in § 173.314(c), which lists the authorized tank car specifications for specific compressed gases. The changes replace the last specification delimiter ''I'' with ''W'' to reflect the change of the interim HM–246 tank car specification standard for PIH materials to a permanent standard.

W. Section 178.35

Section 178.35 prescribes the manufacturing and testing specifications for cylinders used for the transportation of hazardous materials in commerce. PHMSA is proposing to modify § 178.35(b) and (c) to clarify inspection requirements as stipulated in CGA C–11.

X. Section 178.521

Section 178.521 prescribes the requirements for paper bags used as non-bulk packagings for hazardous materials. In this NPRM, PHMSA is proposing to revise § 178.521(b)(4) to allow for a weight tolerance of ±10 percent from the nominal basis weight reported in the initial design qualification test report instead of ±5 percent.

Y. Section 179.22

Section 179.22 specifies additional marking requirements for tank cars. In this NPRM, PHMSA is proposing to modify § 179.22(e) to replace the letter ''I'' with the letter ''W'' to facilitate making the interim HM–246 tank car specification standards permanent for the transportation of PIH materials by rail.

Z. Section 180.417

Section 180.417 prescribes the reporting and record retention requirements pertaining to cargo tanks. Currently § 180.417(a)(3)(i) and § 180.417(a)(3)(ii) allow the use of alternative reports when a manufacturer's certificate and related papers are not available for DOT specification cargo tanks that were manufactured before September 1, 1995. PHMSA is proposing to remove the provision that limits alternative reports to those DOT specification cargo tanks ''manufactured before September 1, 1995'' from § 180.417(a)(3).

IV. Regulatory Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This rulemaking is published under the authority of Federal Hazardous Materials Transportation Law (Federal hazmat law; 49 U.S.C. 5101 *et seq.*), which authorizes the Secretary of Transportation to ''prescribe regulations for the safe transportation, including security, of hazardous materials in intrastate, interstate, and foreign commerce.'' The Secretary has delegated the authority granted in the Federal Hazardous Materials Law to the PHMSA Administrator at 49 CFR 1.97. This rulemaking proposes to amend several sections of the HMR in response to 24 petitions for rulemaking received from the regulated community.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

Background

In this NPRM, PHMSA is responding to 24 petitions that have been submitted by the public in accordance with the Administrative Procedure Act (5 U.S.C. 553(e)) and PHMSA's rulemaking procedure regulations (49 CFR 106.95). Overall, this rulemaking maintains the continued safe transportation of hazardous materials while producing a net cost savings. PHMSA's findings are summarized here and described in further detail in the preliminary Regulatory Impact Analysis (PRIA), which can be found in the regulatory docket (Docket ID: PHMSA–2017–0120) at *www.regulations.gov*.

Summary of Findings

PHMSA estimates a present value of quantified net cost savings of approximately $1.74 million annualized at a 7 percent discount rate. These estimates do not include non-monetized and qualitative cost/cost savings discussed in the PRIA.

PHMSA's cost/cost savings analysis relies on the monetization of impacts for four petitions included in this rulemaking. All of these petitions have annualized cost savings. The following table presents a summary of the four petitions that would have monetized impacts upon codification and contribute to PHMSA's estimation of quantified net cost savings.

TABLE 1—SUMMARY OF COST/COST SAVINGS OF PETITIONS FOR REGULATORY REFORM

Monetized costs/(cost savings) by petition			
Petition #	Petition topic	Total cost savings (millions)	Annualized cost savings (millions)
P–1677	*Mobile Refrigerator Units*	$14.40	$1.00
P–1688	*Weight Tolerances for Paper Shipping Sacks*	1.60	0.11
P–1710	*Incorporation of an Institute of Makers of Explosives (IME) Standard*	5.10	0.36
P–1711	*Incorporation of American Pyrotechnic Association Standard*	3.90	0.27

TABLE 1—SUMMARY OF COST/COST SAVINGS OF PETITIONS FOR REGULATORY REFORM—Continued

Monetized costs/(cost savings) by petition			
Petition #	Petition topic	Total cost savings (millions)	Annualized cost savings (millions)
Total		25.00	1.74

In addition to these four items, PHMSA described an additional 19 items that are deregulatory in nature but lack of monetization of their cost savings impacts. While information gaps prevent quantification of cost savings for these items, PHMSA believes that they provide relief from unnecessary requirements or provide additional flexibility, and therefore should be considered deregulatory in nature.

Conclusion

In conclusion, this NPRM is not considered a significant regulatory action within the meaning of Executive Order 12866 (E.O. 12866) and DOT policies and procedures. *See* 44 FR 11034 (Feb. 26, 1979). PHMSA made this determination by finding that the economic effects of this regulatory action would not have an effect on the economy that exceeds the $100 million annual threshold defined by E.O. 12866 and that the regulatory action is not otherwise significant. PHMSA estimates a present value of quantified net cost savings of approximately $25 million over a perpetual time horizon and $1.74 million annualized at a 7 percent discount rate. Please see the PRIA in the regulatory docket for additional detail and a description of PHMSA's methods and calculations.

C. Executive Order 13771

This proposed rule is expected to be an E.O. 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule's economic analysis.

D. Executive Order 13132

This rulemaking was analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism'') and the presidential memorandum (''Preemption'') that was published in the **Federal Register** on May 22, 2009 [74 FR 24693]. Executive Order 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This rulemaking may preempt State, local, and Tribal requirements, but does not propose any regulation that has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal hazmat law (49 U.S.C. 5101–5128) contains an express preemption provision [49 U.S.C. 5125(b)] that preempts State, local, and Indian tribal requirements on the following subjects:

(1) The designation, description, and classification of hazardous materials;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This proposed rule addresses covered subject items above and preempts State, local, and Indian tribe requirements not meeting the ''substantively the same'' standard. This proposed rule is necessary to provide cost savings and regulatory flexibility to the regulated community. This rulemaking proposes to address 24 petitions for rulemaking submitted by the regulated community. PHMSA invites those with an interest in the issues presented in this NPRM to comment on the effect that the adoption of specific proposals may have on State or local governments.

E. Executive Order 13175

This rulemaking was analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Executive Order 13175 requires agencies to assure meaningful and timely input from Indian tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship and distribution of power between the Federal Government and Indian tribes. PHMSA does not view this rulemaking as having substantial tribal implications. Therefore, the funding and consultation requirements of Executive Order 13175 do not apply.

However, we invite Indian tribal governments to provide comments on the costs and effects that this or a future rulemaking could potentially have on Tribal communities.

F. Regulatory Flexibility Act, Executive Order 13272, and DOT Procedures and Policies

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Flexibility Fairness Act of 1996, requires Federal regulatory agencies to prepare an Interim Regulatory Flexibility Analysis (IRFA) for any NPRM subject to notice-and-comment rulemaking under the Administrative Procedure Act unless the agency head certifies that the rule would not have a significant economic impact on a substantial number of small entities. While PHMSA expects that this proposed rule would facilitate new technologies or other changes that provide safety equivalence at lower cost, streamline or reduce recordkeeping and other paperwork and reporting requirements, and address other changes to reduce the regulatory burden of the hazardous materials regulations (HMR), PHMSA has limited data on how the proposed rule would impact small entities. Therefore, PHMSA prepared an IRFA which is available in the docket for the rulemaking.

G. Paperwork Reduction Act

This NPRM does not impose new information collection requirements. Depending on the results of our request

for comments to this NPRM, there may be a decrease in the annual burden and costs under OMB-proposed changes to incorporate provisions contained in certain widely used or longstanding special permits with an established safety record.

PHMSA specifically requests comments on the information collection and recordkeeping burdens associated with developing, implementing, and maintaining these requirements for approval under this NPRM.

Address written comments to the Dockets Unit as identified in the **ADDRESSES** section of this NPRM. We must receive comments regarding information collection burdens prior to the close of the comment period identified in the **DATES** section of this NPRM.

H. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulatory and Deregulatory Actions (''Unified Agenda''). The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

I. Unfunded Mandates Reform Act

This proposed rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $160.8 million or more, adjusted for inflation, to either State, local, or tribal governments, in the aggregate, or to the private sector in any one year, and is the least burdensome alternative that achieves the objective of the rule.

J. Environmental Assessment

The National Environmental Policy Act, 42 U.S.C. 4321–4375, requires Federal agencies to analyze proposed actions to determine whether the action would have a significant impact on the human environment. The Council on Environmental Quality (CEQ) regulations require Federal agencies to conduct an environmental review considering: (1) The need for the proposed action; (2) alternatives to the proposed action; (3) probable environmental impacts of the proposed action and alternatives; and (4) the agencies and persons consulted during the consideration process.

Need for the Proposed Action

In response to petitions for rulemaking submitted by the regulated community, PHMSA proposes to amend the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) to update, clarify, or provide relief from miscellaneous regulatory requirements. Specifically, PHMSA is proposing amendments that include, but are not limited to, the following: Incorporating by Reference (IBR) multiple publications from both the CGA, IME, the American Society of Mechanical Engineers (ASME) and the APA; Phase-out of non-normalized steel for transportation of PIH materials, harmonizing the limited quantity exceptions for more than 100 entries for corrosive materials in the HMT, allowing for the continued use of Portable and Mobile Refrigerator Systems placed into service prior to 1991 that are rated to a minimum service pressure of 250 pounds per square inch (psi), revising the basis weight tolerance for paper shipping sacks, and allowing non-EPA waste to be managed in accordance with the Lab Pack exception.

These amendments are intended to promote safety and provide clarity and regulatory relief. The proposed changes were identified in response to petitions from stakeholders affected by the HMR. These proposed minor changes would clarify the HMR and enhance safety, while offering some net economic benefits.

This action is necessary to: (1) Fulfill our statutory directive to promote transportation safety; (2) fulfill our statutory directive under the Administrative Procedure Act that requires Federal agencies to give interested persons the right to petition an agency to issue, amend, or repeal a rule (5 U.S.C. 553(e)); (3) support governmental efforts to eliminate unnecessary burdens on the regulated community; (4) address safety concerns raised by petitioners and remove identified regulatory ambiguity; and (5) simplify and clarify the regulations in order to promote understanding and compliance.

These regulatory revisions would offer more efficient and effective ways of achieving the PHMSA goal of safe and secure transportation, protecting both people and the environment, of hazardous materials in commerce.

Alternatives

In proposing this rulemaking, PHMSA is considering the following alternatives:

Alternative 1: No Action

If PHMSA chose this alternative, it would not proceed with any rulemaking on this subject and the current regulatory standards would remain in effect. This option would not address outstanding petitions for rulemaking. We rejected the no action alternative.

Alternative 2: Go Forward With the Proposed Amendments to the HMR in This NPRM

This alternative is the current proposal as it appears in this NPRM, applying to transport of hazardous materials by highway, rail, vessel, and aircraft. The proposed amendments encompassed in this alternative are more fully addressed in the preamble and regulatory text sections of the NPRM.

Probable Environmental Impacts of the Alternatives

When developing potential regulatory requirements, PHMSA evaluates those requirements to consider the environmental impact of each amendment. Specifically, PHMSA evaluates the: Risk of release and resulting environmental impact; risk to human safety, including any risk to first responders; longevity of the packaging; and if the proposed regulation would be carried out in a defined geographic area, the resources, especially any sensitive areas, and how they could be impacted by any proposed regulations. The regulatory changes proposed in this rulemaking have been determined to be clarification, technology/design updates, harmonization, regulatory flexibility, standard incorporation, or editorial in nature. As such, these amendments have little or no impact on: The risk of release and resulting environmental impact; human safety; or longevity of the packaging. None of these amendments would be carried out in a defined geographic area, *i.e.,* this is a nationwide rulemaking.

Alternative 1: No Action

If PHMSA were to select the No Action Alternative, current regulations would remain in place, and no new provisions would be added. However, efficiencies gained through harmonization in updates to transport standards, lists of regulated substances, definitions, packagings, markings requirements, shipper requirements, modal requirements, etc., would not be realized. Foregone efficiencies in the No Action Alternative also include freeing up limited resources to concentrate on hazardous materials transportation issues of potentially much greater environmental impact. Not adopting the proposed environmental and safety requirements in the NPRM under the No Action Alternative would result in a lost opportunity for reducing negative environmental and safety-related

impacts. Greenhouse gas emissions would remain the same under the No Action Alternative.

Alternative 2: Go Forward With the Proposed Amendments to the HMR in This NPRM:

The Preferred Alternative encompasses enhanced and clarified regulatory requirements, which would result in increased compliance and fewer negative environmental and safety impacts. The table below summarizes the possible environmental benefits, and any potential negative impacts, for the amendments proposed in the NPRM.

SUMMARY OF PROBABLE ENVIRONMENTAL IMPACTS BY AMENDMENTS

Proposed amendment(s) to HMR (lettered as above herein)	Type of amendment(s)	Probable environmental impact(s) anticipated
A. Phase-Out of Non-Normalized Tank Cars Used to Transport Poison by Inhalation (PIH) material.	Regulatory Flexibility	No impacts—slightly positive benefits.
B. Limited Quantity Shipments of Hydrogen Peroxide	Regulatory Flexibility—Harmonization	No impacts.
C. Markings on Portable Tanks	Regulatory Flexibility	No impacts.
D. Reconditioning of Metal Drums	Regulatory Flexibility	No impacts.
E. Limited Quantity Harmonization	Regulatory Flexibility—Harmonization	No impacts.
F. Mobile Refrigeration Units	Regulatory Flexibility	No impacts.
G. Incorporation by Reference of Compressed Gas Association (CGA) Standards.	Standard Incorporation	No impacts.
H. Special Provision for Explosives	Regulatory Flexibility	No impacts.
I. EX Numbers and Safety Devices	Regulatory Flexibility	No impacts.
J. Cargo Tank Reports	Regulatory Flexibility	No impacts.
K. Weight Tolerances for Paper Shipping Sacks	Regulatory Flexibility	No impacts.
L. Markings on Closed Transport Containers	Regulatory Flexibility	No impacts.
M. Finalization of the HM–246 Tank Car Standard	Regulatory Flexibility	No impacts—slightly positive benefits.
N. Phase-out of non-HM–246 Tank Cars	Harmonization	No impacts—positive benefits.
O. Allow Non-RCRA Waste to Use Lab Pack Exception	Regulatory Flexibility	No impacts.
P. Incorporation of ASME Code Sections II, VIII, and IX	Standard Incorporation	No impacts.
Q. Import of Foreign Pi-Marked Cylinders	Regulatory Flexibility—Harmonization	No impacts.
R. Use of Alternative Leakproofness Test	Regulatory Flexibility	No impacts.
S. Placement of the word ''stabilized'' in shipping description.	Regulatory Flexibility	No impacts.
T. Incorporation of an Institute of Makers of Explosives (IME) Standard.	Standard Incorporation	No impacts.
U. Incorporation of American Pyrotechnic Association Standard.	Standard Incorporation	No impacts.

Agencies Consulted

This NPRM would affect some PHMSA stakeholders, including hazardous materials shippers and carriers by highway, rail, vessel, and aircraft, as well as package manufacturers and testers. PHMSA sought comment from the following Federal Agencies and modal partners:

- Federal Aviation Administration
- Federal Motor Carrier Safety Administration
- Federal Railroad Administration
- U.S. Coast Guard

PHMSA did not receive any adverse comments on the amendments proposed in this NPRM from these Federal Agencies.

Conclusion

The proposed amendments are intended to update, clarify, or provide relief from certain existing regulatory requirements to promote safer transportation practices; eliminate unnecessary regulatory requirements; facilitate international commerce; and make these requirements easier to understand. These proposed amendments, if adopted, would foster a greater level of compliance with the HMR because they offer clarity and regulatory flexibility, making it easier for the regulated community to comply with the HMR. Accordingly, the net environmental impact of this proposal would be slightly positive.

The provisions of this proposed rule build on current regulatory requirements to enhance the transportation safety and security of shipments of hazardous materials transported by highway, rail, aircraft and vessel, thereby reducing the risks of an accidental or intentional release of hazardous materials and consequent environmental damage. PHMSA believes that there are no non-negligible environmental impacts associated with this proposed rule.

PHMSA welcomes any views, data, or information related to environmental impacts that may result if the proposed requirements are adopted, as well as possible alternatives and their environmental impacts.

K. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

L. Executive Order 13609 and International Trade Analysis

Under Executive Order 13609, ''Promoting International Regulatory Cooperation,'' agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. *See* 77 FR 26413 (May 4, 2012). In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements. This proposed rule does

not negatively impact international trade.

M. Executive Order 13211

Executive Order 13211 (''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'') [66 FR 28355; May 22, 2001] requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' Under the executive order, a ''significant energy action'' is defined as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation (including a notice of inquiry, ANPRM, and NPRM) that: (1)(i) Is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

PHMSA does not anticipate that this rulemaking would result in significant energy action, but welcomes any data or information related to energy impacts that may result from this NPRM, as well as possible alternatives and their energy impacts. Please describe the impacts and the basis for the comment.

N. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs Federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specification of materials, test methods, or performance requirements) that are developed or adopted by voluntary consensus standards bodies. This NPRM involves multiple voluntary consensus standards which are listed in § 171.7.

List of Subjects

49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Incorporation by reference, Packaging and containers, Penalties, Reporting and recordkeeping requirements.

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements, Definitions and abbreviations.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Training, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 178

Hazardous materials transportation, Incorporation by reference, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 179

Hazardous materials transportation, Incorporation by reference, Railroad safety, Reporting and recordkeeping requirements.

49 CFR Part 180

Hazardous materials transportation, Incorporation by reference, Motor carriers, Motor vehicle safety, Packaging and containers, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, we are proposing to amend 49 CFR Chapter I as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

■ 1. The authority citation for part 107 is revised to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–121, sections 212–213; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 4 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 2. In Appendix A to Subpart D of Part 107, in the List of Frequently Cited Violations, revise the references for the APA documents in ''Offeror Requirements—Specific hazardous materials'' in section B.2 to read as follows:

Appendix A to Subpart D of Part 107—Guidelines for Civil Penalties

* * * * *

Violation description	Section or cite	Baseline assessment
* * * *	*	* *
Offeror Requirements—Specific hazardous materials		
* * * *	*	* *
B. Class 1—Explosives:		
1. Failure to mark the package with the EX number for each substance contained in the package or, alternatively, indicate the EX number for each substance in association with the description on the shipping description.	172.320	$1,000.
2. Offering an unapproved explosive for transportation:	173.54, 173.56(b).	
a. Division 1.4 fireworks meeting the chemistry requirements of APA Standard 87–1A.		5,000.
b. Division 1.3 fireworks meeting the chemistry requirements of APA Standard 87–1A.		7,500.
c. All other explosives (including forbidden)		12,500 and up.
3. Offering an unapproved explosive for transportation that minimally deviates from an approved design in a manner that does not impact safety:.	173.54, 173.56(b).	
a. Division 1.4		3,000.
b. Division 1.3		4,000.
c. All other explosives		6,000.
4. Offering a leaking or damaged package of explosives for transportation:	173.54(c).	

Violation description	Section or cite	Baseline assessment
a. Division 1.3 and 1.4	.....	12,500.
b. All other explosives	.....	16,500.
5. Offering a Class 1 material that is fitted with its own means of ignition or initiation, without providing protection from accidental actuation.	173.60(b)(5)	15,000.
6. Packaging explosives in the same outer packaging with other materials	173.61	9,300.
7. Transporting a detonator on the same vehicle as incompatible materials using the approved method listed in 177.835(g)(3) without meeting the requirements of IME Standard 22.	177.835(g)(3)	10,000.

* * * * * * *

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■ 3. In § 107.402, revise introductory text in paragraph (d) to read as follows:

§ 107.402 Application for designation as a certification agency.

* * * * *

(d) *Fireworks Certification Agency.* Prior to reviewing, and certifying Division 1.4G consumer fireworks (UN0336) for compliance with the APA Standard 87–1A (IBR, see § 171.7 of this chapter) as specified in part 173 of this chapter, a person must apply to, and be approved by, the Associate Administrator to act as a Fireworks Certification Agency.

* * * * *

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 4. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 4 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 5. In § 171.7 revise paragraphs (f), (g), (n)(4), (n)(6), (n)(9), (n)(20), (p) and paragraph (r) introductory text; and add paragraphs (r)(3), and (dd)(4) to read as follows:

§ 171.7171.7 Reference material.

* * * * *

(f) *American Pyrotechnics Association* (APA), P.O. Box 30438, Bethesda, MD 20824, (301) 907–8181, *www.americanpyro.com.*

(1) APA Standard 87–1A: Standard for the Construction, Classification, Approval and Transportation of Consumer Fireworks, January 1, 2018 version into §§ 107.402(d); 173.59; 173.64; 173.65; and appendix A to subpart D of part 107 (Guidelines for Civil Penalties).

(2) APA Standard 87–1B: Standard for the Construction, Classification, Approval, and Transportation of Display Fireworks, January 1, 2018 version into § 173.64 and appendix A to subpart D of part 107 (Guidelines for Civil Penalties).

(3) APA Standard 87–1C: Standard for the Construction, Classification, Approval, and Transportation of Entertainment Industry and Technical (EI&T) Pyrotechnics, January 1, 2018 version into § 173.64 and appendix A to subpart D of part 107 (Guidelines for Civil Penalties).

(g) *The American Society of Mechanical Engineers* (ASME), 150 Clove Road, Little Falls, NJ 07424–2139, telephone: 1–800–843–2763, *http://www.asme.org.*

(1) ASME Boiler and Pressure Vessel Code (ASME Code), 2017 Edition, July 1, 2017 (as follows), into §§ 172.102; 173.3; 173.5b; 173.24b; 173.306; 173.315; 173.318; 173.420; 178.255–1; 178.255–2; 178.255–14; 178.255–15; 178.273; 178.274; 178.276; 178.277; 178.320; 178.337–1; 178.337–2; 178.337–3; 178.337–4; 178.337–6; 178.337–16; 178.337–18; 178.338–1; 178.338–2; 178.338–3; 178.338–4; 178.338–5; 178.338–6; 178.338–13; 178.338–16; 178.338–18; 178.338–19; 178.345–1; 178.345–2; 178.345–3; 178.345–4; 178.345–7; 178.345–14; 178.345–15; 178.346–1; 178.347–1; 178.348–1; 179.400–3; 180.407:

(i) Section II—Materials—Part A—Ferrous Materials Specifications.

(ii) Section II—Materials—Part B—Nonferrous Material Specifications.

(iii) Section V—Nondestructive Examination.

(iv) Section VIII—Rules for Construction of Pressure Vessels Division 1.

(v) Section IX—Welding, Brazing, and Fusing Qualifications.

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(4) CGA C–6.1, Standards for Visual Inspection of High Pressure Aluminum Compressed Gas Cylinders, 2013, Sixth Edition, into §§ 180.205; 180.209.

* * * * *

(6) CGA C–6.3, Guidelines for Visual Inspection and Requalification of Low Pressure Aluminum Compressed Gas Cylinders, 2013, Third Edition into §§ 180.205; 180.209.

* * * * *

(9) CGA C–11, Recommended Practices for Inspection of Compressed Gas Cylinders at Time of Manufacture, 2013, Fifth Edition, into § 178.35.

* * * * *

(20) CGA S–7, Method for Selecting Pressure Relief Devices for Compressed Gas Mixtures in Cylinders, 2013, Fifth Edition, into § 173.301.

* * * * *

(p) Directive 2010/35/EU of the European Parliament and of the Council, June 16, 2010, into § 171.23.

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(r) *Institute of Makers of Explosives,* 1212 New York Ave NW #650, Washington, DC 20005.

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(3) IME/AESC JPG Standard, Guide to Obtaining DOT Approval of Jet Perforating Guns using AESC/IME Perforating Gun Specifications, Ver. 02, dated September 1, 2017, into § 173.67.

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(dd) * * *

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(4) European Agreement concerning the International Carriage of Dangerous Goods by Road, 2017, into § 171.23.

* * * * *

■ 6. In § 171.8, add the definition for ''waste material'' in alphabetical order to read as follows:

§ 171.8171.8 Definitions and abbreviations.

* * * * *

Waste material means, for the purposes of lab pack requirements in § 173.12 of this subchapter, all hazardous materials which are destined for disposal or recovery, and not so limited to only those defined as a hazardous waste in this section.

* * * * *

■ 7. In § 171.23, revise paragraph (a) to read as follows:

§ 171.23 Requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Transport Canada TDG Regulations, or the IAEA Regulations.

* * * * *

(a) *Conditions and requirements for cylinders and pressure receptacles.* (1) Except as provided in this paragraph (a), a filled cylinder (pressure receptacle) manufactured to other than a DOT specification or a UN standard in accordance with part 178 of this subchapter, a DOT exemption or special permit cylinder, a TC, CTC, CRC, or BTC cylinder authorized under § 171.12, or a cylinder used as a fire extinguisher in conformance with § 173.309(a) of this subchapter, may not be transported to, from, or within the United States.

(2) Cylinders (including UN pressure receptacles) transported to, from, or within the United States must conform to the applicable requirements of this subchapter. Unless otherwise excepted in this subchapter, a cylinder must not be transported unless—

(i) The cylinder is manufactured, inspected and tested in accordance with a DOT specification or a UN standard prescribed in part 178 of this subchapter, or a TC, CTC, CRC, or BTC specification set out in the Transport Canada TDG Regulations (IBR, see § 171.7), except that cylinders not conforming to these requirements must meet the requirements in paragraph (a)(3), (4), or (5) of this section;

(ii) The cylinder is equipped with a pressure relief device in accordance with § 173.301(f) of this subchapter and conforms to the applicable requirements in part 173 of this subchapter for the hazardous material involved;

(iii) The openings on an aluminum cylinder in oxygen service conform to the requirements of this paragraph, except when the cylinder is used for aircraft parts or used aboard an aircraft in accordance with the applicable airworthiness requirements and operating regulations. An aluminum DOT specification cylinder must have an opening configured with straight (parallel) threads. A UN pressure receptacle may have straight (parallel) or tapered threads provided the UN pressure receptacle is marked with the thread type, *e.g.* ''17E, 25E, 18P, or 25P'' and fitted with the properly marked valve; and

(iv) A UN pressure receptacle is marked with ''USA'' as a country of approval in conformance with §§ 178.69 and 178.70 of this subchapter, or ''CAN'' for Canada.

(3) *Pi-marked pressure receptacles.* Pressure receptacles that are marked with a pi mark in accordance with the European Directive 2010/35/EU on transportable pressure equipment (TPED) and that comply with the requirements of Packing Instruction P200 or P208 and 6.2.2 of the Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) concerning pressure relief device (PRD) use, test period, filling ratios, test pressure, maximum working pressure, and material compatibility for the lading contained or gas being filled, are authorized as follows:

(i) Import: Filled pressure receptacles may be imported into the United States, transported to point of use, including storage incidental to movement, and discharged and exported.

(ii) Export: Pressure receptacle may be filled with a gas in the United States and offered for transportation and transported, including storage incidental to movement, for export.

(iii) The bill of lading or other shipping paper must identify the cylinder and include the following certification: ''This cylinder has (These cylinders have) conform to the requirements for pi-marked cylinders found in 171.23(a)(3).''

(4) *Importation of cylinders for discharge within a single port area.* A cylinder manufactured to other than a DOT specification or UN standard in accordance with part 178 of this subchapter, or a TC, CTC, BTC, or CRC specification cylinder set out in the Transport Canada TDG Regulations (IBR, see § 171.7), and certified as being in conformance with the transportation regulations of another country may be authorized, upon written request to and approval by the Associate Administrator, for transportation within a single port area, provided—

(i) The cylinder is transported in a closed freight container;

(ii) The cylinder is certified by the importer to provide a level of safety at least equivalent to that required by the regulations in this subchapter for a comparable DOT, TC, CTC, BTC, or CRC specification or UN cylinder; and

(iii) The cylinder is not refilled for export unless in compliance with paragraph (a)(5) of this section.

(5) *Filling of cylinders for export or for use on board a vessel.* A cylinder not manufactured, inspected, tested and marked in accordance with part 178 of this subchapter, or a cylinder manufactured to other than a UN standard, DOT specification, exemption or special permit, or other than a TC, CTC, BTC, or CRC specification, may be filled with a gas in the United States and offered for transportation and transported for export or alternatively, for use on board a vessel, if the following conditions are met:

(i) The cylinder has been requalified and marked with the month and year of requalification in accordance with subpart C of part 180 of this subchapter, or has been requalified as authorized by the Associate Administrator;

(ii) In addition to other requirements of this subchapter, the maximum filling density, service pressure, and pressure relief device for each cylinder conform to the requirements of this part for the gas involved; and

(iii) The bill of lading or other shipping paper identifies the cylinder and includes the following certification: ''This cylinder has (These cylinders have) been qualified, as required, and filled in accordance with the DOT requirements for export.''

(6) *Cylinders not equipped with pressure relief devices.* A DOT specification or a UN cylinder manufactured, inspected, tested and marked in accordance with part 178 of this subchapter and otherwise conforms to the requirements of part 173 of this subchapter for the gas involved, except that the cylinder is not equipped with a pressure relief device may be filled with a gas and offered for transportation and transported for export if the following conditions are met:

(i) Each DOT specification cylinder or UN pressure receptacle must be plainly and durably marked ''For Export Only'';

(ii) The shipping paper must carry the following certification: ''This cylinder has (These cylinders have) been retested and refilled in accordance with the DOT requirements for export.''; and

(iii) The emergency response information provided with the shipment and available from the emergency response telephone contact person must indicate that the pressure receptacles are not fitted with pressure relief devices and provide appropriate guidance for exposure to fire.

* * * * *

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

■ 8. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 9. In § 172.101, add paragraph (c)(17) and amend the Hazardous Materials Table to revise entries under ''[REVISE]'' in the appropriate alphabetical sequence to read as follows:

§ 172.101 Purpose and use of the hazardous materials table.

* * * * *

(c) * * *

(17) Unless it is already included in the proper shipping name in the § 172.101 Table, the qualifying word ''stabilized'' may be added in association with the proper shipping name, as appropriate, where without stabilization the substance would be forbidden for transportation according to § 173.21(f) of this subchapter.

* * * * *

BILLING CODE 4909–60–P

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification Numbers	PG	Label Codes	Special Provisions (§ 172.102)	(8) Packaging (§ 173.***)			(9) Quantity limitations (see §§ 173.27 and 175.75)		(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	[REVISE]												
	Allyl isothiocyanate, stabilized	6.1	UN1545	II	6.1, 3	387, A3, A7, IB2, T7, TP2	153	202	243	Forbidden	60 L	D	25, 40
	*		*		*		*		*		*		*
	Aluminum smelting by-products *or* Aluminum remelting by-products	4.3	UN3170	II	4.3	128, B115, IB7, IP2, IP21, T3, TP33, W31, W40	151	212	242	15 kg	50 kg	B	13, 85, 103, 148
				III	4.3	128, B115, IB8, IP21, T1, TP33, W31	None	213	241	25 kg	100 kg	B	13, 85, 103, 148
	*		*		*		*		*		*		*
G	Amine, liquid, corrosive, flammable, n.o.s. or Polyamines, liquid, corrosive, flammable, n.o.s.	8	UN2734	I	8, 3	A3, A6, N34, T14, TP2, TP27	None	201	243	0.5L	2.5L	A	52
				II	8, 3	IB2, T11, TP2, TP27	154	201	243	1L	30L	A	52
	*		*		*		*		*		*		*
	Amyl mercaptan	3	UN1111	II	3	A3, A6, IB2, T4, TP1	150	202	242	5 L	60 L	B	95, 102
	*		*		*		*		*		*		*
	Antimony pentachloride, liquid	8	UN1730	II	8	B2, IB2, T7, TP2	154	202	242	1 L	30 L	C	40
	*		*		*		*		*		*		*

	Antimony pentafluoride	8	UN1732	II	8, 6.1	A3, A6, A7, A10, IB2, N3, N36, T7, TP2	154	202	243	Forbidden	30 L	D	40, 44, 89, 100, 141
	*		*		*		*		*		*		*
	Batteries, dry, containing potassium hydroxide solid, *electric storage*	8	UN3028		8	237	154	213	None	25 kg	230 kg	A	52
	*		*		*		*		*		*		*
	Borneol	4.1	UN1312	III	4.1	A1, IB8, IP3, T1, TP33	151	213	240	25 kg	100 kg	A	
	*		*		*		*		*		*		*
	5-tert-Butyl-2,4,6-trinitro-m-xylene *or* Musk xylene	4.1	UN2956	III	4.1	159	151	223	None	Forbidden	Forbidden	D	12, 25, 40, 127
	*		*		*		*		*		*		*
	1,4-Butynediol	6.1	UN2716	III	6.1	A1, IB8, IP3, T1, TP33	153	213	240	100 kg	200 kg	C	52, 53, 70
	*		*		*		*		*		*		*
	Calcium resinate	4.1	UN1313	III	4.1	A1, A19, IB6, T1, TP33	151	213	240	25 kg	100 kg	A	
	Calcium resinate, fused	4.1	UN1314	III	4.1	A1, A19, IB4, T1, TP33	151	213	240	25 kg	100 kg	A	
	*		*		*		*		*		*		*
	Camphor, *synthetic*	4.1	UN2717	III	4.1	A1, IB8, IP3, T1, TP33	151	213	240	25 kg	100 kg	A	
	*		*		*		*		*		*		*
	Celluloid, *in block, rods, rolls, sheets, tubes, etc., except scrap*	4.1	UN2000	III	4.1	420	151	213	240	25 kg	100 kg	A	
	*		*		*		*		*		*		*
	Cerium, *slabs, ingots, or rods*	4.1	UN1333	II	4.1	IB8, IP2, IP4, N34, W100	151	212	240	15 kg	50 kg	A	13, 74, 91, 147, 148
	*		*		*		*		*		*		*

	Chloric acid aqueous solution, *with not more than 10 percent chloric acid*	5.1	UN2626	II	5.1	IB2, T4, TP1, W31	152	229	None	Forbidden	Forbidden	D	56, 58
	*		*		*		*		*		*		*
	1-Chloropropane	3	UN1278	II	3	IB2, IP8, N34, T7, TP2	150	202	242	Forbidden	60 L	E	
	Chromium trioxide, anhydrous	5.1	UN1463	II	5.1, 6.1, 8	IB8, IP2, IP4, T3, TP33, W31	152	212	242	5 kg	25 kg	A	66, 90
	*		*		*		*		*		*		*
	Corrosive liquids, flammable, n.o.s.	8	UN2920	I	8, 3	A6, B10, T14, TP2, TP27	None	201	243	0.5 L	2.5 L	C	25, 40
				II	8, 3	B2, IB2, T11, TP2, TP27	154	202	243	1 L	30 L	C	25, 40
	*		*		*		*		*		*		*
G	Corrosive liquids, oxidizing, n.o.s.	8	UN3093	I	8, 5.1	A6, A7	None	201	243	Forbidden	2.5 L	C	89
				II	8, 5.1	A6, A7, IB2	154	202	243	1 L	30 L	C	89
	*		*		*		*		*		*		*
	Corrosive solids, flammable, n.o.s.	8	UN2921	I	8, 4.1	IB6, T6, TP33	None	211	242	1 kg	25 kg	B	12, 25
				II	8, 4.1	IB8, IP2, IP4, T3, TP33	154	212	242	15 kg	50 kg	B	12, 25
	*		*		*		*		*		*		*
G	Corrosive solids, oxidizing, n.o.s.	8	UN3084	I	8, 5.1	T6, TP33	None	211	242	1 kg	25 kg	C	
				II	8, 5.1	154, IB6, IP2, T3, TP33	154	212	242	15 kg	50 kg	C	
	*		*		*		*		*		*		*
G	Corrosive solids, water-reactive, n.o.s.	8	UN3096	I	8, 4.3	IB4, IP1, T6, TP33	None	211	243	1 kg	25 kg	D	13, 148

				II	8, 4.3	IB6, IP2, T3, TP33, W100	154	212	242	15 kg	50 kg	D	13, 148
G	Corrosive liquids, oxidizing, n.o.s.	8	UN3093	I	8, 5.1	A6, A7	None	201	243	Forbidden	2.5 L	C	89
				II	8, 5.1	A6, A7, IB2	154	202	243	1 L	30 L	C	89
	*		*		*		*		*		*		*
G	Corrosive solids, oxidizing, n.o.s.	8	UN3084	I	8, 5.1	T6, TP33	None	211	242	1 kg	25 kg	C	
				II	8, 5.1	154, IB6, IP2, T3, TP33	154	212	242	15 kg	50 kg	C	
G	Corrosive solids, self-heating, n.o.s.	8	UN3095	I	8, 4.2	T6, TP33	None	211	243	1 kg	25 kg	C	
				II	8, 4.2	IB6, IP2, T3, TP33	154	212	242	15 kg	50 kg	C	
	*		*		*		*		*		*		*
G	Corrosive solids, water-reactive, n.o.s.	8	UN3096	I	8, 4.3	IB4, IP1, T6, TP33	None	211	243	1 kg	25 kg	D	13, 148
				II	8, 4.3	IB6, IP2, T3, TP33, W100	154	212	242	15 kg	50 kg	D	13, 148
*	*	*	*	*	*	*	*	*	*	*	*	*	**
	Cyanuric chloride	8	UN2670	II	8	IB8, IP2, IP4, T3, TP33	None	212	240	15 kg	50 kg	A	12, 25, 40
	*		*		*		*		*		*		*
	Cyclohexylamine	8	UN2357	II	8, 3	IB2, T7, TP2	154	202	243	1 L	30 L	A	40
	*		*		*		*		*		*		*
	Decaborane	4.1	UN1868	II	4.1, 6.1	A19, A20, IB6, IP2, T3, TP33, W31	151	212	None	Forbidden	50 kg	A	74
	*		*		*		*		*		*		*
	Detonator assemblies, non-electric, for blasting	1.4B	UN0361		1.4B	148	63(f), 63(g)	62	None	Forbidden	75 kg	05	25
	*		*		*		*		*		*		*

	Detonators, electric, for blasting	1.4B	UN0255		1.4B	148	63(f), 63(g)	62	None	Forbidden	75 kg	05	25
	*		*		*		*		*		*		*
	Detonators for ammunition	1.4B	UN0365		1.4B		None	62	None	Forbidden	75 kg	05	25
	*		*		*		*		*		*		*
	Detonators, non-electric, for blasting	1.4B	UN0267		1.4B		63(f), 63(g)	62	None	Forbidden	75 kg	05	25
	*		*		*		*		*		*		*
	Diethyl sulfide	3	UN2375	II	3	IB2, T7, TP1, TP13	150	202	243	5 L	60 L	E	
	*		*		*		*		*		*		*
	2-Diethylaminoethanol	8	UN2686	II	8, 3	B2, IB2, T7, TP2	154	202	243	1 L	30 L	A	
	*		*		*		*		*		*		*
	N,N-Diethylethylenediamine	8	UN2685	II	8, 3	IB2, T7, TP2	154	202	243	1 L	30 L	A	
	*		*		*		*		*		*		*
	Diethylthiophosphoryl chloride	8	UN2751	II	8	B2, IB2, T7, TP2	154	212	240	15 kg	50 kg	D	12, 25, 40
	*		*		*		*		*		*		*
	Difluorophosphoric acid, anhydrous	8	UN1768	II	8	A6, A7, B2, IB2, N5, N34, T8, TP2	154	202	242	1 L	30 L	A	40
	*		*		*		*		*		*		*
	Di-n-butylamine	8	UN2248	II	8, 3	IB2, T7, TP2	154	202	243	1 L	30 L	A	
	*		*		*		*		*		*		*
	Ethyl bromoacetate	6.1	UN1603	II	6.1, 3	IB2, T7, TP2	153	202	243	Forbidden	Forbidden	D	40

	*		*		*		*		*		*		*
	Fibers *or* Fabrics impregnated with weakly nitrated nitrocellulose, n.o.s.	4.1	UN1353	III	4.1	A1, IB8, IP3	151	213	240	25 kg	100 kg	D	
	*		*		*		*		*		*		*
	Films, nitrocellulose base, *gelatine coated (except scrap)*	4.1	UN1324	III	4.1		151	183	None	25 kg	100 kg	D	28
	*		*		*		*		*		*		*
	Firelighters, solid *with flammable liquid*	4.1	UN2623	III	4.1	A1, A19	151	213	None	25 kg	100 kg	A	52
	*		*		*		*		*		*		*
G	Flammable solid, oxidizing, n.o.s.	4.1	UN3097	II	4.1, 5.1	131	151	214	214	Forbidden	Forbidden	E	40
				III	4.1, 5.1	131, T1, TP33	151	214	214	Forbidden	Forbidden	D	40
	*		*		*		*		*		*		*
	Flammable solids, corrosive, organic, n.o.s.	4.1	UN2925	II	4.1, 8	A1, IB6, IP2, T3, TP33	151	212	242	15 kg	50 kg	D	40
				III	4.1, 8	A1, IB6, T1, TP33	151	213	242	25 kg	100 kg	D	40
	*		*		*		*		*		*		*
	Fluorophosphoric acid anhydrous	8	UN1776	II	8	A6, A7, B2, IB2, N3, N34, T8, TP2	154	202	242	1 L	30 L	A	
	*		*		*		*		*		*		*
	Fluorosilicic acid	8	UN1778	II	8	A6, A7, B2, B15, IB2, N3, N34, T8, TP2	154	202	242	1 L	30 L	A	
	*		*		*		*		*		*		*
	Gallium	8	UN2803	III	8	T1, TP33	154	162	240	20 kg	20 kg	B	25

	*		*		*		*		*		*		*
	Hafnium powder, wetted *with not less than 25 percent water (a visible excess of water must be present) (a) mechanically produced, particle size less than 53 microns; (b) chemically produced, particle size less than 840 microns*	4.1	UN1326	II	4.1	A6, A19, A20, IB6, IP2, N34, T3, TP33, W31, W40	151	212	241	15 kg	50 kg	E	74
	*		*		*		*		*		*		*
	Hexadienes	3	UN2458	II	3	IB2, T4, TP1	150	202	242	5 L	60 L	B	
	*		*		*		*		*		*		*
	Hexafluorophosphoric acid	8	UN1782	II	8	A6, A7, B2, IB2, N3, N34, T8, TP2	154	202	242	1 L	30 L	A	
	*		*		*		*		*		*		*
	Hexamethylenediamine solution	8	UN1783	II	8	IB2, T7, TP2	154	202	242	1 L	30 L	A	
				III	8	IB3, T4, TP1	154	203	241	5 L	60 L	A	
	*		*		*		*		*		*		*
	Hydrazine aqueous solution, *with more than 37% hydrazine, by mass*	8	UN2030	I	8, 6.1	B16, B53, T10, TP2, TP13	None	201	243	Forbidden	2.5 L	D	40, 52
				II	8, 6.1	B16, B53, IB2, T7, TP2, TP13	154	202	243	Forbidden	30 L	D	40, 52
				III	8, 6.1	B16, B53, IB3, T4, TP1	154	203	241	5 L	60 L	D	40, 52
	*		*		*		*		*		*		*
	Hydrogen peroxide and peroxyacetic acid mixtures, stabilized *with acids, water, and not more than 5 percent peroxyacetic acid*	5.1	UN3149	II	5.1, 8	145, A2, A3, A6, B53, IB2, IP5, T7, TP2, TP6, TP24	152	202	243	1 L	5 L	D	25, 66, 75.

	Hydrogen, peroxide, aqueous solutions with more than 40 percent but not more than 60 percent hydrogen peroxide (stabilized as necessary)	5.1	UN2014	II	5.1, 8	12, A60, B53, B80, B81, B85, IB2, IP5, T7, TP2, TP6, TP24, TP37	152	202	243	Forbidden	Forbidden	D	25, 66, 75
	Hydrogen peroxide, aqueous solutions with not less than 20 percent but not more than 40 percent hydrogen peroxide (stabilized as necessary)	5.1	UN2014	II	5.1, 8	A2, A3, A6, B53, IB2, IP5, T7, TP2, TP6, TP24, TP37	152	202	243	1 L	5 L	D	25, 66, 75
	*		*		*		*		*		*		*
	Hydrogendifluoride, solid, n.o.s.	8	UN1740	II	8	IB8, IP2, IP4, N3, N34, T3, TP33	154	212	240	15 kg	50 kg	A	25, 40, 52
				III	8	IB8, IP3, N3, N34, T1, TP33	154	213	240	25 kg	100 kg	A	25, 40, 52
	*		*		*		*		*		*		*
	Iodine monochloride, solid	8	UN1792	II	8	B6, IB8, IP2, IP4, N41, T7, TP2	154	212	240	Forbidden	50 kg	D	40, 66, 74,
	*		*		*		*		*		*		*
	Lead phosphite, dibasic	4.1	UN2989	II	4.1	IB8, IP2, IP4, T3, TP33	151	212	240	15 kg	50 kg	B	34.
				III	4.1	IB8, IP3, T1, TP33	151	213	240	25 kg	100 kg	B	34.
	*		*		*		*		*		*		*
	Mercaptans, liquid, flammable, toxic, n.o.s. *or* Mercaptan mixtures, liquid, flammable, toxic, n.o.s.	3	UN1228	II	3, 6.1	IB2, T11, TP2, TP27	150	202	243	Forbidden	60 L	B	40, 95, 102
				III	3, 6.1	A6, B1, IB3, T7, TP1, TP28	150	203	242	5 L	220 L	A	40, 95, 102
	*		*		*		*		*		*		*
	2-Methyl-2-butene	3	UN2460	II	3	IB2, IP8, T7, TP1	150	202	242	5 L	60 L	E	

	*		*		*		*		*		*		*
	Methylal	3	UN1234	II	3	IB2, IP8, T7, TP2	150	202	242	5 L	60 L	E	
	*		*		*		*		*		*		*
	Nitrating acid mixtures spent *with not more than 50 percent nitric acid*	8	UN1826	II	8	A7, B2, IB2, T8, TP2	154	158	242	Forbidden	30 L	D	40
	*		*		*		*		*		*		*
	Nitrating acid mixtures *with not more than 50 percent nitric acid*	8	UN1796	II	8	A7, B2, IB2, T8, TP2, TP13	154	158	242	Forbidden	30 L	D	40
	*		*		*		*		*		*		*
	Nitric acid *other than red fuming, with at least 65 percent, but not more than 70 percent nitric acid*	8	UN2031	II	8, 5.1	A6, B2, B47, B53, IB2, IP15, T8, TP2	154	158	242	Forbidden	30 L	D	66, 74, 89, 90
	Nitric acid *other than red fuming, with more than 20 percent and less than 65 percent nitric acid*	8	UN2031	II	8	A6, A212, B2, B47, B53, IB2, IP15, T8, TP2	154	158	242	Forbidden	30 L	D	44, 66, 74, 89, 90
	Nitric acid *other than red fuming with not more than 20 percent nitric acid*	8	UN2031	II	8	A6, B2, B47, B53, IB2, T8, TP2	154	158	242	1 L	30 L	D	
	*		*		*		*		*		*		*
	Octafluorobut-2-ene *or* Refrigerant gas R 1318	2.2	UN2422		2.2		306	304	314, 315	75 kg	150 kg	A	
	Octafluorocyclobutane, *or* Refrigerant gas RC 318	2.2	UN1976		2.2	T50	306	304	314, 315	75 kg	150 kg	A	
	Octafluoropropane*or* Refrigerant gas R 218	2.2	UN2424		2.2	T50	306	304	314, 315	75 kg	150 kg	A	
	*		*		*		*		*		*		*
G	Organometallic substance, liquid, water-reactive	4.3	UN3398	I	4.3	T13, TP2, TP7, TP36, TP47, W31	None	201	244	Forbidden	1 L	D	13, 40, 52, 148
				II	4.3	IB1, IP2, T7, TP2, TP7, TP36, TP47,	151	202	243	1 L	5 L	D	13, 40, 52, 148

						W31							
				III	4.3	IB2, IP4, T7, TP2, TP7, TP36, TP47, W31	151	203	242	5 L	60 L	E	13, 40, 52, 148
G	Organometallic substance, liquid, water-reactive, flammable	4.3	UN3399	I	4.3, 3	T13, TP2, TP7, TP36, TP47, W31	None	201	244	Forbidden	1 L	D	13, 40, 52, 148
				II	4.3, 3	IB1, IP2, T7, TP2, TP7, TP36, TP47, W31	151	202	243	1 L	5 L	D	13, 40, 52, 148
				III	4.3, 3	IB2, IP4, T7, TP2, TP7, TP36, TP47, W31	151	203	242	5 L	60 L	E	13, 40, 52, 148
	*		*		*		*		*		*		*
G	Organometallic substance, solid, water-reactive, self-heating	4.3	UN3397	I	4.3, 4.2	N40, T9, TP7, TP33, TP36, TP47, W31	None	211	242	Forbidden	15 kg	E	13, 40, 52, 148
				II	4.3, 4.2	IB4, T3, TP33, TP36, TP47, W31	151	212	242	15 kg	50 kg	E	13, 40, 52, 148
				III	4.3, 4.2	IB6, T1, TP33, TP36, TP47, W31	151	213	241	25 kg	100 kg	E	13, 40, 52, 148
	*		*		*		*		*		*		*
G	Oxidizing liquid, corrosive, n.o.s.	5.1	UN3098	I	5.1, 8	62, A6	None	201	244	Forbidden	2.5 L	D	13, 56, 58, 138
				II	5.1, 8	62, IB1	152	202	243	1 L	5 L	B	13, 56, 58, 138
				III	5.1, 8	62, IB2	152	203	242	2.5 L	30 L	B	13, 56, 58, 138
	*		*		*		*		*		*		*
G	Oxidizing solid, water reactive, n.o.s.	5.1	UN3121	I	5.1, 4.3	62	None	214	214	Forbidden	Forbidden		13, 148
				II	5.1, 4.3	62	152	214	214	Forbidden	Forbidden		13, 148

	Perchloric acid *with not more than 50 percent acid by mass*	8	UN1802	II	8, 5.1	IB2, N41, T7, TP2	154	202	243	Forbidden	30 L	C	66
	*		*		*		*		*		*		*
	Peroxides, inorganic, n.o.s.	5.1	UN1483	II	5.1	A7, A20, IB6, IP2, N34, T3, TP33, W100	152	212	242	5 kg	25 kg	C	13, 52, 66, 75, 148
				III	5.1	A7, A20, B134, IB8, IP21, N34, T1, TP33, W100	152	213	240	25 kg	100 kg	C	13, 52, 66, 75, 148
	*		*		*		*		*		*		*
	Phosphorus heptasulfide, *free from yellow or white phosphorus*	4.1	UN1339	II	4.1	A20, IB4, N34, T3, TP33, W31	151	212	240	15 kg	50 kg	B	13, 74, 147, 148
	*		*		*		*		*		*		*
	Phosphorus, amorphous	4.1	UN1338	III	4.1	A1, A19, B1, B9, B26, IB8, IP3, T1, TP33	151	213	243	25 kg	100 kg	A	74
	*		*		*		*		*		*		*
	Phosphorus oxybromide	8	UN1939	II	8	B8, IB8, IP2, IP4, N41, N43, T3, TP33	154	212	240	Forbidden	50 kg	C	12, 25, 40
	*		*		*		*		*		*		*
	Phosphorus pentachloride	8	UN1806	II	8	A7, IB8, IP2, IP4, N34, T3, TP33	154	212	240	Forbidden	50 kg	C	40, 44, 89, 100, 141
	Phosphorus sesquisulfide, *free from yellow or white phosphorus*	4.1	UN1341	II	4.1	A20, IB4, N34, T3, TP33, W31	151	212	240	15 kg	50 kg	B	74
	Phosphorus tribromide	8	UN1808	II	8	A3, A6, A7, B2, B25, IB2, N34, N43, T7, TP2	154	202	242	Forbidden	30 L	C	40

	*		*		*		*		*		*		*
	Phosphorus trisulfide, *free from yellow or white phosphorus*	4.1	UN1343	II	4.1	A20, IB4, N34, T3, TP33, W31	151	212	240	15 kg	50 kg	B	13, 74, 147, 148
	*		*		*		*		*		*		*
	Propionitrile	3	UN2404	II	3, 6.1	IB2, T7, TP1, TP13	150	202	243	Forbidden	60 L	E	40
	*		*		*		*		*		*		*
	1,2-Propylenediamine	8	UN2258	II	8, 3	A3, A6, IB2, N34, T7, TP2	154	202	243	1 L	30 L	A	40
	*		*		*		*		*		*		*
	Pyridine	3	UN1282	II	3	IB2, T4, TP2	150	202	242	5 L	60 L	B	21, 100
	*		*		*		*		*		*		*
	Safety devices, pyrotechnic	1.4G	UN0503		1.4G	A200	166	62	166	Forbidden	75 kg	02	25
	*		*		*		*		*		*		*
	Silicon powder, amorphous	4.1	UN1346	III	4.1	A1, IB8, IP3, T1, TP33	151	213	240	25 kg	100 kg	A	74
	*		*		*		*		*		*		*
	Sludge, acid	8	UN1906	II	8	A3, A7, B2, IB2, N34, T8, TP2, TP28	154	202	242	Forbidden	30 L	C	14
	*		*		*		*		*		*		*
	Sodium chlorite	5.1	UN1496	II	5.1	A9, IB8, IP2, IP4, N34, T3, TP33	152	212	242	5 kg	25 kg	A	56, 58
	*		*		*		*		*		*		*
I	Sulfur	4.1	UN1350	III	4.1	30, B120, IB8, IP3, T1, TP33	151	None	240	25 kg	100 kg	A	25, 74
	*		*		*		*		*		*		*

	Sulfuric acid, spent	8	UN1832	II	8	A3, A7, B2, B83, B84, IB2, N34, T8, TP2	154	202	242	Forbidden	30 L	C	14
	Tetrafluoromethane or Refrigerant gas R 14	2.2	UN1982		2.2		306	302	None	75 kg	150 kg	A	
	*		*		*		*		*		*		*
	Tetrahydrofuran	3	UN2056	II	3	IB2, T4, TP1	150	202	242	5 L	60 L	B	
	Thiophosphoryl chloride	8	UN1837	II	8	A3, A7, B2, B8, B25, IB2, N34, T7, TP2	154	202	242	Forbidden	30 L	C	40
	*		*		*		*		*		*		*
	Titanium hydride	4.1	UN1871	II	4.1	A19, A20, IB4, N34, T3, TP33, W31, W40	151	212	241	15 kg	50 kg	E	
	*		*		*		*		*		*		*
	Titanium powder, wetted *with not less than 25 percent water (a visible excess of water must be present) (a) mechanically produced, particle size less than 53 microns; (b) chemically produced, particle size less than 840 microns*	4.1	UN1352	II	4.1	A19, A20, IB6, IP2, N34, T3, TP33, W31, W40	151	212	240	15 kg	50 kg	E	74
	Titanium sponge granules *or* Titanium sponge powders	4.1	UN2878	III	4.1	A1, B134, IB8, IP21, T1, TP33, W100	151	213	240	25 kg	100 kg	D	13, 74, 147, 148
	*		*		*		*		*		*		*

G	Toxic liquids, water-reactive, n.o.s.	6.1	UN3123	I	6.1, 4.3	A4	None	201	243	Forbidden	1 L	E	13,40, 148
				II	6.1, 4.3	IB2	153	202	243	1 L	5 L	E	13, 40, 148
	*		*		*		*		*		*		*
G	Toxins, extracted from living sources, liquid, n.o.s.	6.1	UN3172	I	6.1	141	None	201	243	1 L	30 L	B	40
				II	6.1	141, IB2	153	202	243	5 L	60 L	B	40
				III	6.1	141, IB3	153	203	241	60 L	220 L	B	40
G	Toxins, extracted from living sources, solid, n.o.s.	6.1	UN3462	I	6.1	141, IB7, IP1, T6, TP33	None	211	243	5 kg	50 kg	B	
				II	6.1	141, IB8, IP2, IP4, T3 TP33	153	212	243	25 kg	100 kg	B	
				III	6.1	141, IB8, IP3, T1 TP33	153	213	241	100 kg	200 kg	A	
	*		*		*		*		*		*		*
G	Toxins, extracted from living sources, solid, n.o.s.	6.1	UN3462	I	6.1	141, IB7, IP1, T6, TP33	None	211	243	5 kg	50 kg	B	G
				II	6.1	141, IB8, IP2, IP4, T3 TP33	153	212	243	25 kg	100 kg	B	
				III	6.1	141, IB8, IP3, T1 TP33	153	213	241	100 kg	200 kg	A	
	*		*		*		*		*		*		*
	Triallylamine	3	UN2610	III	3, 8	B1, IB3, T4, TP1	150	203	242	5 L	60 L	A	40
	*		*		*		*		*		*		*
G	Water-reactive liquid, corrosive, n.o.s.	4.3	UN3129	I	4.3, 8	T14, TP2, TP7, TP13	None	201	243	Forbidden	1 L	D	13, 148
				II	4.3, 8	IB1, T11, TP2, TP7	151	202	243	1 L	5 L	E	13, 85, 148
				III	4.3, 8	IB2, T7, TP2, TP7	151	203	242	5 L	60 L	E	13, 148
G	Water-reactive liquid, n.o.s.	4.3	UN3148	I	4.3	T13, TP2, TP7, TP41, W31	None	201	244	Forbidden	1 L	E	13, 40, 148

				II	4.3	IB1, T7, TP2, TP7, W31	151	202	243	1 L	5 L	E	13, 40, 148
				III	4.3	IB2, T7, TP2, TP7, W31	151	203	242	5 L	60 L	E	13, 40, 148
G	Water-reactive liquid, toxic, n.o.s.	4.3	UN3130	I	4.3, 6.1	A4	None	201	243	Forbidden	1 L	D	13, 148
				II	4.3, 6.1	IB1	151	202	243	1 L	5 L	E	13, 85, 148
				III	4.3, 6.1	IB2	151	203	242	5 L	60 L	E	13, 85, 148
	*		*		*		*		*		*		*
G	Water-reactive, solid, oxidizing, n.o.s.	4.3	UN3133	II	4.3, 5.1		151	214	214	Forbidden	Forbidden	E	13, 40, 148
				III	4.3, 5.1		151	214	214	Forbidden	Forbidden	E	13, 40, 148
	*		*		*		*		*		*		*
	Zinc ammonium nitrite	5.1	UN1512	II	5.1	IB8, IP4, T3, TP33	152	212	242	5 kg	25 kg	E	
	*		*		*		*		*		*		*
	Zinc chloride, anhydrous	8	UN2331	III	8	IB8, IP3, T1, TP33	154	213	240	25 kg	100 kg	A	
	*		*		*		*		*		*		*
	Zirconium hydride	4.1	UN1437	II	4.1	A19, A20, IB4, N34, T3, TP33, W31, W40	151	212	240	15 kg	50 kg	E	
	*		*		*		*		*		*		*
	Zirconium powder, wetted *with not less than 25 percent water (a visible excess of water must be present) (a) mechanically produced, particle size less than 53 microns; (b) chemically produced, particle size less than 840 microns*	4.1	UN1358	II	4.1	A19, A20, IB6, IP2, N34, T3, TP33, W31, W40	151	212	241	15 kg	50 kg	E	13, 74, 147, 148

	*		*		*		*		*		*		*
	Zirconium suspended in a liquid	3	UN1308	I	3		None	201	243	Forbidden	Forbidden	B	
				II	3	IB2	150	202	242	5 L	60 L	B	
				III	3	B1, IB2	150	203	242	60 L	220 L	B	
	*		*		*		*		*		*		*

§ 172.102 [Amended]

■ 10. In § 172.102, in paragraph (c)(1) remove special provision 103.

■ 11. In § 172.302, revise paragraph (b)(2) to read as follows:

§ 172.302 General marking requirements for bulk packagings.

* * * * *

(b) * * *

(2) Have a width of at least 4.0 mm (0.16 inch) and a height of at least 12 mm (0.47 inch) for portable tanks with capacities of less than 3,785 L (1,000 gallons) and a width of at least 4.0 mm (0.16 inch) and a height of 25 mm (one inch) for IBCs; and

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 12. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 13. In § 173.5b, revise paragraph (b) to read as follows:

§ 173.5b Portable and mobile refrigeration systems.

* * * * *

(b) *Refrigeration systems placed into service prior to June 1, 1991.* (1) For refrigeration systems placed into service prior to June 1, 1991, each pressure vessel and associated piping must be rated at a MAWP of not less than 250 psig. During transportation, pressure in the components that are part of the evaporating line may not exceed 150 psig.

(2) Each pressure vessel and associated piping that is part of the evaporating line must be marked ''LOW SIDE'' in a permanent and clearly visible manner. The evaporating line must have a pressure gauge with corresponding temperature markings mounted in a manner that is easily readable when standing on the ground. The gauge must be permanently marked or tagged ''SATURATION GAUGE.''

(3) Each pressure vessel and associated piping containing liquid anhydrous ammonia must be isolated using appropriate means from piping and components marked ''LOW SIDE.''

(4) Prior to transportation, each pressure vessel and associated piping must be relieved of enough gaseous lading to ensure that the MAWP is not exceeded at transport temperatures up to 54 °C (130 °F).

* * * * *

■ 14. In § 173.28, revise (c)(1)(i) to read as follows:

§ 173.28 Reuse, reconditioning and remanufacture of packagings.

* * * * *

(c) * * *

(1) * * *

(i) Cleaning to base material of construction, with all former contents and internal and external corrosion removed, and any external coatings and labels substantially removed to the extent that tightly adhering paint, mill scale, and rust may remain on no more than 10 percent of each unit's surface area;

* * * * *

■ 15. In § 173.31, revise paragraph (e) to read as follows;

§ 173.31 Use of tank cars.

* * * * *

(e) *Special requirements for poisonous by inhalation (PIH) material.* (1) *Interior heater coils.* Tank cars used for PIH material may not have interior heater coils.

(2) *Tank car specifications.* A tank car used for a PIH material must have a tank test pressure of 20.7 Bar (300 psig) or greater, head protection, and a metal jacket (*e.g.,* DOT 105S300W), except that—

(i) A higher test pressure is required if otherwise specified in this subchapter; and

(ii) Each tank car constructed on or after March 16, 2009, and used for the transportation of PIH materials must meet the applicable authorized tank car specifications and standards listed in § 173.244(a)(2) or (3) and § 173.314(c) or (d).

(iii) A tank car owner retiring or otherwise removing a tank car from service transporting PIH material, other than because of damage to the car, must retire or remove cars constructed of non-normalized steel in the head or shell before removing any car in service transporting PIH materials constructed of normalized steel meeting the applicable DOT specification.

(3) After December 31, 2020, tank cars manufactured with non-normalized steel for head or shell construction may not be used for the transportation of PIH material.

(4) After December 31, 2027, tank cars not meeting the HM–246 tank car standard may not be used for the transportation of PIH material.

* * * * *

■ 16. In § 173.56, revise paragraph (b) introductory text to read as follows:

§ 173.56 New explosives—definition and procedures for classification and approval.

* * * * *

(b) *Examination, classification and approval.* Except as provided in §§ 173.64, 173.65, and 173.67, no person may offer a new explosive for transportation unless that person has specified to the examining agency the ranges of composition of ingredients and compounds, showing the intended manufacturing tolerances in the composition of substances or design of articles which will be allowed in that material or device, and unless it has been examined, classed and approved as follows:

* * * * *

■ 17. In § 173.59, revise the definition for consumer fireworks to read as follows:

§ 173.59 Description of terms for explosives.

* * * * *

Consumer firework. Any finished firework device that is in a form intended for use by the public that complies with any limits and requirements of the APA Standard 87–1A (IBR, see § 171.7 of this subchapter) and the construction, performance, chemical composition, and labeling requirements codified by the U.S. Consumer Product Safety Commission in 16 CFR parts 1500 and 1507. A consumer firework does not include firework devices, kits or components banned by the U.S. Consumer Product Safety Commission in 16 CFR 1500.17(a)(8).

* * * * *

■ 18. In § 173.64, revise paragraphs (a)(1) and (3) to read as follows:

§ 173.64 Exceptions for Division 1.3 and 1.4 fireworks.

(a) * * *

(1) The fireworks are manufactured in accordance with the applicable requirements in APA Standard 87–1A, 87–1B, and 87–1C (IBR, see § 171.7 of this subchapter);

* * *

(3) The manufacturer applies in writing to the Associate Administrator following the applicable requirements in APA Standard 87–1A, 87–1B, and 87–1C and is notified in writing by the Associate Administrator that the fireworks have been classed, approved, and assigned an EX number. Each application must be complete and include all relevant background data and copies of all applicable drawings, test results, and any other pertinent information on each device for which approval is being requested. The manufacturer must sign the application and certify that the device for which approval is requested conforms to APA Standard 87–1, that the descriptions and technical information contained in the application are complete and accurate,

and that no duplicate application has been submitted to a fireworks certification agency. If the application is denied, the manufacturer will be notified in writing of the reasons for the denial. The Associate Administrator may require that the fireworks be examined by an agency listed in § 173.56(b)(1) of this part.

* * * * *

■ 19. In § 173.65, revise paragraphs (a)(1), (a)(3)(i), and (a)(4)(iv) to read as follows:

§ 173.65 Exceptions for Division 1.4G consumer fireworks.

(a) * * *

(1) The fireworks are manufactured in accordance with the applicable requirements in APA Standard 87–1A (IBR, see § 171.7 of this subchapter);

* * * * *

(3) * * *

(i) Certified that it complies with APA Standard 87–1A, and meets the requirements of this section; and

* * * * *

(4) * * *

(iv) Signed certification declaring that the device for which certification is requested conforms to the APA Standard 87–1A, that the descriptions and technical information contained in the application are complete and accurate, and that no duplicate applications have been submitted to PHMSA. If the application is denied, the Fireworks Certification Agency must notify the manufacturer in writing of the reasons for the denial. As detailed in the DOT-approval issued to the Fireworks Certification Agency, following the issuance of a denial from a Fireworks Certification Agency, a manufacturer may seek reconsideration from the Fireworks Certification Agency, or may appeal the reconsideration decision of the Fireworks Certification Agency to PHMSA's Associate Administrator.

* * * * *

■ 20. Add § 173.67 to read as follows:

§ 173.67 Exceptions for Division 1.1 jet perforating guns.

(a) Notwithstanding the requirements of § 173.56(b), Division 1.1 jet perforating guns may be classed and approved by the Associate Administrator without prior examination and offered for transportation if the following conditions are met:

(1) The jet perforating guns are manufactured in accordance with the applicable requirements in IME/AESC JPG Standard (IBR, see § 171.7 of this subchapter);

(2) The jet perforating gun must be of a type described in the IME/AESC JPG Standard;

(3) The applicant applies in writing to the Associate Administrator following the applicable requirements in the IME/AESC JPG Standard, and is notified in writing by the Associate Administrator that the jet perforating gun has been classed, approved, and assigned an EX number. Each application must be complete and include all relevant background data, the applicable drawings, and any other pertinent information as described in the IME/AESC JPG Standard on each jet perforating gun for which approval is being requested. The manufacturer must sign the application and certify that the jet perforating gun for which approval is requested conforms to the IME/AESC JPG Standard and that the descriptions and technical information contained in the application are complete and accurate. If the application is denied, the applicant will be notified in writing of the reasons for the denial. The Associate Administrator may require that the jet perforating gun be examined as provided under § 173.56(b)(1).

(b) [Reserved]

* * * * *

■ 21. In § 173.151, revise paragraphs (b)(1)(i) and (ii) to read as follow:

§ 173.151 Exceptions for Class 4

* * * * *

(b) * * *

(1) * * *

(i) For flammable solids in Packing Group II, inner packagings not over 1.0 kg (2.2 pounds) or 1 L (0.3 gallon) net capacity each, packed in a strong outer packaging.

(ii) For flammable solids in Packing Group III, inner packagings not over 5.0 kg (11 pounds) or 0.5 L (1.3 gallon) net capacity each, packed in a strong outer packaging.

* * * * *

■ 22. In § 173.244, revise paragraph (a)(2) table to read as follows:

§ 173.244 Bulk packaging for certain pyrophoric liquids (Division 4.2), dangerous when wet (Division 4.3) materials, and poisonous liquids with inhalation hazards (Division 6.1).

* * * * *

(a) * * *

(2) * * *

TABLE 1 TO PARAGRAPH (a)(2)

Proper shipping name	Authorized tank car specification
Acetone cyanohydrin, stabilized (Note 1)	105J500W 112J500W
Acrolein (Note 1)	105J600W
Allyl Alcohol	105J500W 112J500W
Bromine	105J500W
Chloropicrin	105J500W 112J500W
Chlorosulfonic acid	105J500W 112J500W
Dimethyl sulfate	105J500W 112J500W
Ethyl chloroformate	105J500W 112J500W
Hexachlorocyclopentadiene	105J500W 112J500W
Hydrocyanic acid, aqueous solution *or* Hydrogen cyanide, aqueous solution *with not more than 20% hydrogen cyanide (Note 2).*	105J500W 112J500W
Hydrogen cyanide, stabilized (Note 2)	105J600W
Hydrogen fluoride, anhydrous	105J500W 112J500W
Poison inhalation hazard, Zone A materials not specifically identified in this table	105J600W

TABLE 1 TO PARAGRAPH (a)(2)—Continued

Proper shipping name	Authorized tank car specification
Poison inhalation hazard, Zone B materials not specifically identified in this table	105J500W 112J500W
Phosphorus trichloride	105J500W 112J500W
Sulfur trioxide, stabilized	105J500W 112J500W
Sulfuric acid, fuming	105J500W 112J500W
Titanium tetrachloride	105J500W 112J500W

Note 1: Each tank car must have a reclosing pressure relief device having a start-to-discharge pressure of 10.34 Bar (150 psig). Restenciling to a lower test pressure is not authorized.

Note 2: Each tank car must have a reclosing pressure relief device having a start-to-discharge pressure of 15.51 Bar (225 psig). Restenciling to a lower test pressure is not authorized.

* * * * *

■ 23. In § 173.302, revise paragraph (a) to read as follows:

§ 173.302 Filling of cylinders with nonliquefied (permanent) compressed gases or adsorbed gases.

(a) *General Requirements.* (1) Except as provided in § 171.23(a)(3) of this subchapter, a cylinder filled with a non-liquefied compressed gas (except gas in solution) must be offered for transportation in accordance with the requirements of this section and § 173.301 of this subpart. In addition, a DOT specification cylinder must meet the requirements in §§ 173.301a, 173.302a, and 173.305 of the subpart, as applicable. UN pressure receptacles must meet the requirements in §§ 173.301b and 173.302b of this subpart, as applicable. Where more than one section applies to a cylinder, the most restrictive requirements must be followed.

(2) *Adsorbed gas.* Except as provided in § 171.23(a)(3) of this subchapter, a cylinder filled with an adsorbed gas must be offered for transportation in accordance with the requirements of paragraph (d) of this section, and §§ 173.301, and 173.302c of this subpart. UN cylinders must meet the requirements in §§ 173.301b and 173.302b of this subpart, as applicable. Where more than one section applies to a cylinder, the most restrictive requirements must be followed.

* * * * *

■ 24. In § 173.304, revise paragraph (a) introductory text to read as follows:

§ 173.304 Filling of cylinders with liquefied compressed gases.

(a) *General requirements.* Except as provided in § 171.23(a)(3) of this subchapter, a cylinder filled with a liquefied compressed gas (except gas in solution) must be offered for transportation in accordance with the requirements of this section and the general requirements in § 173.301 of this subpart. In addition, a DOT specification cylinder must meet the requirement in §§ 173.301a, 173.304a, and 173.305 of this subpart, as applicable. UN pressure receptacles must be shipped in accordance with the requirements in §§ 173.301b and 173.304b of this subpart, as applicable.

* * * * *

■ 25. In § 173.308, revise paragraph (d) to read as follows:

§ 173.308 Lighters.

* * * * *

(d) *Shipping paper and marking requirements.* (1) In addition to the requirements of subpart C of part 172, shipping papers must be annotated with the lighter design test report identifier (see paragraph (b)(4)(i)(C) of this section) traceable to the test report assigned to the lighters or, if applicable, the previously issued approval number (*i.e.,* T***), in association with the basic description.

(2) In addition to the requirements of subpart D of part 172, a lighter design test report identifier (see paragraph (b)(4)(i)(C) of this section) or, if applicable, the previously issued approval number (*i.e.,* T***), must be marked on a package containing lighters.

* * * * *

■ 26. In § 173.314, in paragraph (c), revise the table to read as follows:

§ 173.314 Compressed gases in tank cars and multi-unit tank cars.

* * * * *

(c) * * *

Proper shipping name	Outage and filling limits (see note 1)	Authorized tank car class (see note 11)	Authorized tank car specification (see note 12)
Ammonia, anhydrous, or ammonia solutions >50 percent ammonia.	Notes 2, 10	105, 112, 114, 120	105J500W, 112J500W
	Note 3	106	
Ammonia solutions with >35 percent, but ≤50 percent ammonia by mass.	Note 3	105, 109, 112, 114, 120	
Argon, compressed	Note 4	107	
Boron trichloride	Note 3	105, 106	
Carbon dioxide, refrigerated liquid	Note 5	105	
Chlorine	Note 6	105	105J600W
	125	106	
Chlorine trifluoride	Note 3	106, 110	
Chlorine pentafluoride	Note 3	106, 110	
Dimethyl ether	Note 3	105, 106, 110, 112, 114, 120	
Dimethylamine, anhydrous	Note 3	105, 106, 112	
Dinitrogen tetroxide, inhibited	Note 3	105, 106, 112	105J500W

Proper shipping name	Outage and filling limits (see note 1)	Authorized tank car class (see note 11)	Authorized tank car specification (see note 12)
Division 2.1 materials not specifically identified in this table	Notes 9, 10	105, 106, 110, 112, 114, 120	
Division 2.2 materials not specifically identified in this table	Note 3	105, 106, 109, 110, 112, 114, 120.	
Division 2.3 Zone A materials not specifically identified in this table.	None	See § 173.245	105J600W
Division 2.3 Zone B materials not specifically identified in this table.	Note 3	105, 106, 110, 112, 114, 120	105J600W
Division 2.3 Zone C materials not specifically identified in this table.	Note 3	105, 106, 110, 112, 114, 120	105J500W
Division 2.3 Zone D materials not specifically identified in this table.	Note 3	105, 106, 109, 110, 112, 114, 120.	105J500W, 112J500W
Ethylamine	Note 3	105, 106, 110, 112, 114, 120	
Helium, compressed	Note 4	107	
Hydrogen	Note 4	107	
Hydrogen chloride, refrigerated liquid	Note 7	105	105J600W, 112S600W
Hydrogen sulfide	Note 3	105, 106, 110, 112, 114, 120	105J600W
Hydrogen sulfide, liquefied	68	106	
Methyl bromide	Note 3	105, 106	105J500W
Methyl chloride	Note 3	105, 106, 112	
Methyl mercaptan	Note 3	105, 106	105J500W
Methylamine, anhydrous	Note 3	105, 106, 112	
Nitrogen, compressed	Note 4	107	
Nitrosyl chloride	124	105	105J500W
	110	106	
Nitrous oxide, refrigerated liquid	Note 5	105	
Oxygen, compressed	Note 4	107	
Phosgene	Note 3	106	
Sulfur dioxide, liquefied	125	105, 106, 110	105J500W
Sulfuryl fluoride	120	105	
Vinyl fluoride, stabilized	Note 8	105	

Notes: 1. The percent filling density for liquefied gases is hereby defined as the percent ratio of the mass of gas in the tank to the mass of water that the tank will hold. For determining the water capacity of the tank in kilograms, the mass of 1 L of water at 15.5 °C in air is 1 kg. (the mass of one gallon of water at 60 °F in air is 8.32828 pounds).

2. The liquefied gas must be loaded so that the outage is at least two percent of the total capacity of the tank at the reference temperature of 46 °C (115 °F) for a noninsulated tank; 43 °C (110 °F) for a tank having a thermal protection system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 10.22 kilojoules per hour per square meter per degree Celsius (0.5 Btu per hour/per square foot/per degree F) temperature differential; and 41 °C (105 °F) for an insulated tank having an insulation system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 1.5333 kilojoules per hour per square meter per degree Celsius (0.075 Btu per hour/per square foot/per degree F) temperature differential.

3. The requirements of § 173.24b(a) apply.

4. The gas pressure at 54.44 °C (130 °F.) in any non-insulated tank car may not exceed 7/10 of the marked test pressure, except that a tank may be charged with helium to a pressure 10 percent in excess of the marked maximum gas pressure at 54.44 °C (130 °F.) of each tank.

5. The liquid portion of the gas at −17.77 °C (0 °F.) must not completely fill the tank.

6. The maximum permitted filling density is 125 percent. The quantity of chlorine loaded into a single unit-tank car may not be loaded in excess of the normal lading weights nor in excess of 81.65 Mg (90 tons).

7. 89 percent maximum to 80.1 percent minimum at a test pressure of 6.2 Bar (90 psig).

8. 59.6 percent maximum to 53.6 percent minimum at a test pressure of 7.2 Bar (105 psig).

9. For a liquefied petroleum gas, the liquefied gas must be loaded so that the outage is at least one percent of the total capacity of the tank at the reference temperature of 46 °C (115 °F) for a noninsulated tank; 43 °C (110 °F) for a tank having a thermal protection system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 10.22 kilojoules per hour per square meter per degree Celsius (0.5 Btu per hour/per square foot/per degree F) temperature differential; and 41 °C (105 °F) for an insulated tank having an insulation system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 1.5333 kilojoules per hour per square meter per degree Celsius (0.075 Btu per hour/per square foot/per degree F) temperature differential.

10. For liquefied petroleum gas and anhydrous ammonia, during the months of November through March (winter), the following reference temperatures may be used: 38 °C (100 °F) for a noninsulated tank; 32 °C (90 °F) for a tank having a thermal protection system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 10.22 kilojoules per hour per square meter per degree Celsius (0.5 Btu per hour/per square foot/per degree F) temperature differential; and 29 °C (85 °F) for an insulated tank having an insulation system incorporating a metal jacket and insulation that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 1.5333 kilojoules per hour per square meter per degree Celsius (0.075 Btu per hour/per square foot/per degree F) temperature differential. The winter reference temperatures may only be used for a tank car shipped directly to a consumer for unloading and not stored in transit. The offeror of the tank must inform each customer that the tank car was filled based on winter reference temperatures. The tank must be unloaded as soon as possible after March in order to retain the specified outage and to prevent a release of hazardous material which might occur due to the tank car becoming liquid full at higher temperatures.

11. For materials poisonous by inhalation, the single unit tank car tanks authorized are only those cars approved by the Tank Car Committee for transportation of the specified material and built prior to March 16, 2009.

12. Except as provided by paragraph (d) of this section, for materials poisonous by inhalation, fusion-welded tank car tanks built on or after March 16, 2009 used for the transportation of the PIH materials noted, must meet the applicable authorized tank car specification and must be equipped with a head shield as prescribed in § 179.16(c)(1).

* * * * *

PART 178—SPECIFICATIONS FOR PACKAGINGS

■ 27. The authority citation for part 178 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 28. In § 178.35, revise paragraphs (b)(2) and (c) as follows:

§ 178.35 General requirements for specification cylinders.

* * * * *

(b) * * *

(2) For DOT Specifications 3B, 3BN, 3E, 4B, 4BA, 4B240ET, 4AA480, 4L, 8, 8AL, 4BW, 4E, 4D (with a water capacity less than 1,100 cubic inches) and Specification 39 (with a marked service pressure 900 psig or lower) and manufactured within the United States, a competent inspector of the manufacturer.

(c) *Duties of inspector.* The inspector shall determine that each cylinder made is in conformance with the applicable specification. Inspections shall conform to CGA C–11 (IBR, see § 171.7 of this subchapter) except as otherwise specified in the applicable specification.

(1) Seamless cylinders shall be inspected in accordance with Section 5 of CGA C–11. For cylinders made by the billet-piercing process, billets must be inspected and shown to be free from piping (laminations), cracks, excessive segregation and other injurious defects after parting or, when applicable, after nick and cold break.

(2) Welded cylinders shall be inspected in accordance with Section 6 of CGA C–11. Note: The recommended locations for test specimens are depicted in Figures 1 through 5 in appendix A to subpart C of part 178.

(3) Non-refillable cylinders shall be inspected in accordance with Section 7 of CGA C–11.

(4) *Inspector's report.* The inspector shall prepare a report containing, at a minimum, the applicable information listed in CGA C–11. Any additional information or markings that are required by the applicable specification must be shown on the test report. The signature of the inspector on the reports certifies that the processes of manufacture and heat treatment of cylinders were observed and found satisfactory. The inspector must furnish the completed test reports required by this subpart to the maker of the cylinder and, upon request, to the purchaser. The test report must be retained by the inspector for 15 years from the original test date of the cylinder.

* * * * *

■ 29. In § 178.521, revise paragraph (b)(4) as follows:

§ 178.521 Standards for paper bags.

* * * * *

(b) * * *

(4) UN5M1 and UN5M2 multi-wall paper bags that have paper wall basis weights that vary by not more than plus or minus 10 percent from the nominal basis weight reported in the initial design qualification test report.

PART 179—SPECIFICATIONS FOR TANK CARS

■ 30. The authority citation for part 179 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 31. In § 179.22, revise paragraph (e) as follows:

§ 179.22 Marking.

* * * * *

(e) Each tank car manufactured after March 16, 2009 to meet the requirements of § 173.244(a)(2) or (3) or § 173.314(c) or (d) that is marked with the letter ''I'' in the specification marking, following the test pressure, shall be re-marked with the letter ''W'' at the tank car's next qualification. (Example: DOT 105J600I would be re-marked as 105J600W.)

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

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

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 33. In § 180.417, revise paragraph (a)(3) introductory text to read as follows:

§ 180.417 Reporting and record retention requirements.

* * * * *

(a) * * *

(3) *DOT Specification cargo tanks.*

* * * * *

Issued in Washington, DC, on July 31, 2019, under authority delegated in 49 CFR 1.97.

William S. Schoonover,

Associate Administrator of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

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